

CLIENT ALERT: November 13, 2008

**EMERGENCY DoN AMENDMENTS CONCERNING
AMBULATORY SURGERY CENTERS (ASCs) &
CAPITAL EXPENDITURES FOR OUTPATIENT PROJECTS**

(Eff. 12/12/08; Implementing Chapter 305 of the Acts of 2008: An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care)

On November 12, 2008, the Public Health Council (“PHC”) approved emergency amendments to the DoN Regulations (the “Regulations”) implementing the grandfathering provisions of Chapter 305, the recent cost containment legislation. The Regulations and DPH summary are attached to this communication.

- For hospital outpatient projects of at least \$25 million, the Regulations delineate the progress such projects shall have made under DPH’s current two-step plan review process and set a date by which applicants must submit initial, as well as final plan materials.
- For ASCs, the definition of “under construction” requires that persons planning to operate an ASC must have progressed at least to the point that either the proposed location is under construction or renovation, or funds have been committed for the acquisition of a majority of the equipment.

The Regulations also enable the DoN program to permit electronic filings.

A public hearing will be scheduled on December 5, 2008, and DPH intends to return to the PHC in January or February after processing any public comments with permanent regulations.

Note that DPH also intends to update the clinic licensure regulations for physician-owned ASCs that are currently in operation. In addition, the DoN program is in the process of updating its DoN guidelines for review of ASC projects. We will continue to monitor these developments.

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105 CMR 100.000: DETERMINATION OF NEED

100.001: Purpose and Objective

105 CMR 100.000 is set forth for the purpose of interpreting and implementing M.G.L. c. 111, §§ 25B to 25G, §§ 51 through 53, 51A, and 71, the principal provisions of the Massachusetts General Laws conferring responsibility upon the Department of Public Health for making determinations of need.

The objective of the determination of need process shall be the allocation of health care resources and the improvement of health care delivery systems such that adequate health care services are made reasonably available to every person within Massachusetts at the lowest reasonable aggregate cost and to ensure the non-duplication of services. In making individual determinations, the Department shall advance this objective to the extent permitted under the governing statutes and regulations.

100.002: Citation

105 CMR 100.000 shall be known, and may be cited, as “Massachusetts Determination of Need Regulation.”

100.010: Department's Jurisdiction to Determine Need

105 CMR 100.000 shall govern determination of need in every instance where, under statutory authority, the Department has jurisdiction to determine the need for any facility or any part or service of any such facility.

100.011: Determinations under M.G.L. c. 111, § 25C

(A) (1) Under the provisions of M.G.L. c. 111, § 25C, no person or government agency may make a substantial capital expenditure for construction of a health care facility or a substantial change in the services of any such facility, unless the Department has determined that there is a need for such substantial capital expenditure or substantial change in service. This general requirement is subject to the following limited exceptions:

(a) No determination of need shall be required for any substantial capital expenditure for construction or any substantial change in service which shall be related solely to the conduct of research in the basic biomedical or applied medical research areas and shall at no time result in any increase in the clinical bed capacity or outpatient load capacity of a health care facility, provided that any person undertaking any such expenditure which shall exceed or may reasonably be regarded as likely to exceed \$150,000 or change in service related solely to such research shall file with the Department the notice of assurance required by 105 CMR 100.230.

(b) Under the authority of M.G.L. c. 111, § 25C½(a), an HMO or a health care facility controlled or leased by an HMO shall be exempt from determination of need review for a substantial capital expenditure related to the provision of inpatient services or for a substantial change in inpatient services if, upon application by the HMO or facility, the Department finds that such substantial

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capital expenditure or substantial change in services meets certain prescribed criteria. *See* 105 CMR 100.260 regarding application for exemption for HMO inpatient services.

(c) Under the authority of M.G.L. c. 111, § 25C½(c), in the case of a health care facility which is controlled directly or indirectly by an HMO or combination of HMOs, no determination of need shall be required under M.G.L. c. 111, § 25C for a substantial capital expenditure related solely to the provision of outpatient services or for a substantial change in outpatient services.

(d) Under the authority of M.G.L. c. 111, § 25C½(a), no determination of need shall be required for a long-term care facility, an infirmary maintained in a town, a convalescent or nursing home, or a rest or charitable home for the aged as defined in M.G.L. c. 111, § 71 that satisfies the requirements set out at 105 CMR 100.608 *et seq.* and receives department exemption pursuant to those sections.

(e) Under the authority of 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 Crippled Children.

(2) Under the provisions of M.G.L. c. 111, § 25C an acute care hospital, at its option, may apply for a determination of need which involves a capital expenditure but for which a determination of need is not required subject to the following provisions: the application may be withdrawn by the hospital at any time; the application shall be dismissed by the Program Director at any time during the application's pendency that the hospital begins implementation of any part of that which is proposed in the application; and, the application shall be dismissed by the Program Director if any implementation of any part of that which is proposed in the application occurred prior to the application's submission.

(B) Under the provisions of M.G.L. c. 111, § 25C, no person or government agency may acquire for location in other than a health care facility a unit of medical, diagnostic, or therapeutic equipment with a fair market value in excess of \$150,000 unless the person or agency files a notice of intent with the Department. Under certain circumstances such acquisitions shall be subject to determination of need review. *See* 105 CMR 100.240 through 100.246.

(C) Under the provisions of M.G.L. c. 111, § 25C, no person or government agency shall acquire an existing health care facility unless the person or agency files a notice of intent with the Department. Under certain circumstances such acquisitions shall be subject to determination of need review. *See* 105 CMR 100.250 through 100.255. Note that the coverage required by this provision of M.G.L. c. 111, § 25C is in addition to, and not in place of, the coverage required by M.G.L. c. 111, §§ 51 through 53.

100.012: Determination Required Under M.G.L. c. 111, §§ 51 through 53

Under the authority of M.G.L. c. 111, §§ 51 through 53, no person shall be issued an original license to establish or maintain a hospital, an institution for unwed mothers, a freestanding ambulatory surgery center, an inpatient unit of a health care facility off the premises of the facility, or the placement of inpatient services at a previously-licensed outpatient satellite of a healthcare facility unless the Department has determined that there is a need for the proposed facility at the designated location. However, no such determination shall be required with respect to original licensure of any hospital or ambulatory surgery center which, pursuant to the provisions of M.G.L. c. 111, § 25C, is exempt from the provisions of M.G.L. c. 111, § 25C. A determination made for purposes of M.G.L. c. 111, § 25C, shall also be valid for purposes of c. 111, §§ 51 through 53, as long as such determination remains in effect. *See* 105 CMR 100.020 for definition of original license and 105 CMR 100.600 for alternative procedures for Departmental approval of changes in ownership.

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100.013: Determination Required Under M.G.L. c. 111, § 71

Under provisions of M.G.L. c. 111, § 71, no person or government agency shall be issued an original license to establish or maintain an intermediate care facility for the mentally retarded unless the Department has determined that there is need for the facility at the designated location. A determination made for purposes of M.G.L. c. 111, § 25C, shall also be valid for purposes of c. 111, § 71, as long as the determination remains in effect.

100.014: Effect of St. 2008, c. 305.

(A) **Freestanding ambulatory surgery centers.** Notwithstanding any other provision in 105 CMR 100.000, a freestanding ambulatory surgery center that was exempt from licensure as a clinic pursuant to M.G.L. c. 111, § 51 because it was in operation before August 10, 2008 is not required to obtain a determination of need as a condition of licensure. Notwithstanding any other provision in 105 CMR 100.000, a freestanding ambulatory surgery center that was exempt from licensure as a clinic pursuant to M.G.L. c. 111, § 51 and under construction before August 10, 2008 is not required to obtain a determination of need as a condition of licensure. For purposes of review of the transfer of site or transfer of ownership of any such freestanding ambulatory surgery center, the Department shall deem that such center received a determination of need prior to its licensure.

(B) **Capital expenditures for outpatient projects.** Notwithstanding any other provision in 105 CMR 100.000, a capital expenditure for an outpatient project for which a person has submitted design development plans prior to December 1, 2008 and sought written approval of final architectural plans prior to February 10, 2009 is not required to obtain a determination of need as a condition of licensure.

(C) **Definitions.** For the purposes of 105 CMR 100.014, the following terms have the following meanings.

(1) **In operation** means actively treating patients.

(2) **Design Development Plans** means the submission required by the Department's Plan Review Application and Project Information Form for Abbreviated Part 1 Review, including the completed form and all plans required as attachments.

(3) **Sought written approval of final architectural plans** means that the person has filed final architectural plans with the Department's plan review office following the review of design development plans that include all of the following in accordance with the plan review office guidelines:

(a) Final construction plans for the proposed project, including complete architectural, plumbing, mechanical and electrical plans, and incorporating revisions required by the Department as a result of the review of design development plans;

(b) Written responses to the Department's plan review comments;

(c) Completed plan review forms required for the submission of final construction plans, which may include architect compliance checklists, architect and licensee affidavits and physical plant waiver request forms.

(4) **Under construction** means that the person seeking to operate a freestanding ambulatory surgery center can provide documentation of any of the following:

(a) the active construction of a new ambulatory surgery center;

(b) the alteration of, expansion of, making of major repairs to, remodeling of, renovation of, or replacement of an existing facility, including documentation that such activity was

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**undertaken specifically for the purpose of operating a freestanding ambulatory surgery center; or
(c) the purchase of, or an obligation to make an expenditure for, the equipment or a majority of the equipment necessary to operate a freestanding ambulatory surgery center.**

100.015: Related Jurisdiction under M.G.L. c. 111, § 25D

(A) Under the provisions of M.G.L. c. 111, § 25D, no person shall make a solicitation of funds from the general public or enter into any agreement in order to secure financing for the construction of a health care facility or for a substantial change in the services of a health care facility, unless such person, at least 30 days prior thereto, has filed written notice of its intent with the Department. If the Department requires an application for determination of need under M.G.L. c. 111, § 25C, such person shall not make any solicitation of funds until such application has been acted upon by the Department and need has been found to exist.

(B) Each agency of the Commonwealth of Massachusetts desiring to make a substantial capital expenditure for construction of a health care facility or a substantial change in service of the facility shall apply for a determination of need. Any such agency may, if it deems it desirable, submit a request, through the executive office in which it is located, for a capital appropriation for such a project at the same time as or after it has filed an application. For the information of such agencies, the current policy of the Executive Office of Health and Human Services (EOHHS) and for Administration and Finance (A&F) is set forth in 105 CMR 100.015(B). EOHHS will forward capital outlay requests to A&F with a statement listing those projects which are subject to 105 CMR 100.000 and a status report showing the date an application was filed and its current status for each such project. No request for such a project will be forwarded to A&F until an application has been filed, unless delay in forwarding the request would be contrary to the public interest. A&F will decide whether to forward any such request to the General Court before the Department has acted on the application, but intends to do so only where there is good cause to believe that need will be found and where delay in forwarding the request would be contrary to the public interest. A&F will file a similar status report with requests to the General Court before the Department has acted on the application, but intends to do so only where there is good cause to believe that need will be found and where delay in forwarding the request would be contrary to the public interest. A&F will file a similar status report with requests so forwarded. The Department shall file its report on each such application with EOHHS, A&F and, for requests which have been forwarded, the General Court.

100.020: Definitions

As used in 105 CMR 100.000, the following terms have the following meanings unless the context or subject matter clearly requires a different interpretation.

Acute Care Hospital means any hospital licensed under M.G.L. c. 111, § 51, which contains a majority of medical-surgical, pediatric, and maternity beds as defined by 105 CMR 130.026 and 130.601.

Acute Psychiatric Service means a service for inpatients in need of intensive, 24 hour per day, psychiatric and nursing care and supervision, not including persons hospitalized for substance abuse problems, and which includes a staff of mental health specialists who provide psychiatric, psychological and social evaluation, treatment and aftercare planning.

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Addition means

(1) the initial provision of an innovative service or procedure or acquisition of medical equipment defined as new technology or

(2) the initial provision of any services which may be provided by facilities which are not acute care hospitals.

Affiliate means any entity which is owned or controlled, directly or indirectly, by a health care facility, or any entity which is owned or controlled, directly or indirectly, by an entity which owns or controls a health care facility.

Ambulatory Surgery means surgical services, the majority of which are elective or non-urgent, provided in a freestanding, outpatient setting.

Bed capacity (or clinical bed capacity) means the capacity of a building to accommodate a bed and the necessary physical appurtenances in accordance with the applicable standards imposed as a condition of operation under state law. It shall include a room designed or able to accommodate a bed and necessary physical appurtenances, whether or not a bed and all such appurtenances are actually in place, with any necessary utilities (*e.g.*, drinking water, sprinkler lines, oxygen, electric current, electric signals, etc.), with either outlets or capped lines within the room. The term “bed” shall encompass renal dialysis stations. *See* definition of “Licensed Bed Capacity.”

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 for architectural, engineering, legal, accounting, and other professional services, any interest charges or other financing cost capitalized throughout the construction period of the project, and/or any site acquisition cost; or

(2) any expenditure, or obligation to make an expenditure, past, present, or future, for the obtaining by lease or comparable arrangement of 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 herein.

See definitions of “Construction” and “Substantial Capital Expenditure.”

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

Comparable applications mean those applications filed within the same filing period, or at the discretion of the Program Director, within different filing periods in the same filing year, which propose similar or reasonably interchangeable health care services for applicable service areas which are the same in whole or in significant part.

Construction means 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 such facility; and the acquisition of consulting, architectural, and engineering 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 under 105 CMR 100.000. *See* definitions of “Capital Expenditure” and “Substantial Capital Expenditure.”

Conversion means the substitution of a service or technology which is defined as a substantial change in service by the Department, in place of a current service or technology.

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Council means the Public Health Council.

Criteria means those guidelines, factors, standards, and measures, used in evaluating an application for a determination of need.

Department means the Department of Public Health.

Determination of Need means the formal decision of the Department made pursuant to 105 CMR 100.000 relative to the need for the project proposed in an application.

Determination of Need Program means the program established within the Department for the administration of M.G.L. c. 111, §§ 25B to 25G, §§ 51 through 53, 51A, and 71 as they relate to determination of need, and to the extent and in the manner set forth in 105 CMR 100.000.

Emergency situation means a situation where the public health has been injured or there is a clear and present danger of such injury, or where the existing health care facility has been destroyed or otherwise substantially damaged or there is a clear and present danger of such damage.

Expansion means

- (1) addition to an existing innovative service, new technology or freestanding ambulatory surgery center, for which a determination of need has been issued, through increase in the licensed number of beds or stations, or increase in the number of operating rooms, cardiac catheterization laboratories and/or special procedures rooms, or acquisition of equipment defined as new technology;
- (2) upgrades of existing equipment defined as new technology; or
- (3) for non-acute services, any increase in bed capacity, other than a single increase or cumulative series of increases, totaling not more than 12 beds.

Expenditure Minimum

(1) Expenditure Minimum with Respect to Substantial Capital Expenditures means, with respect to expenditures and acquisitions made by or for

- (a) acute care hospitals and comprehensive cancer centers as defined in M.G.L. c. 118G, § 1, 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 and set forth in an informational bulletin, except that expenditures for or the acquisition of, major movable equipment not otherwise defined by the department as new technology or innovative services shall not require a determination of need, and shall not be included in the calculation of the expenditure minimum; and
- (b) health care facilities, other than acute care hospitals, with respect to expenditures for, or the acquisition of, medical, diagnostic or therapeutic equipment, and all other expenditures and acquisitions, 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 and set forth in an informational bulletin.

(2) Expenditure Minimum with Regard to Substantial Change in Service or Increase in Staff means, with respect to any health care facility other than an acute care hospital, \$350,000 in annual operating costs, including staffing costs.

Notwithstanding 105 CMR 100.020 Expenditure Minimum (1) and (2), expenditures and acquisitions concerned solely with outpatient services other than freestanding ambulatory surgery centers, not otherwise defined as new technology or innovative services by the department, **shall not require a determination of need and shall not be included in the calculation of the expenditure minimum, unless the expenditures and acquisitions are at least \$25,000,000, in which case a determination of need shall be required.**

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Notwithstanding 105 CMR 100.020 Expenditure Minimum (1) and (2), and expenditures for, or the acquisition of, any replacement of medical, diagnostic or therapeutic equipment defined as new technology or innovative services for which a determination of need has issued or which was exempt from determination of need, shall not require a determination of need and shall not be included in the calculation of the expenditure minimum.

Facility means a health care facility.

Factor means each of the several general requirements, established in 105 CMR 100.000, which are to be uniformly applied to applications for determination of need, subject to variation based upon differences in the nature and scope of projects, and to exception in the limited circumstances set forth in 105 CMR 100.00. *See* definitions of “Criteria” and “Standard.”

Filing date means the first business day of the month specified for a particular application.

Filing period means that period of time from and including one filing date until, but not including, the following filing date.

Freestanding Ambulatory Surgery ServiceCenter means an ~~independently licensed~~ ambulatory surgery center **licensed as a clinic pursuant to M.G.L. c. 111, § 51 but not an ambulatory surgery center licensed as a service or satellite of a hospital.**

Government agency means any agency of the Commonwealth of Massachusetts or of any political subdivision of Massachusetts, including a city, town, or county, but not an agency of the United States even if such agency maintains a medical institution within Massachusetts.

Guideline means criteria which have been adopted by the Public Health Council but not promulgated as regulations.

Health care facility means a hospital, an institution for unwed mothers or a **freestanding ambulatory surgery center licensed as a clinic**, as defined under M.G.L. c. 111, § 52; or a long-term care facility, including an infirmary maintained in a town, a convalescent or nursing home, a rest home, a charitable home for the aged, or an intermediate care facility for the mentally retarded, as defined under M.G.L. c. 111, § 71; a clinical laboratory subject to licensing under M.G.L. c. 111D; or a public medical institution as defined in 105 CMR 100.020.

Health maintenance organization or HMO means a public or private organization as defined under M.G.L. c. 176G, § 1.

Innovative service means a service or procedure such as dialysis, neonatal intensive care, and transplant services, which for reasons of quality, access, or cost is determined to be innovative by the Department. The Department shall issue a list of services determined to be innovative in the form of an Informational Bulletin, and shall update the list annually.

Inpatient Services means health care services requiring at least one overnight stay, provided to patients on an elective, urgent, or emergency basis.

License means a permit from the Department, either full or provisional, and not transferable, authorizing the maintenance of a facility by the person named therein and at the premises named therein.

Licensed bed capacity means the portion of bed capacity, by number of beds, which a provider under its license, as issued or subsequently modified, is authorized to use for patient occupancy, or, in the case of a facility operated by a government agency, the number of beds approved by the Department. *See* definition of “Bed Capacity or Clinical Bed Capacity.” (Note: Related licensing regulations (105 CMR 130.000 *et seq.*) provide for automatic reduction of licensed bed capacity under certain circumstances.)

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Location or Premises means:

- (1) the street address(es) of the facility; and
- (2) in the case of a facility located within a physically contiguous campus of an institution such as a school, university or hospital, that campus; and
- (3) those places at which a health care facility provides outpatient services which:
 - (a) are open no more than 20 hours per week;
 - (b) offer no more than 40 staff hours of service per week; and
 - (c) are located within the same health service area as the health care facility.

Major Movable Equipment means equipment that is not permanently attached to the building and that has a depreciable life of three or more years.

Measure means the several elements or components of a standard.

New Technology means equipment intended primarily for use in the provision of medical or surgical services, whether for diagnostic or treatment purposes, which has received approval from the U.S. Food and Drug Administration, or which has been authorized for physician use by appropriate professional societies, but which is determined by the Department not to be in general use in Massachusetts for patient care by physicians qualified to operate such equipment. The Department shall issue a list of equipment determined to be new technology in the form of an Informational Bulletin, and shall update the list annually.

Obligation to Make an Expenditure means the binding of a person to make an expenditure by a promise, contract, sense of duty, etc. Examples include, but are not to be limited to the following:

- (1) entering into an enforceable contract to make an expenditure;
- (2) formal action by the governing board of a health care facility to commit its own funds for a construction project undertaken by the facility as its own contractor; or
- (3) in the case of donated property, completion of the gift.

Original license means the first license issued to a person for the premises named therein, including the first license issued for the initial establishment of an inpatient unit of a health care facility off the premises of the facility (*i.e.*, the establishment of a satellite clinic of a health care facility), or the placement of inpatient services at a previously-licensed outpatient satellite. An original license is granted either upon initial licensure of a facility, change of location, or change of ownership of a health care facility.

Party of record means, during the pendency of an application, the applicant, the Division of Health Care Finance and Policy, the Department of Elder Affairs if relevant pursuant to 105 CMR 100.152, the Department of Mental Health if relevant pursuant to 105 CMR 100.153, any ten taxpayer groups duly registered pursuant to 105 CMR 100.140, and any comparable applicants designated pursuant to 105 CMR 100.304.

Person means an individual or his or her estate upon his or her death, or a corporation, 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.

Premises. See definition of Location.

Primary/Preventive Health Care Services and Community Contributions Necessary for Underserved Populations means those primary and preventive health care services which have been identified by Department Staff in an Informational Bulletin as necessary for underserved populations within Massachusetts. The Department shall update the Informational Bulletin annually. To the extent practicable, such Informational Bulletin shall rank such services according to need, and shall identify projected costs for the provision of such services.

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Project means any construction or substantial change in services subject to Determination of Need under M.G.L. c. 111, § 25C; or original licensure of a facility under M.G.L. c. 111, §§ 51 through 53, 51A, or 71.

Program Director means the employee of the Department who, under the general supervision of the Commissioner, administers the Determination of Need Program.

Public Medical Institution means any medical institution, including an institution for the mentally ill or retarded, 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 licensing, approval or certification by the Department for participation in programs administered under Titles XVIII or XIX of the Federal Social Security Act.

Services which may be Provided by Facilities which are not Acute Care Hospitals (or Non-Acute Services) means freestanding ambulatory surgery, and the following if provided on an inpatient basis: skilled nursing, chronic, rehabilitation, acute psychiatric, and substance abuse.

Site means land and/or any building or part thereof.

Solicitation of Funds from the General Public means the act of approaching any member of the general public with a request or plea for a donation of funds to be used for construction or a substantial change in services of a health care facility. For such purposes, "general public" shall exclude for 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.

Staff means employees of the Department.

Standards means criteria which have been promulgated as regulations.

Substantial Capital Expenditure means a capital expenditure which 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. For acute care hospitals only, the acquisition of major movable equipment not otherwise defined by the Department as new technology or innovative services shall not be included in the calculation of the expenditure minimum for purposes of calculating a substantial capital expenditure. See definitions of "Capital Expenditure," "Construction," and "Expenditure Minimum."

Substantial Change in Services means:

- (1) with regard to acute care hospitals only, the addition or expansion of, or conversion to
 - (a) a new technology, innovative service, or freestanding ambulatory surgery service, regardless of whether an expenditure minimum is exceeded; or,
 - (b) any services which may be provided by facilities which are not acute care hospitals.
- (2) for any health care facility other than an acute care hospital:
 - (a) the addition of a service or increase in staff which 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 new technology or innovative service regardless of whether an expenditure minimum is exceeded;
 - (d) the addition or expansion of or conversion to ambulatory surgery centers; or

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(e) upgrading Level IV beds, freestanding residential care facilities, to skilled nursing and intermediate care beds (Level II and III).

Taxpayer means any individual residing in Massachusetts and subject to any income, excise, or property tax of Massachusetts or of any political subdivision of Massachusetts during the calendar year in which he or she signs a written request for a public hearing or a statement of registration under 105 CMR 100.140 or in which he or she signs comments with respect to an application under 105 CMR 100.400.

Transfer of Ownership of a Determination of Need means:

- (1) where the holder of the authorization contained in a determination of need is a limited or general partnership, any transfer of 25% or more of the partnership interest;
- (2) where the holder is a for-profit corporation, a transfer of 25% or more of any class of the stock therein; and
- (3) where the holder is a non-profit corporation, such changes in the corporate membership and/or directors as the Department determines to constitute a shift of 50% or more in the control of the holder.

Underbedded Area means, for the purposes of conversions of acute care services to skilled nursing, rehabilitation, acute psychiatric, or substance abuse services, that health service area in which need exists for inpatient beds, as defined by the guidelines applicable to each of the services above.

Unique application means an application for any of the following projects:

- (1) An application for a nursing home which is:
 - (a) part of a so-called continuing care retirement community,
 - (b) open only to residents of such community and
 - (c) supported entirely by private funds, pursuant to M.G.L. c. 111, § 25C, or an application for an original license for a hospital, institution for unwed mothers, a freestanding ambulatory surgery center, to be issued pursuant to M.G.L. c. 111, §§ 51 through 53, or 51A, or an intermediate care facility for the mentally retarded pursuant to M.G.L. c. 111, § 71;
- (2) An application pursuant to M.G.L. c. 111, § 25C for a project which is inherently not comparable in nature and concerns solely an institution or institutions operated by the Department of Public Health, the Department of Mental Health, or the Department of Correction.
- (3) An application pursuant to M.G.L. c. 111, § 25C for certification for conversion pursuant to 105 CMR 100.604;
- (4) An application for a determination of need filed with respect to a project exempted under 105 CMR 100.308, provided it is filed within the exemption period; or
- (5) An application pursuant to M.G.L. c. 111, § 25C½ for exemption from determination of need pursuant to 105 CMR 100.608.

100.100: Submission of Communications and Other Written Materials

(A) Any communications or other written materials directed to the Program Director, the Commissioner, or the Department shall be submitted, by hand delivery, or by first-class, certified, or registered mail, to the Department at the offices of the Program Director unless different instructions are given either in 105 CMR 100.000 requiring such submission or in writing by a staff member of the Department.

(B) Whenever a party of record sends any written communication or submits any written materials to the Department concerning an application for which the Program Director has determined, pursuant to 105 CMR 100.303, that the applicable filing requirements have been met, copies of such communication or materials shall be sent to all other parties of record.

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(C) Notwithstanding any other provision of 105 CMR 100.000, the Program Director may direct alternate means, including but not limited to electronic submissions, for filing any application, written communication or any other written materials required to be submitted to any party, including the Department, pursuant to 105 CMR 100.000.

100.101: Computation of Time

Any period of time specified in 105 CMR 100.000 or otherwise in connection with the determination of need program shall include every calendar day, whether the offices of the Department are open on that day or not, except that, when the last day of the period falls on a day when the offices are closed, such period shall end instead on the next day on which the Department is open for business.

100.102: Availability of Forms

Any forms prepared in accordance with 105 CMR 100.000 shall be available upon request made in person or in writing to the Program Director. Any changed forms shall be mailed by the staff to any person whose application is pending and is affected by the change in the forms.

100.110: Prohibition of Improper Contacts

(A) Rule When No Application Is Pending. Prior to the filing of an application, and after final Department action upon an application, verbal and written communications shall be freely permitted with the staff and the Commissioner; provided, however, that in no event is any member of the staff, the Program Director, or the Commissioner authorized to give any indication of what specific action the Council would take upon the merits of any application which may be filed. General advice, however, can be given as to the manner of making application, the procedures to be followed in processing the application, and the nature of standards and criteria applied by the Department in considering applications.

(B) Communications With Program Director and Staff When Application Is Pending. Persons and government agencies subject to 105 CMR 100.000 may freely communicate orally or in writing with the Program Director and staff regarding a pending application. No party shall expect that an oral communication will be incorporated or reflected in the staff summary or that the oral communication will form the basis of the staff recommendation. Parties are encouraged to submit all communications in writing pursuant to 105 CMR 100.000.

(C) Communications with Commissioner and Public Health Council When Application Is Pending. Except as provided in 105 CMR 100.110, during such time as an application for determination of need is before the Department, neither the applicant nor any party of record nor any employee or agent of such applicant or party nor any other interested person shall initiate any oral or written communication with the Commissioner, or any member of the Council concerning an application. Applicants or other parties shall be permitted to make written inquiry from the Commissioner and written or verbal inquiry from the staff concerning the status or progress of an application.

(D) Sanction for Improper Communication. Notice is hereby given that, if an applicant or ten taxpayer group, either directly or through an employee or agent, makes a communication which is prohibited under 105 CMR 100.110 or which is otherwise clearly improper, or fails to send copies of communications or written materials, as required by 105 CMR 100.100, the Department may dismiss its application under 105 CMR 100.531, or revoke its status as ten taxpayer group under 105 CMR 100.140(D).

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100.120: Advisory Rulings

Under the provisions of M.G.L. c. 30A, § 8, the Department may upon the request of any interested person or government agency, 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 or related regulations or the applicable statutes under which such regulations are adopted.

(A) Any interested person or governmental agency desiring an advisory ruling shall direct its request in writing to the Department, Attention: Office of the General Counsel, and shall forward a copy of the request to the Program Director.

(B) Each such request shall be titled "Request for Advisory Ruling" and shall set forth, clearly and succinctly, the following: name and address of the person making the request; its interest in or relationship to the health care facility involved; a statement of the facts with respect to which the ruling is requested; and the statutory provision or the section of 105 CMR 100.000 involved. The person or governmental agency making such request may also include its views and opinions as to the proper ruling.

(C) It shall be within the discretion of the General Counsel whether or not to make an advisory ruling. Each advisory ruling shall be made by an attorney within the Office of General Counsel on behalf of the Department, but shall be subject to review by the Public Health Council upon written request filed with the Office of General Counsel within 14 days of notice of such ruling.

(D) A copy of all advisory rulings rendered under 105 CMR 100.000 shall be kept on file both in the Office of General Counsel and in the Office of the Determination of Need Program and shall be available for public inspection. The Office of General Counsel shall mail one copy of each advisory ruling to the Division of Health Care Finance and Policy, the Department of Elder Affairs if relevant pursuant to 105 CMR 100.152 and the Department of Mental Health if relevant pursuant to 105 CMR 100.153.

100.130: Public Information

(A) The Program Director, at his or her offices, shall maintain a file, open to public inspection, which shall contain all records of a public nature concerning every application for a determination of need. In addition, at the office of the Commissioner, the Secretary of the Council shall maintain a file, also open to public inspection, of the record of every Department action, including every notice of determination of need.

(B) Each of the following documents relating to an application for a determination of need shall be treated as a public record: an application for determination of need; an amendment to an application; any withdrawal of an application; written comments by parties of record; staff report prepared pursuant to 105 CMR 100.420; staff memoranda to the Public Health Council; and notices of Department action.

100.131: Program Director's Status Report

(A) The Program Director shall ~~cause a status report to be prepared~~ **a status report at the request of the commissioner.**

(B) The report shall contain the following information:

- (1) the name of each applicant with a pending application for determination of need, together with the location and a brief description of the project for which application is made; and

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(2) a synopsis of all determinations of need made by the Department since the last report, including the name of the applicant, and the location and a brief description of the project for which such determination has been made.

(C) Copies of this report shall be available for inspection at the offices of the Program Director and at the Commissioner's office. In addition, one copy of this report shall be sent as appropriate to the Division of Health Care Finance and Policy, the Department of Elder Affairs, and the Department of Mental Health.

100.140: Ten Taxpayer Groups

Under 105 CMR 100.000 various opportunities are provided citizens of Massachusetts organized as a group of ten taxpayers for notice concerning, and participation in, the review of an application for determination of need.

(A) In order to avail themselves of such opportunities, interested persons shall register with the Department in one of the following ways:

- (1) during the period provided under 105 CMR 100.410 in which a public hearing may be requested, by filing a written request for such a hearing;
- (2) at any time during the first 30 days after an application has been filed with the Department or notice of the same has been published in the newspaper, whichever is later;
- (3) during the period provided under 105 CMR 100.351(B) in which a public hearing may be requested, by filing a written request for such a hearing; or
- (4) during the first ten days after a public hearing held under 105 CMR 100.410.

(B) Any such request or statement shall be signed by each taxpayer, and shall, in clearly legible print:

- (1) list each taxpayer by name and resident address;
- (2) for each taxpayer, state whether or not that taxpayer is acting as an agent for another party. If the 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.

(C) Upon receipt of any such request or statement, the Program Director shall promptly send a copy to each party of record.

(D) The Commissioner may, upon recommendation of the Program Director, revoke the ten taxpayer group status of any group which has failed to comply with the requirements of 105 CMR 100.100, 100.110 or 100.140.

(E) If more than one ten taxpayer group registers in connection with an application, the Program Director may issue an order to show cause why written communications and materials should not be distributed to only one ten taxpayer group registered in connection with such application. Thereafter, unless good cause to continue distribution of written materials and communications to all such ten taxpayer groups is shown, written communications and materials shall be distributed only to the parties of record designated by the Program Director, and the designated party or parties of record shall distribute copies thereof to the remaining parties of record in accordance with the Program Director's order.

100.152: Department of Elder Affairs Participation

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(A) The Department of Elder Affairs may participate in proceedings under M.G.L. c. 111, § 25C, involving geriatric long-term care facilities, a convalescent or nursing home, a rest home, or a charitable home for the aged subject to licensure under M.G.L. c. 111, § 71. Whenever 105 CMR 100.000 calls for any person to send any application, notice, or document of any kind to the Department of Elder Affairs as a party of record or for review or comment on any application or other participation by the Department of Elder Affairs, the same shall be construed to apply only to applicants under M.G.L. c. 111, § 25C involving geriatric long-term care facilities.

(B) Any paper directed to the Department of Elder Affairs shall be submitted by hand-delivery, or by first-class mail, at the offices of the Department of Elder Affairs, unless different instructions are given in writing by a staff member of the Department of Public Health or Elder Affairs.

100.153: Department of Mental Health Participation

(A) The Department of Mental Health (DMH) has the statutory responsibilities, pursuant to M.G.L. c. 19, § 1, to “take cognizance of all matters affecting the mental health of the citizens of the commonwealth” and, pursuant to M.G.L. c. 19, § 16 to “develop a comprehensive, area-based system to provide community mental health services” in Massachusetts. The Department of Mental Health may review and comment upon any application relating to a facility, part, unit, beds, or other services designed exclusively or primarily for the mentally ill.

(B) Whenever 105 CMR 100.000 calls for any person to send any application, notice, or document of any kind to the Department of Mental Health as a party of record or calls for review or comment on applications or other participation by the Department of Mental Health, the same shall be construed to apply only to applications under M.G.L. c. 111, § 25C, § 51 or § 71 involving a facility part, unit, beds or other services designed exclusively or primarily for the mentally ill.

(C) Two copies of all papers required above shall be submitted to the Department of Mental Health. One copy shall be submitted by hand-delivery, or by first-class mail, to the Director of Health Policy at the Department of Mental Health, and a second copy shall be submitted by hand-delivery or first-class mail, to the appropriate DMH Regional Administrator. Addresses may be obtained from the Program Director.

100.154: Division of Health Care Finance and Policy Participation

Pursuant to M.G.L. c. 118G, § 16 the Division of Health Care Finance and Policy may review and comment upon any application for a determination of need for a capital expenditure project including, but not limited to, less costly or more effective alternatives to the proposal; the immediate and long-term financial feasibility; the probable impact of the proposal on costs of charges for services; and the availability of funds for capital and operating needs. Whenever 105 CMR 100.000 requires any person to send any application, notice or documentation of any kind to a party of record two copies shall be submitted to the Division of Health Care Finance and Policy.

100.160: Environmental Impact

(A) The Department must comply with the provisions of M.G.L. c. 30, §§ 61-62H [Massachusetts Environmental Protection Act (MEPA)] and 301 CMR 11.00 *et seq.* (the Executive Office of Environmental Affairs) prior to granting a determination of need.

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Pursuant to 301 CMR 11.00, an environmental notification form shall be completed by the applicant and filed with the Secretary of Environmental Affairs at any time prior to, but not later than, ten days after filing of the determination of need application unless the project is exempted under 301 CMR 11.00.

(B) Applicants are urged to familiarize themselves with the provisions of 301 CMR 11.00, MEPA, and the relevant regulations of the Executive Office of Environmental Affairs prior to submitting an application for determination of need. In addition, prior to filing an application, applicants are urged to consider those sections of 105 CMR 100.000 which specifically relate to environmental impact.

100.200: Notification Before Any Public Solicitation Required

Any person intending to make a solicitation of funds from the general public or to enter into any agreement in order to secure financing for construction or a substantial change in service shall file notice of its intent, at least 30 days before taking such action and, if public solicitation is intended, shall be subject to such order as the Commissioner may issue under 105 CMR 100.205. (105 CMR 200.000 through 205.000 is not applicable to government agencies.) The provisions of 105 CMR 100.200 through 100.205 shall not apply with respect to any project for which a determination of need has been granted.

100.201: Notice of Intent to Secure Financing

The notice of intent under 105 CMR 100.200 shall be titled "Notice of Intent to Secure Financing" and shall contain at least the following information: name and address of person giving notice; location of project (by street address if site has been selected), including the name of any existing health care facility involved; description of project, including specification of licensing category of facility to be constructed or involved in project and of any change in services contemplated; target population by medical category and applicable service area; amount, type, and sources of financing to be sought; and best estimate of capital expenditure necessary for project.

100.202: Filing of Notice of Intent With Department

Notices of intent to secure financing under 105 CMR 100.200 shall be submitted for filing, with an original and three copies, to the Program Director. Each notice shall be signed by the person under a duty to file same, or by its chief executive officer. Such signature shall constitute certification by the signer that he or she has read the document and that every statement contained therein is true to the best of his or her knowledge. Each notice submitted hereunder shall be deemed filed on the day of receipt by the Department; provided, however, that the Program Director shall refuse to accept for filing, and after filing, shall revoke his or her acceptance of any notice not conforming to the requirements of 105 CMR 100.204 or 105 CMR 201.000.

100.203: Filing of Notice of Intent With Agency Advisors

Upon filing of a notice of intent to secure financing under 105 CMR 100.202, copies shall be provided to the Division of Health Care Finance and Policy, the Department of Elder Affairs if relevant pursuant to 105 CMR 100.152, and the Department of Mental Health if relevant pursuant to 105 CMR 100.153.

100.204: General Fundraising Exempted From Notice Requirement

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The provisions of 105 CMR 100.200 through 100.205 shall not apply to any solicitation or securing of financing where the undertaking to be funded is not sufficiently specific to constitute the subject matter of an application for determination of need pursuant to 105 CMR 100.000. However, the provisions of 105 CMR 100.200 through 100.205 shall apply to any person who intends or reasonably expects to apply a portion of funds so raised to an undertaking sufficiently specific to constitute the subject matter of application for determination of need.

100.205: Order Postponing Public Solicitation

(A) Within 30 days of receipt of a notice of intent filed with the Department, the Commissioner may direct the person filing the notice not to make a public solicitation without a determination of need.

(B) Where the Commissioner does not issue an order under this section the person filing notice of intent to solicit funds from the general public may make such solicitation without first applying for a determination of need. Failure by the Commissioner to issue an order, however, shall not be interpreted in any way as constituting a determination of need. Representation to the contrary for the purpose of securing funds shall be grounds for dismissal of an application for determination of need under 105 CMR 100.531.

100.220: Statement Required From Health Care Facilities

Every health care facility shall submit annually no later than August 1st of each year to the Program Director a statement describing those anticipated projects which will require a determination of need. Each statement shall separately identify those projects planned for the forthcoming filing year.

100.221: Effect of Statement Upon Health Care Facilities

(A) A health care facility shall not be bound to undertake any project presented in its statement of anticipated projects. In assessing whether a health care facility has made the required demonstration under 105 CMR 100.533(B)(1), the Department will take into account an applicant's compliance with 105 CMR 100.220.

(B) Acceptance or favorable comment upon a statement shall not be construed as a commitment by the Staff or by the Department to any particular project in a plan.

100.230: Requirement of Notification for Research Projects

Any health care facility undertaking a substantial capital expenditure or a substantial change in service related solely to the conduct of research in the basic biomedical or applied medical research areas shall give written notice thereof to the Department and the Division of Health Care Finance and Policy. The notice shall be received at least 60 days before undertaking such expenditure or change in service.

100.231: Form of Notice of Assurance for Research Projects

A notice of assurance form shall be available from the Program Director upon request. All notices of assurance must be made upon the prescribed form and be completed in full.

100.232: Manner of Filing Notice of Assurance for Research Projects

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Notices of assurance shall be submitted for filing with an original and two copies to the Program Director and a copy to the Division of Health Care Finance and Policy. Each notice shall be signed by the health care facility's chief executive officer and the chairperson of the board of trustees. Such signatures shall constitute certification by the signers that they have read the document and that every statement contained within is true to the best of their knowledge. Each notice submitted hereunder shall be deemed filed on the day of receipt by the Program Director.

100.233: Review of Notice and Approval of Research Projects

(A) If the notice of assurance is not completed in full upon its original filing, the Program Director shall reject the notice and return it within 60 days of the date of filing to the person who filed it along with a written statement of reasons for the rejection. The proposed project shall not be undertaken until at least 60 days after filing of a complete notice of assurance. The Program Director may waive the waiting time if, upon review of a complete notice of assurance, he or she sends written notice to the facility that a determination of need is not required.

(B) A health care facility undertaking a research project under 105 CMR 100.233 shall not file an application for determination of need for such capital expenditure or change in services until at least one year after commencing such research project.

(C) Any health care facility undertaking a research project under 105 CMR 100.233 shall periodically report information concerning such research project as the Program Director may reasonably request, provided, however, that such reports shall not be required more frequently than once every six months.

(D) A research exemption granted under 105 CMR 100.233 shall not be deemed to constitute evidence of need in any determination of need application.

100.234: Order Requiring Filing of Application

(A) Any person subject to the notice requirements of 105 CMR 100.230 shall be required to file an application for a determination of need under any of the following circumstances:

- (1) The notice of assurance required by 105 CMR 100.230 through 100.233 is not filed;
- (2) The Program Director finds, within 60 days after receipt of a complete notice of assurance form, that the proposed substantial capital expenditure or substantial change in service will not be related solely to research in the basic biomedical or applied research areas, or will result in an increase in the clinical bed capacity or outpatient capacity of a health care facility, or will be included within or cause an increase in the gross patient service revenues of a facility; or
- (3) The Program Director finds, within 60 days after receipt of a complete notice of assurance form, that an application for determination of need from the health care facility is pending for a reasonably similar capital expenditure or change in services.

(B) After a person has undertaken a research project it shall be required to file an application for a determination of need if the Program Director finds that the research project has: resulted in an increase in the clinical bed capacity or outpatient capacity of the health care facility; been included within or caused an increase in the gross patient service revenues of such facility; or it is not related solely to research in the basic biomedical or applied research areas.

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(C) If the Program Director makes a finding pursuant to 105 CMR 100.234(A) or (B), he or she shall order the filing of a determination of need application by sending written notice of such finding to the person who filed the notice of assurance.

100.235: Review by the Council of Order Pursuant to 105 CMR 100.234

Any person receiving a written order that a determination of need is required pursuant to 105 CMR 100.234 may have such order reviewed by the Council by filing a written request for review within 14 days of receipt of the notice with the Program Director and the Office of General Counsel.

100.240: Requirement of Notification of Intent to Acquire Equipment

Any person or agency intending to acquire by purchase, lease, or other arrangement for location other than on the premises of a health care facility (or a unit or satellite thereof), a unit of medical, diagnostic, or therapeutic equipment with a fair market value in excess of \$150,000, other than equipment used to provide an innovative service or which is a new technology, and any health care facility, controlled directly or indirectly by an HMO, intending to acquire for the purpose of serving outpatients, such a unit of equipment (including equipment used to provide an innovative service or which is a new technology), shall give written notice thereof to the Department. The notice shall be received by the Department at least 30 days before the equipment is acquired or contractual arrangements are implemented to acquire the equipment.

100.241: Form of Notice Pursuant to 105 CMR 100.240

The notice shall, at a minimum, contain the following information: name of the person acquiring the equipment; the medical application of the equipment; the anticipated capital expenditure; a description of those instances where the equipment will be used to provide services to inpatients of a hospital; and a complete description of the legal, financial, administrative, medical, and physical relationship to any existing health care facility.

100.242: Manner of Notification Pursuant to 105 CMR 100.240

An original and two copies of a notice of intent required by 105 CMR 100.240 shall be submitted for filing to the Program Director. Each notice shall be signed by the person or agency under a duty to file same or a duly authorized agent thereof. Such signature shall constitute certification by the signer that he or she has read the document and that every statement contained therein is true to the best of his or her knowledge. Except as otherwise provided in 105 CMR 100.243, each notice submitted hereunder shall be deemed filed on the day of receipt by the Program Director.

100.243: Review of Notice by Program Director

If the notice of intent is not complete upon its original filing, the Program Director shall send notice that it is not complete to the person filing the notice of intent within 30 days of the date of filing. The 30 day period for Departmental review of such notice shall commence upon the date a complete notice of intent is filed. The equipment shall not be acquired nor shall contractual arrangements to acquire the equipment be entered into until at least 30 days after the filing of a complete notice of intent unless the Program Director finds that a determination of need is not required and waives the waiting period in writing.

100.244: Order Requiring Filing of Application

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(A) Any person or agency subject to the notice requirements of 105 CMR 100.240 shall be required to file an application for a determination of need for acquisition of medical equipment if the requirements for exemption pursuant to 105 CMR 100.263 are not met, and if the notice of intent required by 105 CMR 100.240 is not filed.

(B) If the Program Director makes a finding pursuant to 105 CMR 100.244(A), he or she shall order the filing of a determination of need application by sending written notice of such finding to the person required to make such filing.

100.245: Review by Council of Order Pursuant to 105 CMR 100.244

Any person directed to file a determination of need application pursuant to 105 CMR 100.244(A) may have such order reviewed by the Council by filing a written request for review within 14 days of receipt of the notice with the Program Director and the Office of General Counsel.

100.246: Determination of Need Review for Innovative Service and New Technology

(A) No person or agency shall provide an innovative service or use a new technology in any location other than a health care facility unless the person or agency first is issued a determination of need by the Department.

(B) No person may acquire medical equipment that is used to provide an innovative service or that is a new technology pursuant to a notice of intent filed with the Department before December 29, 1993, unless such person has made substantial and continuing progress as that term is defined in 105 CMR 100.246(F) on the acquisition of such medical equipment by September 1, 2008, and unless such equipment is fully operational by July 1, 2009.

(C) No person who, prior to such acquisition being subject to determination of need, acquired medical, diagnostic or therapeutic equipment designed or intended to provide an innovative service or that is a new technology, for location other than in a health care facility, may implement an addition, expansion, conversion, transfer of site or transfer of ownership of such equipment unless the Department is first notified pursuant to 105 CMR 100.246(C) and determines there is need therefore, or unless an exemption is granted pursuant to 105 CMR 100.263. For purposes of review of the addition, expansion, conversion, transfer of site or transfer of ownership of such equipment, the Department shall deem that such equipment was acquired pursuant to a determination of need.

(D) No person who, pursuant to a notice of intent filed with the Department before December 29, 1993, acquired medical equipment that is used to provide an innovative service or that is a new technology for location other than in a health care facility, may implement an addition, expansion, conversion, transfer of site or transfer of ownership of such equipment unless the Department is first notified pursuant to 105 CMR 100.246(D) and determines there is need therefore, or unless an exemption is granted pursuant to 105 CMR 100.263. For purposes of review of the addition, expansion, conversion, transfer of site or transfer of ownership of such equipment, the Department shall deem that such equipment was acquired pursuant to a determination of need.

(E) Any person who, prior to such acquisition being subject to determination of need, or pursuant to a notice of intent filed with the Department before December 29, 1993 acquired medical, diagnostic or therapeutic equipment that is used to provide an innovative service or that is a new technology, for location other than in

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a health care facility, shall be deemed, for purposes of 105 CMR 100.551(K) and (L), to have acquired such equipment pursuant to a determination of need.

- (F) For the purposes of 105 CMR 100.246, “substantial and continuing progress” shall mean either
- (1) the site has received approval from the Department’s plan review office; or
 - (2) demonstration of a binding contract for the purchase or lease of the equipment with a party unrelated to the letter holder or ultimate provider of the innovative service or new technology.

100.250: Requirement of Notification of Intent to Acquire a Health Care Facility

Any person or agency intending to acquire an existing health care facility by purchase, lease or other arrangement, shall give written notice to the Department of such person’s or agency’s intent and of the facility’s existing and proposed services and bed capacity. The notice shall be received by the Department at least 30 days before the facility is acquired or contractual arrangements are implemented to acquire the facility, except that facilities licensed under the provisions of M.G.L. c. 111 § 71, shall provide notice at least 90 days before the facility is acquired or contractual arrangements are implemented to acquire the facility.

100.251: Form of Notice Pursuant to 105 CMR 100.250

The notice shall, at a minimum, contain the following information: name and address of the health care facility being acquired; name and address of the seller; name and address of the buyer; the anticipated changes, if any, in the services of the health care facility; and the anticipated changes, if any, in the bed capacity or licensed bed capacity of the facility.

100.252: Manner of Notification of Intent to Acquire a Health Care Facility

An original and two copies of a notice of intent shall be submitted to the Program Director. Each notice shall be signed by the person or agency under a duty to file same or a duly authorized agent thereof. Such signature shall constitute certification by the signer that he or she has read the document and that every statement contained therein is true to the best of his or her knowledge. Except as otherwise provided in 105 CMR 100.253, each notice submitted pursuant to 105 CMR 100.250 shall be deemed filed on the day of receipt by the Program Director.

100.253: Review of Notice of Intent to Acquire a Health Care Facility

If the notice of intent is not completed in full upon its original filing, the Program Director shall send notice that it is not complete to the person filing the form within 30 days of the date of filing. The 30 day period for Departmental review of such notice shall commence upon the date a complete notice of intent form is filed. Contractual arrangements to acquire the facility shall not be implemented until at least 30 days after filing of the complete notice of intent unless the Program Director finds that a determination of need is not required and waives the waiting period in writing.

100.254: Order Requiring Filing of Application

(A) Any person intending to acquire an existing health care facility shall file an application for a determination of need for such acquisition if the requirements for exemption pursuant to 105 CMR 100.263 are not met and if:

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- (1) The acquisition is a transfer of ownership subject to determination of need review pursuant to M.G.L. c. 111, § 51 (see 105 CMR 100.012 and 100.600);
- (2) The notice of intent required by 105 CMR 100.250 is not filed; or
- (3) The Program Director finds within 30 days of receipt of a complete notice of intent that there will be a substantial change in the services of the facility being acquired.

(B) If the Program Director makes a finding pursuant to 105 CMR 100.254(A)(3), he or she shall order the filing of a determination of need application by sending written notice of such finding to the person required to make such filing.

100.255: Review by Council of Order Pursuant to 105 CMR 100.254

Any person directed to file a determination of need application pursuant to 105 CMR 100.254(B) may have such order reviewed by the Council by filing a written request for review within 14 days of receipt of the order with the Program Director and the Office of General Counsel.

100.260: Submission of Request for Inpatient Exemption Pursuant to M.G.L. c. 111, § 25C½

M.G.L. c. 111, § 25C½ provides that certain substantial capital expenditures for construction related to the provision of inpatient services and certain substantial changes in inpatient services shall be exempt from the determination of need requirements of M.G.L. c. 111, § 25C. In addition, certain acquisitions of medical equipment to be used to provide services to hospital inpatients and certain acquisitions of existing health care facilities providing inpatient services which would otherwise be subject to determination of need review pursuant to 105 CMR 100.244 and 105 CMR 100.254 respectively, shall be eligible for exemption. Any person seeking such exemption shall submit a request on a form if available from the Program Director. The request shall be completed in full and shall be signed by the person or agency under a duty to file same or a duly authorized agent thereof and shall provide evidence as to why the proposed expenditure or change in services meets the requirements of M.G.L. c. 111, § 25C½. Such signature shall constitute certification by the signer that he or she has read the document and that every statement contained therein is true to the best of his or her knowledge. An original and three copies shall be filed with the Program Director. A request for exemption may be filed on any business day.

100.261: Copies of Request to Division of Health Care Finance and Policy

A person filing a request for exemption pursuant to 105 CMR 100.260 shall provide a copy to the Division of Health Care Finance and Policy.

100.262: Completeness Review

If the request pursuant to 105 CMR 100.260 is not completed in full, the Program Director shall reject the request and send notice within 60 days of the date of filing along with a written statement of the reasons for the rejection.

100.263: Standard for Review of Request Pursuant to 105 CMR 100.260

(A) The Program Director shall approve or disapprove a request within 60 days of the filing of the completed form. A request shall be approved when, based on a clear and convincing demonstration made by the person filing the request, the Program Director finds that the proposed substantial capital expenditure for

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construction related to the provision of inpatient services, the proposed substantial change in inpatient services, or the proposed acquisition of medical equipment or an existing health care facility will be made by or on behalf of one of the following:

- (1) An HMO or combination of HMOs if:
 - (a) the HMO or combination of HMOs has in the service area of the HMO or the service areas of the HMOs in combination an enrollment of at least 50,000 individuals;
 - (b) the facility in which the services will be provided is or will be geographically located so that the services will be reasonably accessible to such enrolled individuals; and
 - (c) at least 75% of the patients who can reasonably be expected to receive the inpatient service or services proposed by the project will be individuals enrolled with such HMO or HMOs in combination; or
- (2) A health care facility if:
 - (a) the facility primarily provides or will provide inpatient services;
 - (b) the facility is or will be controlled, directly or indirectly, by an HMO or combination of HMOs which has in the service area of the HMO or service areas of the HMOs in combination an enrollment of at least 50,000 individuals;
 - (c) the facility is or will be geographically located so that the services will be reasonably accessible to such enrolled individuals; and
 - (d) at least 75% of the patients who can reasonably be expected to receive the inpatient service or services proposed by the project will be individuals enrolled with such HMO or HMOs in combination; or
- (3) A health care facility or portion thereof if:
 - (a) the facility is or will be leased by an HMO or combination of HMOs which has in the service area of the HMO or the service areas of the HMOs in combination an enrollment of at least 50,000 individuals and on the date the application is submitted at least 15 years remain in the term of the lease;
 - (b) the facility is or will be geographically located so that the services will be reasonably accessible to such enrolled individuals; and
 - (c) at least 75% of the patients who can reasonably be expected to receive the inpatient service or services proposed by the project will be individuals enrolled with such HMO or HMOs in combination.

(B) The Program Director shall approve a request submitted under 105 CMR 100.260 only if the applicable requirements prescribed by 105 CMR 100.263 have been met on the date the proposed activity for which an exemption was requested will be undertaken. The method of payment for services (*e.g.*, prepaid or fee-for-service), shall not be relevant in determining whether a project qualifies for exemption.

100.264: Denial of Request for Exemption Pursuant to 105 CMR 100.260

Denial of a request for exemption shall not constitute a finding concerning need for the proposed project, and shall not prejudice an application for determination of need for the project. An exemption shall not be transferable and shall be valid only for the project for which granted.

100.300: Submission of Applications

Every person or government agency seeking a determination of need shall submit an original application and two copies to the Program Director and, prior to or at the same time as the submission, shall submit one

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copy of the application to the Division of Health Care Finance and Policy, one copy to the appropriate Regional Health Office, two copies to the Department of Elder Affairs if necessary under 105 CMR 100.152, and two copies to the Department of Mental Health if necessary under 105 CMR 100.153. However, in the case of an emergency application or an exhibit to any application numbering more than ten pages, only an original and one copy need be submitted to the Department, and only one copy to each of the other agencies. **Notwithstanding any other provision of 105 CMR 100.000, the Program Director may direct alternate means, including but not limited to electronic submissions, for filing any application, written communication or any other written materials required to be submitted to any party, including the Department, pursuant to 105 CMR 100.000.**

100.301: Acceptance of Applications for Filing

(A) Without regard to the day on which an application is received, an application shall not be considered filed until the appropriate filing day as set forth under 105 CMR 100.302, except as otherwise provided in 105 CMR 100.303(D).

(B) No application shall be accepted for filing unless

(1) according to the Department's guidelines, as they are in effect as of the appropriate filing day, there is unmet need (*i.e.*, unsatisfied health care requirements, as defined in and pursuant to 105 CMR 100.533(B)(2)) for the project which is the subject of the application after accounting for all approved, exempted and certified projects, including without limitation, authorized but unimplemented projects or

(2) the application is for renovation or replacement of an existing health care facility and the proposed renovation or replacement may be permissible under applicable guidelines or Department policy.

100.302: Filing Days for Applications and Amendments

(A) The filing day for emergency applications and for applications eligible for delegated review shall be the business day on which the application is received.

(B) The filing day for unique applications shall be the business day on which the application is received.

(C) The filing day for applications for acute care hospital projects, other than innovative services or new technologies, shall be the business day on which the application is received.

(D) The filing day for applications for convalescent, nursing and rest home projects which are subject to licensure by the Department pursuant to M.G.L. c. 111, § 71 shall be the first business day of May, beginning in May 2010.

(E) The filing day for applications for hospital projects which are subject to licensure by the Department pursuant to M.G.L. c. 111, § 51, other than acute care hospital projects, shall be the business day on which the application is received; provided, however, that the filing day for applications for addition of Long Term Care Hospital beds shall be the first business day of September.

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(F) The filing days for applications for innovative services or new technologies shall be the first business days of February and August; provided, however, that:

- (1) the filing day for applications for Neonatal Intensive Care Units shall be the first business day of August 2007 and thereafter the filing day for such applications shall be the first business days of February and August; and
- (2) the filing day for applications for Radiation Therapy Units shall be the first business day of October 2006 and thereafter the filing day for such applications shall be the first business days of February and August.

(G) The filing day for all amendments shall be the business day on which the amendment is received.

100.303: Completeness Review

(A) Each application shall be subject to a review for completeness by the Program Director who shall, within 30 days of submission, determine whether or not the application is complete and send written notice of such determination to each party of record.

(B) An application shall be considered incomplete if:

- (1) the application was not submitted in accordance with 105 CMR 100.300;
- (2) the content of the application does not conform with the requirements of 105 CMR 100.320 through 100.326;
- (3) notice was not given in accordance with 105 CMR 100.200 through 100.205;
- (4) notice was not given in accordance with 105 CMR 100.330 through 100.334;
- (5) the applicant did not provide any documentation or failed to provide satisfactory documentation of standing as required by 105 CMR 100.306; or
- (6) any section of the application form(s) has not been completed, unless permitted by the Program Director.

(C) The Program Director shall reject an incomplete application, provided however, that the Program Director may, within his or her discretion, give the applicant a reasonable opportunity for correction, except that applications submitted pursuant to 105 CMR 100.604 shall not be given an opportunity for correction, and must be resubmitted. If such opportunity is provided, the Program Director subsequently shall either accept or reject the application and send written notice of his or her determination to each party of record.

(D) Notwithstanding any failure of the Program Director to reject an application, the existence of any of the defects set forth in 105 CMR 100.303(B) shall constitute grounds for dismissal under 105 CMR 100.531.

100.304: Comparable Applications

(A) Designation

- (1) Within 14 days after the Program Director has determined, pursuant to 105 CMR 100.303, that the applicable filing requirements have been met, any party of record may file written recommendations with the Program Director for him **or her** to consider in determining which applications should be designated as comparable under 105 CMR 100.304(A)(2) or (3).
- (2) Mandatory Designation. Within 21 days after the Program Director has determined, pursuant to 105 CMR 100.303, that the applicable filing requirements have been met, the Program Director shall

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determine whether the application is comparable with any other application(s) which were filed within the same filing period.

(3) Discretionary Designation. Within 21 days after the Program Director has determined, pursuant to 105 CMR 100.303, that the applicable filing requirements have been met, the Program Director may, within his or her discretion, designate such application comparable with any pending application filed within a different filing period within the same filing year.

(B) Notice. The Program Director shall promptly notify each affected applicant and other party of record of any decision made under 105 CMR 100.304 and shall, in those cases where a designation of comparability was made, include the name, address and project number of each comparable applicant.

(C) Review by Council. Any party wishing to object to a designation of comparability or a decision of non-comparability (in those cases where a designation of comparability was requested under 105 CMR 100.304(A)(1) and denied), shall file a statement of objection in writing with the Program Director not more than ten days after receipt of notice of said action. The Program Director shall present the statement of objections to the Council which shall review the Program Director's action. Any party which has submitted a written statement shall be provided an opportunity to make a brief presentation to the Council. No action with respect to comparability shall be subsequently changed.

(D) Procedural Safeguards. In addition to the safeguards provided to all applicants in 105 CMR 100.307, designation of an application as comparable in relation to any other application shall entitle the applicant to have its application considered disposed of at the same time as each such application, unless the applicant waives this requirement or the Department determines that action on one comparable application shall have no prejudicial effect upon any other comparable application. The designation of an application as comparable in relation to any other application shall not give rise to any substantive right.

100.305: Assistance Prior to Application

Prospective applicants shall exercise the utmost care in developing projects and in preparing and submitting applications. Prospective applicants shall seek advice from relevant state agencies in the development of projects and in the preparation of applications. Assistance concerning procedures shall be available from Department staff consistent with the staff's other duties under 105 CMR 100.000.

100.306: Standing to Make Application

No person or government agency shall be permitted to make application for determination of need unless such person or agency has sufficient interest in the site or facility, and unless such site may be used for the proposed purpose.

(A) As used hereunder, sufficient interest shall mean one of the following:

- (1) clear legal title to the proposed site;
- (2) a lease for at least five years with options to renew for not less than a total of 15 additional years in the case of a hospital, institution for unwed mothers, long-term care facility, or institution for the mentally ill or retarded, except an intermediate care facility for the mentally retarded;
- (3) a lease for at least one year with options to renew for not less than one additional year in the case of a freestanding ambulatory surgery center or an intermediate care facility for the mentally retarded;
- (4) a legally enforceable agreement to give such title under 105 CMR 100.306(A)(1) or such lease under 105 CMR 100.306(A)(2) or (3), in the event need is determined by the Department;

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(5) permission to use the premises for a period of at least two years in the case of a clinic organized under M.G.L. c. 180 (non-profit corporation); or

(6) 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 agency and, in the case of an agency of the Commonwealth of Massachusetts within an executive office, acceptance of that recommendation by the Secretary of that office.

(7) in the case of a project authorized by an unimplemented determination of need, the period of authorization of which is eligible to be extended pursuant to 105 CMR 100.551(E½)(3), a complete Statement of Interest properly filed in accordance with 105 CMR 100.551(E½)(3).

(B) As used hereunder, “such site may be used for the proposed purpose” shall mean one of the following:

(1) the proposed purpose is authorized under applicable zoning by-laws or ordinances, whether or not a special permit is required;

(2) if the proposed purpose is not authorized under applicable zoning by-laws or ordinances, a variance has been received to permit such use; or

(3) the proposed purpose is exempt from zoning by-laws or ordinances.

(C) Satisfactory documentation of standing as required herein shall be contained in the applicant's statement of application, including a letter from any appropriate municipal authority indicating that the site for the proposed project is properly zoned for the anticipated use of the project or a written explanation of why the proposed purpose is exempt. If no documentation is found or, the documentation submitted is unsatisfactory, the Program Director may reject the application pursuant to 105 CMR 100.303 or may, within his or her discretion, provide a reasonable opportunity for correction. Failure to provide satisfactory documentation shall constitute grounds either for rejection of the application under 105 CMR 100.303 or dismissal of the application under 105 CMR 100.531.

(D) An applicant that loses interest in site after acceptance of the application must notify the Department within two weeks of losing the site. The applicant shall then be given 120 days to submit documentation of interest in a new site through the amendment process found in 100.350 *et seq.* Failure to file a complete amendment within that time may result in dismissal of the application.

100.307: Procedural Safeguards Accorded Applicants

(A) Every person or government agency filing an application shall be entitled to disposition of its application before or at the same time as the Department takes final action on any other application filed on a subsequent filing day if the Program Director determines that action on the later filed application shall have a prejudicial effect upon the earlier filed application.

(B) No substantive right shall accrue to any person or government agency by filing of an application for determination of need.

100.308: Special Exemptions

(A) The Program Director may, in his or her discretion, exempt a project that does not involve a substantial capital expenditure and that involves a substantial change in services or original licensure for a freestanding ambulatory surgery center from any provision of 105 CMR 100.000, subject to such conditions as he or she

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deems appropriate, including but not limited to a condition regarding community initiatives consistent with 105 CMR 100.551(J).

(B) Any person or government agency wishing to apply for this exemption for a proposed project shall submit to the Program Director prior to commencement of the project a written statement describing the project and stating the proposed dates the project will commence and conclude.

(C) If a person or government agency intends to continue a project exempted pursuant to 105 CMR 100.308 for greater than one year, the Program Director may in his or her discretion order the person or government agency to apply for a determination of need within such period as the Program Director may specify. Such application shall be filed in accordance with the provisions governing applications. Failure to submit a complete application within the time specified shall result in the automatic termination of the exemption.

(D) Final action shall be based on the normal standards and criteria used by the Department in reviewing applications of the type involved. Pending final action on any such application filed for determination of need, the exemption shall remain in effect. In the event an appeal of the Department's final action is filed with the Health Facilities Appeals Board, the exemption shall remain in effect until final action is taken by the Board. Any exemption granted under 105 CMR 100.308 shall in no way constitute evidence of need for a project.

100.320: Form of Application

Every application for determination of need shall consist of four parts, as described in 105 CMR 100.321 through 100.324, together with an affidavit of publication of notice of such application as required in 105 CMR 100.332, and such additional information as the applicant may wish to present in accordance with 105 CMR 100.325. All written material submitted hereunder shall be typewritten or written by hand in a legible manner. Materials which are not legible will not be accepted.

100.321: Statement of Application

Every applicant, on a form prepared by the Program Director, shall give a statement of the proposed project. While the form may be changed periodically, the required statement will ordinarily deal with at least the following subjects: identity of applicant, nature, scope, and location of project; description of applicant's existing health care facility, if any; the total capital expenditures required for project, if any (see 105 CMR 100.020); the likely operating costs; proposed method of financing including financing charges, if any; description of applicable service area and target population; and proposed schedule for completion of the project, including impact on cost and financing. Exhibits may be appended.

100.322: Supporting Documentation

(A) Every applicant shall provide, at the time of filing, the information and supporting documentation required on forms and instruction sheets prepared or approved by the Program Director. The Program Director may revise the forms and instruction sheets periodically and may have different forms for different types of projects and may permit the applicant to use forms prepared for other government agencies if said forms contain the same or essentially similar information as the supporting documentation forms. Such supporting documentation forms shall at a minimum solicit information regarding the capital, financing, and operating costs of the project, financial feasibility and capability, environmental impact if any, documentation of planning with providers, community groups, and supportive health planning data such as utilization rates and average lengths of stay. Exhibits may be appended.

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(B) Applications submitted at their option by acute-care hospitals shall include an affidavit assuring the Department that no part of the subject matter of the application has been or shall be implemented prior to or during the application's pendency. In the case of a corporate applicant such affidavit shall be signed by the chief executive officer of the corporation and the chairman of the board on behalf of the corporation; in the case of a trust, all trustees shall sign the affidavit. In addition, the affidavit shall state that after reading the application and any additional information submitted, and after making diligent inquiry of all appropriate agents, to the best of the affiants' knowledge the application and additional information contain no false statement or misrepresentation of fact and that the affiants have read 105 CMR 100.000.

100.323: Filing Fee and Computation Sheet

Every applicant shall accompany its statement of application and supporting documentation with a filing fee, if required, computed in the manner described in 105 CMR 100.323, and a computation sheet on a form prepared by the Department showing all computations. If no fee is required, only the computation sheet shall be submitted, with a statement explaining the basis for exemption. A filing fee is required from every person applying under M.G.L. c. 111, § 25C, except that persons applying solely under M.G.L. c. 111, §§ 51 through 53 or § 71 and government agencies applying under any provision of law, shall be exempt. The filing fee shall be 1/10 of 1% of the proposed capital expenditures, but no less than \$250; provided, however, that if a different filing fee has been established pursuant to 801 CMR 4.02, said provision shall govern. Every applicant required to submit a filing fee shall be on notice that such fee is subject to refund only if its application is rejected pursuant to 105 CMR 100.303, 100.352 or 100.605. Notwithstanding the above, the Program Director may, at his or her discretion, waive a filing fee in the event that an application filed is determined to be substantially the same as one previously withdrawn by the same applicant during the current or previous filing year.

100.324: Affidavit of Truthfulness and Proper Submission

Every applicant shall include with the other parts of its application, on the proper form, a statement signed under the pains and penalties of perjury that after reading the application and any additional information submitted, and after making diligent inquiry of any agents responsible for completing or submitting the application, to the best of the affiant's knowledge the application and additional information contain no false statement or misrepresentation of fact and, that the affiant has read 105 CMR 100.000, that in the case of an application for original licensure the applicant(s) shall be the eventual licensee(s) of the facility, that to the best of the affiant's knowledge copies of the application, in the requisite number, true in every respect, have been sent by mail or delivered by hand to the Department and to each party of record. In the case of a corporate applicant, the chief executive officer of the corporation and the chairman of the board shall sign the affidavit on behalf of the corporation; in the case of a partnership, all partners shall sign the affidavit except that in the case of a limited partnership, the general partner shall sign the affidavit; and in the case of a trust, all trustees shall sign the affidavit.

Acute-care hospitals applying for an optional determination of need are referred to the additional affidavit required pursuant to 105 CMR 100.322(B).

100.325: Additional Information

Every applicant shall be on notice that it is responsible for justifying the need for the project by making a clear and convincing demonstration in its application that the project meets each of the governing factors set forth in 105 CMR 100.533. See also 105 CMR 100.534. Accordingly, in addition to completing the

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application and supporting documentation forms, every applicant shall submit with its application, at the time of filing, whatever additional evidence it wishes to place before the Department in support of its application.

100.326: Calculation of the Estimated Capital Expenditure

In calculating the capital expenditure under 105 CMR 100.321, every applicant shall include not only all expected future expenditures in connection with a project but also any past or present expenditures necessary for its construction, including purchase price of an earlier acquired site, expense of feasibility or other planning studies used in developing a project or preparing an application, expenses incurred in seeking grants, loans, or other financing, and legal or consultant fees. Where construction is to be undertaken on leased property or where equipment to be installed is leased, the fair market value of such property or equipment, as appropriate, in conformance with the terms of M.G.L. c. 111, § 25B, shall be used in calculating the portion of the proposed capital expenditure attributable to such property or equipment. Every calculation must take into account all capital expenditures (see 105 CMR 100.020). As is further explained in the applicable portion of the application forms, all calculations shall be based on costs as of the date of application assuming construction commenced on that date, with no estimate regarding inflation included. In calculating the estimated capital expenditure, applicants should consider the provisions of 105 CMR 100.551 dealing with the project cost condition placed on every determination of need.

100.330: Notice of Application and Amendments

(A) Except in a situation involving an emergency application (see 105 CMR 100.333), every applicant for determination of need shall cause notice of its application, and of any amendment thereto under 105 CMR 100.350, to be published prior to the filing of such application or amendment. The notice shall accurately describe the proposed project in conformance with 105 CMR 100.331(B), provided, however, that if such notice as published contains one or more material typographical errors, the applicant shall cause a corrected notice to be published within a reasonable period of time unless the Program Director waives the re-publication requirement.

(B) Such notice shall be published in the daily newspapers published in the city or town of, or nearest to, the location of the project.

100.331: Form and Content of Notice

Every notice of application or amendment shall conform to the following standards for form and content:

(A) Form. The notice shall be at least two inches high by three columns wide, or at least three inches high by two columns wide; shall appear in the Legal Notice section; and shall be captioned, as appropriate, either “Public Announcement Concerning New Health Care Facility” or “Public Announcement Concerning (name of existing health care facility involved).” An identical notice shall also be published at least once in some other section of the appropriate newspaper.

(B) Content. The notice shall identify the applicant, by name and address, the name and address of the health care facility involved or proposed, shall describe the project briefly, including the type of facility involved, the type of service proposed or involved (e.g., “addition of 40 medical-surgical beds in a new wing”; “construction of a new long-term care facility with 40 Level II beds, 60 Level III beds, and 60 Level IV beds”), shall state the capital expenditure; and shall contain the following statements: “Any ten taxpayers of Massachusetts may register in connection with the application by (date, 30 days from the proposed filing date or publication date, whichever is later). If requested, a public hearing shall be ordered on the application

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(application as amended) at the request of any such ten taxpayers made in writing, not later than (date, 20 days after proposed filing day or publication date, whichever is later). Such registrations or requests for hearing shall be sent to the Department of Public Health, Determination of Need Program, (at its current address). The application (amendment) may be inspected at such address and also at (appropriate Department of Public Health Regional Health Office).”

100.332: Affidavit of Publication of Notice

No application for determination of need, except as provided in 105 CMR 100.333, and no amendment under 105 CMR 100.350 shall be accepted for filing unless the applicant has submitted along with the application or amendment, a statement signed under the pains and penalties of perjury that the applicant has caused notice of the application or amendment to be published in accordance with 105 CMR 100.000 and an original of the newspaper notice(s) is (are) attached to the affidavit.

100.333: Notice of Emergency Application

In the case of an emergency application, notice of the application may be given after the application has been filed with the Department. Publication of notice shall otherwise be as prescribed in 105 CMR 100.330 and 100.331. An affidavit of publication in conformity with 105 CMR 100.332 shall be filed with the Department within ten days after filing of the application.

100.334: Procedure for Emergency Application

(A) Application. Instead of using the application forms described in 105 CMR 100.321 through 100.324, any person or government agency believing an emergency situation exists, as defined in 105 CMR 100.020, may make application for a determination of need by filing with the Department a letter signed under the pains and penalties of perjury which sets forth the identity of the applicant, the nature of the emergency, and the nature, scope, location and cost of the project. The applicant shall comply with the requirements for submission of application at 105 CMR 100.300 and for publication of notice at 105 CMR 100.333.

(B) Designation. Upon receipt of the letter required in 105 CMR 100.334(A) the Program Director shall determine whether there is an emergency situation as defined in 105 CMR 100.020. The Program Director shall give notice of this decision to all appropriate parties. Within the discretion of the Program Director, the applicant may subsequently be required to submit any or all of the usual application forms.

(C) Filing. An application designated as an emergency application under 105 CMR 100.354(B) may be filed on any business day pursuant to 105 CMR 100.302.

(D) Action on Applications deemed to be emergency applications will be acted upon by the Council, unless, in the opinion of the Commissioner, immediate action is required as authorized pursuant to 105 CMR 100.505(A)(8).

100.350: Amendment of Application

After an application has been filed with the Department, it may not be amended except in the limited circumstances set forth in 105 CMR 100.350. No amendment shall be accepted which in the opinion of the Program Director alters the project in nature, scope, financing, applicable service area, or substantially alters or affects the Department's evaluation of the project. No amendment shall be accepted which alters the costs of the project, except that amendments reflecting increases in costs due solely to loss of site may be accepted

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if the Program Director determines that the loss of site was due to contingencies not reasonably within the control of the applicant. The decision of whether to accept an amendment shall rest with the Program Director. The Program Director may determine that the subject of a proposed amendment is merely technical and that the change may be effected without formal amendment to the application. Any change in the ownership of the applicant shall be made by formal amendment except that if such change, figured on a cumulative basis, is in excess of 50% of the ownership interest of the applicant, then no amendment shall be permitted and the application should be resubmitted.

100.351: Manner of Amendment

(A) If an amendment to an application is filed and accepted under 105 CMR 100.350, the applicant must file an affidavit of truthfulness and proper submission (see 105 CMR 100.324) and must submit a copy of the amendment to each party of record.

(B) The Department shall take no action on the amended application until:

- (1) notice of the amendment has been published in accordance with 105 CMR 100.330 through 100.332;
- (2) such amended application has been on file with the Department for at least 30 days;
- (3) a public hearing has been held thereon if requested within 20 days of publication; and
- (4) the parties of record have had 30 days after publication or five days after any public hearing in which to comment thereon.

100.352: Completeness Review

Each amendment shall be subject to a review for completeness by the Program Director within 30 days of submission in order to determine whether or not the necessary filing requirements have been met. The Program Director shall be authorized to reject an amendment if he or she determines that the requirements of 105 CMR 100.351 have not been met.

100.353: Effect of Amendment on Comparability Status

An applicant that is allowed to amend an application which has been designated comparable to one or more other applications loses the right under 105 CMR 100.304 to have the application considered as comparable with, and disposed of at the same time as, the other application(s), unless such amendment is filed within 90 days of the filing date of the original application.

100.354: Limitation on Changes in Supporting Documentation and Submission of Additional Information

(A) An applicant may not change its supporting documentation or submit additional information to the Department after filing of its application unless:

- (1) Department staff request such documentation or information; or
- (2) the Program Director gives his or her written permission to submit such documentation or information.

(B) Staff may request that an applicant submit supporting documentation or additional information at any time. Any written request for information by the staff shall be answered within 14 days of receipt by the applicant.

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(C) A copy of all written requests for additional information by the staff and of all additional information submitted in writing to the Department by any party shall be sent by the person requesting or submitting the additional information to all parties of record.

100.355: Withdrawal of Application

An applicant may withdraw its application at any time by sending written notice thereof to the Program Director. Whenever an application is withdrawn, the Program Director shall promptly notify each party of record. An applicant shall not be entitled to a refund of any filing fee submitted except as provided in 105 CMR 100.323.

100.400: Opportunity for Comment by Parties of Record

(A) With respect to each application for determination of need, except for an emergency application, the Department shall afford reasonable opportunity to comment to all parties of record listed in 105 CMR 100.020. 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 under 105 CMR 100.000.

(B) Comments by parties of record shall be filed with the Program Director not more than 30 days after the Program Director has determined, pursuant to 105 CMR 100.303, that the applicable filing requirements have been met, or after the Program Director has designated, pursuant to 105 CMR 100.304, one application comparable with another, whichever is later. The period for comment shall extend for ten days after any public hearing held pursuant to 105 CMR 100.410. The Program Director may in his or her discretion extend the period for comment upon written request submitted to the Program Director. Parties of record may submit views after the period for comment has expired, but such views shall be treated in accordance with 105 CMR 100.401.

(C) Recommendations shall be treated under 105 CMR 100.000 as specific recommendations only if they appear in written comments filed in a timely and proper manner, recommend either approval, denial or other definite final action with respect to each part of the applicant's request, and set forth specific reasons in support of each recommendation. Comments in the nature of observations shall in no event be considered to be specific recommendations within the meaning of 105 CMR 100.400.

(D) Each commenting party shall provide a copy of its written comments to the affected applicant and to each other party of record, and it shall submit certification of compliance with said requirements when it files such comments with the Program Director.

(E) It shall be within the discretion of the Commissioner whether, and to what extent, to permit review and comment upon an emergency application.

(F) In addition to the opportunity for comment set forth in 105 CMR 100.400, parties of record may seek to affect the Department's action on an application in the following ways:

- (1) by requesting a public hearing under 105 CMR 100.410 as a way of bringing to the Department's attention public opinion concerning the application;
- (2) by filing written reaction to the staff report under 105 CMR 100.421;
- (3) in the case of a category #2 application, by making an oral presentation to the Department under 105 CMR 100.515; and

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(4) by submitting further comments if authorized by the Department under 105 CMR 100.520.

100.401: Opportunity for Comment by the General Public

Persons or agencies other than parties of record listed in 105 CMR 100.020 may make their views known to the Department at the public hearing (if one is ordered under 105 CMR 100.410) or in writing. All written comments must contain the name and address of the commenter, and, if the comments are submitted on behalf of another party, the name and address of the party represented by the commenter. It shall be within the discretion of the Commissioner whether, and to what extent, to permit review and comment upon an emergency application.

100.402: Applicant's Role in Review

(A) An applicant shall cooperate fully with the Department, the Division of Health Care Finance and Policy, the Department of Elder Affairs if relevant pursuant to 105 CMR 100.152, and the Department of Mental Health if relevant pursuant to 105 CMR 100.153.

(B) The opportunity for comment set forth in 105 CMR 100.400 shall be available to an applicant with respect to comparable applications, but not with respect to its own application. With respect to its own application, an applicant may seek to convince the Department of the appropriateness of taking favorable action on its application in the following ways:

- (1) by submitting material supporting its application under 105 CMR 100.322 and 100.325;
- (2) by requesting a public hearing under 105 CMR 100.410;
- (3) by filing written reaction to the staff report under 105 CMR 100.421;
- (4) in the case of a category #2 application, by making an oral presentation to the Department under 105 CMR 100.515.

100.410: Public Hearing

(A) The Program Director shall order a public hearing upon written request made under 105 CMR 100.410, which shall set forth with specificity the issues relevant to the review of the determination of need application to be raised by the requesting party at the public hearing, and which shall be submitted together with an affidavit of truthfulness, or whenever, in his or her opinion, a public hearing would aid the staff in carrying out its duties under 105 CMR 100.420. Any public hearing which may be held with respect to any comparable application shall concern all applications involved in such comparison.

(B) A public hearing shall be ordered provided that such request is filed with the Program Director within 20 days after the date the application is filed or notice is published in the newspaper, whichever is later. Such period for filing, however, shall extend for an additional ten days after a designation of comparability under 105 CMR 100.304 for applications not initially so designated.

(C) The purpose of a public hearing under 105 CMR 100.410 shall be to allow any person to make its views with respect to an application known to the Department through an oral presentation given before its designated representatives. Such hearing shall not be adjudicatory but shall be in the nature of a public forum for the presentation of any comment which may be relevant to the consideration of an application under 105 CMR 100.000.

(D) A public hearing ordered by the Program Director may be held at any time. If feasible, every public hearing shall be held at a location in the applicable service area. The Program Director, at least ten days

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before any public hearing, shall cause notice of the time, place, and nature of such hearing to be mailed, first class, to each party of record and to be announced generally through publication in at least one daily or weekly newspaper distributed in the applicable service area of the project.

(E) A designated representative of the Department shall be responsible for the conduct of any public hearing, including setting the permissible length of presentations, arranging the order of presentations, and serving as presiding officer. Requests to speak shall be made to the presiding officer at the beginning of each public hearing, and if he or she permits, during the hearing. Following each presentation if the speaker is willing, questions may be asked by the presiding officer and by any member, employee, or agent of the Department assisting in the conduct of the public hearing. The presiding officer shall require each speaker to identify him or herself by name and address, and if the speaker is presenting comments on behalf of another party, to identify the party represented by the speaker. The presiding officer shall exclude from presentation at the public hearing comments which are not relevant to the review of the determination of need application or comments submitted by speakers who fail to identify themselves or the party represented by the speaker.

(F) Except in the case of an application subject to delegated action pursuant to 105 CMR 100.506(B), the Program Director shall cause a summary of the comments given at each public hearing to be prepared as part of the staff report under 105 CMR 100.420, provided that the Program Director shall not be required to summarize comments made at a public hearing by parties of record. It shall be the duty of each party of record to file any comments it wishes to make in writing to the Department under 105 CMR 100.400 or 100.401, as the case may be.

100.420: Staff Report

The Program Director shall prepare a written staff report for subsequent transmission to the Council on every application for determination of need unless the application is withdrawn under 105 CMR 100.355 or unless the application is subject to delegated action pursuant to 105 CMR 100.506(B).

(A) The staff report shall contain at least the following: a description of the project applied for, with a summary of any significant supporting material filed by the applicant; a summary of all comments filed in a timely and proper manner under 105 CMR 100.400 as well as any specific recommendations properly filed; a summary of other pertinent comments given at any public hearing; a summary of such other comments as the Program Director wishes to bring to the Council's attention; any additional material or staff analysis which the Program Director believes would aid the Council in its determination; and a statement of the staff's recommendation or suggested options for final or preliminary action upon the application.

(B) The staff report shall be made public and shall be provided to parties of record as follows:

- (1) where the staff report recommends approval in whole or in part of an application and all comparable applications, and it is consistent with all specific recommendations submitted in written comments, the report need not be placed in the public file until at least seven days before the Council's meeting scheduled for consideration of the application or applications;
- (2) where the staff report recommends denial of an application or a comparable application, or where it rejects a specific recommendation submitted in written comments upon such application, the report shall be placed in the public file at least 21 days before the Council's meeting scheduled for consideration of the application or applications.
- (3) At the same time that the staff report is so filed, a copy of the report shall be mailed, first class, to each party of record.

100.421: Written Reaction to Adverse Staff Report

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(A) In advance of the Council's meeting scheduled upon an application, the applicant and other parties of record, including any person whose application is comparable, shall have the right to react in writing to the staff report where the report recommends denial in whole or in part of the application or a comparable application, or rejects a specific recommendation of a party of record.

(B) This right may be claimed only if the written statement together with 35 copies, are submitted to the Program Director at least 12 days prior to the Council meeting, and one copy is simultaneously mailed, first class, to each party of record.

100.500: Prerequisites to Department Action

Except in the case of an emergency application, the Department shall not take preliminary or final action upon an application, unless:

(A) the application and any amendments thereto have been on file with the Department for at least 30 days, and the applicant has provided copies in requisite number to each party of record; and

(B) a public hearing has been held under 105 CMR 100.351 or 100.410, if requested pursuant to 105 CMR 100.351 or 100.410.

100.504: Authority of Commissioner to Approve Applications

The Commissioner and Public Health Council acting as the Department hereby delegate to the Commissioner authority to approve applications for certain projects that meet the requirements of 105 CMR 100.505 and the factors prescribed by 105 CMR 100.533, and are consistent with the purpose and objective of the determination of need process (see 105 CMR 100.001). Such action by the Commissioner shall be known as delegated action and shall constitute final action of the Department within the meaning of 105 CMR 100.530. Applications subject to and approved pursuant to the delegated review process shall not be subject to the provisions of 105 CMR 100.420 through 100.421, and 100.510 through 100.521. However, such applications shall be subject to all other provisions of 105 CMR 100.000, unless otherwise provided.

100.505: Applications Eligible for Delegated Review and Action

(A) Except as provided in 105 CMR 100.505(B), an application is eligible for delegated review and action if it comes within one of the following categories:

- (1) An application for a project under M.G.L. c. 111, § 51 for an original license for change of ownership of a hospital or free-standing ambulatory surgery center (see 105 CMR 100.600);
- (2) An application for a project with a maximum capital expenditure below \$3,000,000 concerned solely with repairs, remodeling or renovation necessary and appropriate to correct cited deficiencies under state or federal regulations governing fire, safety or physical environment, provided that such construction is consistent with the existing scope of health care services offered by the applicant;
- (3) An application for a project concerning a non-acute care facility, with a maximum capital expenditure of less than \$5,000,000 concerned solely with construction involving: administrative services, air conditioning, heating, ventilation, auditorium, boiler, cafeteria, central supply, chapel, dietary services, data processing, telecommunication services, energy conservation or generation, food preparation, lobby, maintenance, roofing, or similar equipment, services or facilities; provided that such construction is consistent with the existing scope of health care services offered by the

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applicant; and provided that the project is not directly related to the medical care or treatment of patients;

(4) An application for a project with a maximum capital expenditure below \$1,000,000 concerned solely with the addition of nursing home beds;

(5) An application for alteration of, making of major repairs to, remodeling of, or replacement of a convalescent, nursing or rest home;

(6) An application submitted by an acute care hospital pursuant to 105 CMR 100.604;

(7) An application deemed to be an emergency application by the Program Director, pursuant to 105 CMR 100.334(B);

(8) An application for a project submitted by an intermediate care facility for the mentally retarded or an agency of the Commonwealth of Massachusetts;

(9) An application submitted for a single specialty, freestanding ambulatory surgery center;

(10) An application submitted for expansion of Magnetic Resonance Imaging (MRI) services;

(11) An application submitted for expansion of megavoltage radiation therapy services; or

(12) An application submitted for expansion of chronic disease or acute inpatient rehabilitation services.

(B) An application shall not be eligible for delegated review although it comes within one of the categories contained in 105 CMR 100.505(A), if it has been designated comparable, pursuant to 105 CMR 100.304, to an application which does not come within one of the categories contained in 105 CMR 100.505(A).

100.506: Procedure for Delegated Review and Action

(A) Applications submitted pursuant to 105 CMR 100.604. The commissioner may issue notice of certification to an applicant that meets the requirements of 105 CMR 100.606 and Department guidelines for the conversion of acute care beds to non-acute care services. Applications which, in the judgment of the Commissioner, are inconsistent with the requirements of 105 CMR 100.606 or with Department guidelines shall be denied without prejudice to a subsequent application submitted pursuant to 105 CMR 100.300 *et seq.*

(B) Applications submitted pursuant to 105 CMR 100.505(A)(1) through (5) and (8) and (9).

(1) Where approval of an application eligible for delegated review would be consistent with all specific recommendations filed in a timely and proper manner under 105 CMR 100.400, as applicable, and where, in the judgment of the Commissioner, the project meets the requirements of 105 CMR 100.533, any relevant criteria (see 105 CMR 100.540), and the objective in 105 CMR 100.001, the Commissioner shall approve the application, provided that the Commissioner has also decided to approve all comparable applications. Written notice of the determination of need shall be issued pursuant to 105 CMR 100.561.

(2) Where approval of an application eligible for delegated review would not be consistent with all specific recommendations filed in a timely and proper manner under 105 CMR 100.400 or where the Commissioner decides not to approve the application or any comparable application, the Commissioner shall cause a staff report to be prepared and the application brought before the Council pursuant to 105 CMR 100.420 and 100.510 through 100.521.

100.511: Notice of Applications Scheduled for Consideration

For the purpose of the determination of need program, at least seven days before every Council meeting, the Commissioner shall designate each determination of need application on the agenda as either category #1 or category #2. No application shall be subsequently added to an agenda, except upon consent of the

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applicant and all other parties of record. An application, however, may be deleted from an agenda at any time by the Commissioner or by the Council. Not later than five days before a meeting, the Commissioner shall cause notice of the agenda to be given orally or sent by mail to each affected applicant, the Division of Health Care Finance and Policy, the Department of Elder Affairs, the Department of Mental Health, and all parties of record.

100.512: Postponement of Consideration of Application

Any party of record may request postponement of the consideration of a particular application until the next meeting of the Council. Said request will rarely be granted and 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 making the request from having its position considered by the Council, and that postponement would not prejudice any other party of record. A request for postponement under 105 CMR 100.512 must be made in writing to the Commissioner, with a copy to the Program Director, and must state why such postponement is necessary. A party of record may be granted a postponement only once.

100.513: Material for Council's Consideration

Prior to the meeting at which an application is being considered, each member of the Council shall receive a copy of the staff report on the application, any written reactions to the staff report filed in a timely and proper manner by parties of record, any responses by staff, together with such other material as the Program Director deems relevant.

100.514: Consideration of Category #1 Applications

(A) An application shall be designated in the agenda as a category #1 application where the staff report is for approval of the application and any comparable applications involved, and is consistent with all specific recommendations filed in a timely and proper manner.

100.515: Consideration of Category #2 Applications

(A) An application which is not designated on the agenda as category #1 shall be a category #2 application. As such, it shall be considered by the Council in accordance with the following procedures:

- (1) Unless the Commissioner directs otherwise, consideration shall begin with an oral presentation by the Program Director or some other member of the staff.
- (2) Any party of record shall then be entitled to make an oral presentation of not greater than five minutes in length. The order of presentation may be varied by the Commissioner.
- (3) Council members may ask unlimited questions of the staff or of any party of record.

(B) All parties shall utilize the time they are allocated for oral presentation to focus on those considerations about which there are differences of opinion as reflected in the staff report and in the written reactions to the staff report under 105 CMR 100.421.

100.516: Ban on Introduction of New Material

No party of record shall be allowed to introduce written or oral material which the Program Director indicates was not submitted in the application or in accordance with 105 CMR 100.354.

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100.517: Rulings at Council Meetings

In the course of consideration of an application, the Commissioner as chairman of the Council, shall make any ruling which may be necessary. Any such ruling may be reversed by the Council upon motion duly made, seconded, and voted.

100.518: Record of Council Meeting

Following every meeting at which the Department acts upon an application, the Commissioner shall cause such action, and the reasons therefore in the case of final action, to be reduced to a written statement. Such records shall be public and shall be on file with the Department.

100.520: Preliminary Action

(A) The Council upon consideration of an application on its agenda, may, when it considers final action inappropriate, by motion duly made, seconded and voted, take preliminary action.

(B) As preliminary action upon an application, the Council may direct the Program Director:

- (1) to notify the applicant and all other participants in the proceeding of its intent to resume consideration of the application at a subsequent meeting;
- (2) to conduct further staff review of the application in the manner directed, and to report in writing to the Council within a specified period and subject to such modification of the procedures specified in 105 CMR 100.420 and 100.421 as the Council may indicate;
- (3) to conduct a public hearing with respect to the application on such subjects and within such period as the Council may specify;
- (4) to request further comments by the Division of Health Care Finance and Policy or parties of record with respect to such issues and within such period as the Council may specify; or
- (5) to take such other action as, in the opinion of the Council, will facilitate final action on the application.

100.530: Right to Determination of Need; Limitations

(A) With respect to every application not withdrawn or dismissed (see 105 CMR 100.355 and 105 CMR 100.531), the Council shall, by motion duly made, seconded, and voted, make a final determination of need under 105 CMR 100.000, subject to the terms and conditions set in accordance with 105 CMR 100.550, 100.551, and 100.552. The Council shall so approve or disapprove in whole or in part each such application for determination of need filed pursuant to M.G.L. c. 111, § 25C within eight months after filing with the Department; provided that the Department may, on one occasion only, delay such action for up to two months after the applicant has provided information which the Department has reasonably requested during such eight month period. Applications remanded to the Department by the Health Facilities Appeals Board pursuant to the provisions of M.G.L. c. 111, § 25E shall be acted upon by the Department within the same time limits for approval or disapproval.

(B) In taking final action, the Council shall not approve or deny an application in part except where it has determined that the part is severable from the remainder of the application for purposes of consideration hereunder, provided, however, that in such circumstances the applicant shall submit to the Department information acceptable to the Program Director which describes the portion of the project recommended for final action, including revised financial data.

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(C) The Council shall consider all specific recommendations filed by parties of record under 105 CMR 100.400.

100.531: Dismissal Without Determination of Need

(A) The Council upon consideration of an application on its agenda, may upon motion duly made, seconded, and voted, dismiss the application without making a determination of need. Dismissal shall be considered final Departmental action.

(B) An application may be dismissed on any one of the following grounds:

- (1) the applicant, in violation of M.G.L. c. 111, § 25D, has failed either to file notice of intent or to comply with an order to postpone public solicitation of funds (see 105 CMR 100.200 through 100.205);
- (2) the applicant, for the purpose of securing funds for construction or substantial change in services, has misrepresented the decision of the Commissioner not to issue an order (see 105 CMR 100.205(B));
- (3) the applicant has made an improper communication to the Commissioner, the Program Director, or any member of the staff or the Council (see 105 CMR 100.110), has failed to send copies of a communication or written materials to all parties of record (see 105 CMR 100.100), or has sought to exert undue influence on any such person or upon a member or employee of the Executive Office of Health and Human Services;
- (4) the applicant has made a false statement or misrepresented a material fact in any oral or written communication to the Department in connection with its application;
- (5) the applicant has otherwise failed substantially or repeatedly to comply with the provisions of 105 CMR 100.000;
- (6) the application is not within the jurisdiction of the Department (see 105 CMR 100.010 through 100.015);
- (7) it would be pointless to determine need, either because the applicant is not suitable or responsible to be licensed to maintain the project, or because the project as proposed is not capable of being licensed for any reason, including, without limitation, the applicant's failure to timely comply, and maintain compliance, with environmental notification form filing requirements and other requirements set forth in 301 CMR 11.00;
- (8) the applicant has failed to meet one or more of the filing requirements as set forth in 105 CMR 100.303(A) or 100.600;
- (9) an applicant for an optional determination of need has begun implementation of any part of that which is proposed in the application (see 105 CMR 100.011(2)); or
- (10) an applicant which fails to submit, as an amendment, documentation of interest in a new site within 135 days of losing a previous site (see 105 CMR 100.306(D)).

(C) Prior to consideration by the Council, the Program Director may, upon information presented by the staff or in the petition of an interested person or agency, order an applicant to show cause why its application should not be dismissed if, on the basis of such information and other known facts, the Program Director has reason to believe that grounds exist for dismissal. Information not presented by the staff shall be in proper affidavit form. The show cause proceeding need not include a formal hearing under M.G.L. c. 30A, unless the Commissioner shall so direct upon the recommendation of the Program Director. Any formal hearing under M.G.L. c. 30A shall be before a hearing examiner designated by the Commissioner.

(D) Administrative review shall be available under 105 CMR 100.980 with respect to a show cause proceeding unless such proceeding shall have included a formal hearing under M.G.L. c. 30A.

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100.533: Factors Applied in Determinations

(A) The Department shall determine that need exists for a project or part thereof where, on the basis of material in the record, the applicant makes a clear and convincing demonstration that the project or part meets each of the governing factors, as set forth in 105 CMR 100.000 and Department guidelines. In making its presentation, the applicant shall use such criteria as are in effect in accordance with 105 CMR 100.540. If the required demonstration is not made with respect to each factor, the determination shall be of no need except where, in the limited circumstances set forth in 105 CMR 100.534, the Department makes an affirmative determination notwithstanding the nonconformity with 105 CMR 100.533(B)(2), (3) or (5)(a) or except in the limited circumstances where the Department makes an affirmative determination pursuant to 105 CMR 100.541.

(B) Factors shall be as follows:

(1) Health Planning Process. The project, as applied for, is the product of a sound health planning process, which takes into account the substantive issues encompassed in factors 105 CMR 100.533(B)(2) through (8), and which includes reasonable consultation, both prior to and after filing, with affected agencies. These agencies include the Department of Mental Health for mental health projects, Department of Elder Affairs for long term care projects, and Division of Medical Assistance for both acute care and long term care projects, where appropriate. The applicant must also demonstrate that the proposed project will not duplicate existing resources in the applicable service area.

(2) Health Care Requirements. The project, upon completion, will satisfy, in whole or in part, health care requirements of the projected population of the applicable service area, without any duplication of services and other adverse service consequences, or with the least such adverse consequences as possible in the circumstances. In assessing services available to the projected population of the applicable service area, the applicant has treated as continuing in existence all services currently being provided except where scheduled to terminate, and all services approved to be established under 105 CMR 100.000. In evaluating compliance, the Department shall take into account, as appropriate, geographic barriers, acute seasonal variations of population, or an unusual mix of patients.

(3) Operational Objectives. The project will produce a facility or service which is capable of operating efficiently and effectively, and which relates to other facilities and services so as to promote and further coordination and consolidation of facilities and services within the applicable service area consistent with the objective of the determination of need process. Projects designed exclusively or primarily for the mentally ill or retarded shall interrelate with the range of mental health and mental retardation services available in Massachusetts.

(4) Standards Compliance. The application provides appropriate and adequate written assurances that necessary measures will be taken in the execution of the project to ensure compliance upon completion with all applicable standards of operation imposed by law, including any imposed as requirements of participation as a provider where the project contemplates such participation.

(5) Reasonableness of Expenditures and Costs. The proposed capital expenditure and the likely operating costs are reasonable, including:

(a) comparison with expenditures and costs involved in similar projects, whether approved, or under consideration;

(b) the likely effect upon charges to the public and reimbursement by third party payers to the applicant and to other providers; and

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(c) the availability of funds for capital and operating costs to support health care services in Massachusetts.

(6) Financial Feasibility and Capability. In the light of past and present operating and capital budgets, present balance sheet, projected cash flow statement, proposed level of financing for the project, and other relevant data, the project is financially feasible and within the financial capability of the applicant and, where appropriate as a matter of standard accounting practice, its affiliates.

(7) Relative Merit. The project, on balance, is superior to alternative and substitute methods for meeting the foreseen health care requirements under 105 CMR 100.533(B)(2). Evaluation of this factor shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the project relative to potential alternatives or substitutes, including theoretical as well as existing models.

(8) Environmental Impact. The application provides appropriate and adequate written assurances, as necessary to satisfy M.G.L. c. 30, §§ 61 through 62H and the applicable regulations thereunder, that all feasible measures will be taken in the execution of the project to avoid or minimize damage to the environment.

(9) Primary/preventive health care services and community contributions. For all projects other than long term care projects, the application includes:

(a) a plan for the provision of primary and preventive health care services in accordance with applicable regulations (see 105 CMR 100.551(J); and

(b) documentation of any such community services and contributions currently provided by the applicant in its service area.

Evaluation of this factor may take into account the applicant's existing commitment to primary/preventive health care services, as well as community contributions. The Program Director may waive this requirement, in whole or in part, at the request of an applicant which has provided or, at the time the application is filed, is providing, substantial primary/preventive health care services and community contributions in its service area.

(C) Nothing stated in 105 CMR 100.533 shall be construed to prohibit the making of a determination that need exists for a project or part thereof where in the case of failure to meet a factor, the defect can be remedied by the setting of an appropriate condition under 105 CMR 100.552. The Council shall not unreasonably refuse a request to set a condition necessary to approve an application, but it need not so act on its own initiative.

100.534: Encouragement of Promising Alternatives Substitutes

In the absence of the required demonstration under 105 CMR 100.533(B)(2), (3), or (6), the Department within its sound discretion may determine that need exists for a project or part thereof where, on the basis of material in the record, the applicant makes a clear and convincing demonstration that:

(A) approval will facilitate development of an alternative or substitute to the usual, existing methods of rendering the health services proposed in the project;

(B) the project has reasonable promise of demonstrating the usefulness and desirability of such alternative or substitute method; and

(C) the foreseeable improvements in health care delivery, should such promise be demonstrated, are such as to warrant approval notwithstanding the adverse findings or doubts under 105 CMR 100.533(B)(2), (3), or (6).

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100.535: Service Area Population Projections Used in Determinations of Need

(A) For purposes of determinations of need under 105 CMR 100.533 and 100.534, the population of the applicable service area shall be projected for an appropriate year by using the most recent Department of Public Health Population Projections.

(B) Except where governed by standards and criteria, the applicable service area shall be deemed to coincide with the geographic area in which the facility is located or is to be located as follows:

- (1) in the case of an institution for the mentally ill or retarded, the geographic area established for mental health planning purposes by the Department of Mental Health;
- (2) in the case of a long term care facility, the Department of Public Health Long-Term Care Planning Areas; and
- (3) in the case of other classes of facilities, the areas established for general planning purposes by the Executive Office of Administration and Finance.

(C) The service area as determined by standards and criteria or under 105 CMR 100.535(B) shall apply, unless it shall be established to the satisfaction of the Department by reliable patient origin data or other reliable information, that a different geographic area significantly better satisfies the objectives of the determination of need process under 105 CMR 100.001.

(D) For purposes of approving transfers of site of licensed long term care facilities under 105 CMR 100.720(I), the service area defined in 105 CMR 100.535(A) through (C) shall apply, except that projects or facilities in underbedded urban areas, as defined in Department guidelines, that meet one or more of the following criteria may transfer only within that city or town:

- (1) The per capita income of the urban area is below the state average;
- (2) The percentage of the population of the urban area below 100% of the poverty level is above the state average; or
- (3) The percentage of the population of the urban area below 200% of the poverty level is above the state average.

Those facilities that are unable to secure a suitable site for transfer in the urban area shall provide written documentation in the application of the unavailability of a site within the city or town.

100.536: Statistics and Other Studies Used in Determinations

The Department in making determinations of need will accept as supporting documentation any statistical or other factual material containing reliable data. The Department will take official notice of vital statistics and other demographic data, facility and bed inventories, and utilization and patient origin data compiled by its staff. A copy of material which the Department regularly uses in making determinations of need, or which the Program Director proposes that the Department rely upon, shall be maintained at the office of the Program Director for public examination and copying.

100.537: Determinations in Comparable Situations

Whenever the Council is presented with comparable applications, it shall first determine whether each application, considered alone, is capable of being approved, and shall exclude from further consideration any application which it determines has to be denied. If under applicable standards and criteria all remaining applications may not be approved, the Council shall approve the application or applications, which, in its

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judgment, best satisfies or satisfy the factors under 105 CMR 100.533 and the objective set forth at 105 CMR 100.001.

100.540: Standards and Criteria Used

(A) Parties to proceedings for determination of need shall utilize the standards and criteria adopted by the Department when evaluating applications against the factors found at 105 CMR 100.533, which govern the determination of need process. Providers shall be guided by these standards and criteria in developing institutional plans (including those called for under 105 CMR 100.220) and in preparing applications.

(B) Determinations of need shall be based upon the written record compiled by the Department during its review of the application and, in the case of applications filed pursuant to M.G.L. c. 111, § 25C, on such criteria consistent with M.G.L. c. 111, §§ 25B through 25F, inclusive, as were in effect on the date of the filing of the application unless waived by the applicant.

(C) Criteria in effect, whether or not in regulatory form, shall be a matter of public record on file with the Department. It is the duty of all prospective applicants to obtain from the Program Director copies of all criteria which may relate to the subject matter of a potential application. Criteria contained in an application shall be deemed to be in effect upon filing of the application.

100.541: Special Needs and Circumstances of HMOs

In the case of project proposed by an HMO or health care facility controlled, directly or indirectly, by an HMO, which is not exempt from determination of need pursuant to M.G.L. c. 111, § 25C ½, the Council shall determine that need exists for and shall approve the project or part thereof where, on the basis of material in the record, the applicant makes a clear and convincing demonstration that:

(A) The project, in whole or in part, will meet the needs of enrolled members and reasonably anticipated new members of the HMO for the health services proposed to be provided; and

(B) The proposed new health services are not available from non-HMO providers or other HMOs in a reasonable and cost effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from non-HMO providers or other HMOs, the Council shall consider only whether the services from these providers and HMOs:

- (1) would be available under a contract of at least five years duration;
- (2) would be available and conveniently accessible through physicians and other health care professionals associated with the HMO (for example: whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital);
- (3) would cost no more than if the services were provided by the HMO; and
- (4) would be available to the HMO in a manner which is administratively feasible.

100.550: Terms and Conditions Prescribed

Every determination of need shall be subject to such terms and conditions as the Department may reasonably prescribe consistent with the objective of the determination of need program (see 105 CMR 100.001). The holder of a determination of need shall comply with all statutes and regulations relating to the construction, licensing, and operation of health care facilities. No determination shall remain in force unless the holder complies with these requirements and with each term and condition the Department may set (see 105 CMR 100.700).

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100.551: Mandatory Terms and Conditions

Every determination of need approving a project in whole or in part shall be subject to the following conditions:

(A) The determination, if made under M.G.L. c. 111, § 25C, shall be subject to administrative review by the Health Facilities Appeals Board, and may be stayed by the Health Facilities Appeals Board (*see* 105 CMR 100.970 and 113 CMR 1.02(6)).

(B) Such determination shall be valid authorization only for the person to whom issued, or the government agency to which issued, and may be transferred only upon the written permission of the Department granted pursuant to 105 CMR 100.710, except that a determination of need issued for an original license or change of ownership of a health care facility shall in no event be transferable.

(C) Except as provided in 105 CMR 100.551(I) and 100.750 through 100.757, such determination shall be valid authorization only for the project for which made and only for the total capital expenditure approved.

(C½) Notwithstanding any of the provisions of 105 CMR 100.551(D) through 100.551(J):

(1) the period of authorization for unimplemented determinations made under M.G.L. c. 111, § 25C for any convalescent, nursing and rest home projects that were approved prior to June 1992, shall be extended until January 1, 2007, if the holder has filed a request for an extension, pursuant to 105 CMR 100.756 and 105 CMR 100.551 (E½), prior to January 1, 2000. The period of authorization for unimplemented determinations made under M.G.L. c. 111, § 25C for any convalescent, nursing and rest home projects that were approved after June 1992, shall be extended until January 1, 2007.

(2) the period of authorization for unimplemented determinations made under M.G.L. c. 111, § 25C for the alteration of, expansion of, making of major repairs to, remodeling of, renovation of, or replacement of an existing convalescent, nursing or rest home facility that were approved prior to June 1992, shall not expire, if the holder has filed a request for an extension pursuant to 105 CMR 100.756 and 105 CMR 10.551(E½), prior to January 1, 2000.

(3) the period of authorization for unimplemented determinations made under M.G.L. c. 111, § 25C for the alteration of, expansion of, making of major repairs to, remodeling of, renovation of, or replacement of an existing convalescent, nursing or rest home facility that were approved after June 1992, shall not expire.

(D) The determination, if made under M.G.L. c. 111, § 25C, shall be valid authorization for three years. If substantial and continuing progress toward completion is not made during the three year authorization period, the authorization shall expire if not extended by the Department for good cause shown (*see* 105 CMR 100.756). Any request for an extension must be filed within such period of authorization. In the event an appeal is filed with the Health Facilities Appeals Board, such period of authorization shall be extended during the time that any stay is in effect (*see* 113 CMR 1.02(6)). Within the period of authorization, the holder shall make substantial and continuing progress toward completion, however, no construction may begin until the holder has received final plan approval in writing from the Division of Health Care Quality.

(E) Substantial and continuing progress shall mean:

(1) in the case of a project involving equipping of a health care facility, such equipment shall have been installed and shall be operational;

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- (2) in the case of a project involving the provision of an innovative service or new technology, provision of such service or use of such technology shall have commenced;
 - (3) 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 (or if not required to be so licensed, such beds shall be in operation);
 - (4) 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;
 - or
 - (b) commencement of the physical assembly of the additional structure; and
 - (5) 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.
- (E½)(1) Except as otherwise provided in 105 CMR 100.551(E½)(2) good cause shall mean:
- (a) the applicant is unable to make substantial and continuing progress within the period of authorization because of
 - 1. unreasonably excessive delay on the part of the Department in processing any application or request, or
 - 2. force majeure, *i.e.*, a natural disaster, labor strike, or other cause beyond the control of the applicant and the Department which could not be avoided by the applicant's exercise of due care, or
 - 3. action of general application by any branch of federal, state or local government; ~~and or~~
 - 4. winter conditions which preclude making substantial and continuing progress toward completion, provided that the applicant would have made such progress within the period of authorization but for such winter conditions, or
 - 5. failure to obtain a financing commitment, provided that, within the period of 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 extension of the period of authorization shall be for a period of not more than four months); and
 - (b) the applicant is prosecuting diligently to completion all matters that are prerequisites to making substantial and continuing progress within the period of authorization.
- (2) Good cause shall exclude:
- (a) transfer of ownership,
 - (b) transfer of site,
 - (c) failure to obtain a financing commitment under circumstances other than those described in 105 CMR 100.551(E½)(1)(a)5.
 - (d) action taken by a person (*i.e.*, a private individual or entity, or a public or governmental entity), related to zoning, which has or may have the effect of limiting the applicant's development rights with respect to a site or sites in one city or town, and
 - (e) any other reason not specifically included in 105 CMR 100.551(E½)(1).
- (3) (a) Notwithstanding anything to the contrary in 105 CMR 100.000, the period of authorization of any authorized but unimplemented determination of need and any determination of need the period of authorization of which expired on or after June 19, 1991 is hereby extended (subject to the requirements of 105 CMR 100.551(E½)(3)(d)) from the date its holder files with the Department a Statement of Interest, jointly executed by the holder and DCAM, until the last of the following to occur:

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1. the expiration date of the period of authorization in effect immediately before the Statement of Interest is filed;
2. the date one year after the holder's interest in the relevant re-use project is terminated, provided, however, that in the case of a determination of need, the period of authorization of which, as it may have been previously extended, expired prior to the filing of the Statement of Interest, the period of authorization shall expire on the date the holder's interest in the relevant re-use project is terminated; or
3. the date two years after the final transfer of a real property interest in the re-use project site to the holder.

(b) A holder that files a Statement of Interest shall, together with such statement and thereafter, provide the Department with all material information related to the status of its project with DCAM.

(c) A holder's interest in a re-use project shall be deemed terminated when the Department is so notified in writing by the holder or DCAM, or when the Program Director otherwise finds that such interest has terminated (effective the date of the termination, not the date of the notice or finding).

(d) The Program Director shall acknowledge each Statement of Interest in writing, and may specify in greater detail the time and content of supplemental filings required by 105 CMR 100.551(E½)(3)(b).

(e) For the purposes of 105 CMR 100.551(E½)(3):

1. "DCAM" means the Division of Capital Asset Management, whether acting on its own behalf or on behalf of another state agency in connection with a re-use project, and may include the state agency associated with a re-use project, as the context may require.
2. "Holder" means the holder of an unimplemented determination of need or the proposed transferee thereof, as evidenced by a legally enforceable agreement.
3. "Re-use project" means a project involving re-use of a facility of the Department of Public Health, the Department of Mental Health or the Department of Mental Retardation.
4. "Statement of Interest" means a reasonably detailed joint statement of a holder (as to 105 CMR 100.551(E½)(3)4.a., b., and c.) and DCAM (as to 105 CMR 100.551(E½)(3)4.a. and b.), including a joint affidavit of truthfulness and proper submission (*see* 105 CMR 100.324), that:
 - a. in accordance with applicable DCAM procedure, the holder has expressed its interest in a re-use project by formally responding to a DCAM request for information, request for proposals or other notice or solicitation (the specific DCAM procedure shall be identified);
 - b. the holder's proposal or expression of interest is under consideration (or has been accepted) by DCAM; and
 - c. the holder's determination of need may be used for the re-use project with no more than a post-determination amendment pursuant to 105 CMR 100.700 *et seq.*

(F) The determination, if not made under M.G.L. c. 111, § 25C, shall be valid authorization for six months or such other period as the Department may specify. Such determination shall expire if not extended by the Department for good cause shown (*see* 105 CMR 100.756). Any request for extension must be filed within such period of authorization. Within such period of authorization, the DoN holder shall submit a complete application for licensure to the Department.

(G) (1) Notwithstanding the period of the determination pursuant to 105 CMR 100.551(D), 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 determination 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 Program Director may approve a written schedule for the phased submission of such plans beyond that period for any project involving construction having an

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authorized capital expenditure in excess of an amount equal to the expenditure minimum with respect to substantial capital expenditures with respect to acute care 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, and shall not exceed the proportional share of the total approved project cost.

(2) Upon written request, the Program Director may grant an extension of the period for submission of final plans established by 105 CMR 100.551 or by an approved schedule for plan submission. A denial of such a request by the Program Director may be reversed by the Council upon written request of the holder filed with the Program Director within 14 days of receipt of notice of such denial.

(3) Failure to submit final, complete plans on the date prescribed by 105 CMR 100.000 or by an approved schedule for plan submission may result in:

(a) the initiation of revocation procedures under 105 CMR 100.700; or

(b) the disallowance of inflation calculated pursuant to 105 CMR 100.551(I)(5) for the amount of time equal to the time period between the due date for submission of final plans as prescribed by the Program Director and the date of actual submission. The disallowance of inflation for this time period shall be calculated as if the time period occurred immediately preceding the commencement of construction.

(4) Construction shall not begin until written, final plan approval has been received from the Division of Health Care Quality.

(H) The time schedule submitted pursuant to 105 CMR 100.551(G) shall be used to measure continuing progress toward completion pursuant to 105 CMR 100.551(D) and 100.551(F).

(I) Within six months of the receipt of approval of plans and specifications (or, in the case of projects for which a schedule of phased plan submission has been approved, each phase submitted) pursuant to 105 CMR 100.551(G), unless extended for good cause by the Program Director, the holder shall submit to the Program Director firm figures specifying the actual capital cost of the project or current phase thereof, as follows:

(1) the figures submitted shall be itemized so as to include a statement of the anticipated costs for each category of expenditure approved by the Department as set forth in the Notice of Determination of Need issued for the project;

(2) the costs, in total, and by category of expenditure, unless amended pursuant to 105 CMR 100.754, 100.755 or 100.756, shall not be greater than those approved by the Department for the project plus any increase in cost due to the allowable rate of inflation, if any, from the date of application for the project, as allowed pursuant to 105 CMR 100.551(I)(5). An amendment request for a cost increase must be submitted pursuant to 105 CMR 100.750~~551(I)(1) and (2)~~ within 180 days of receipt of final plan approval, unless an extension of the deadline for submission of costs has been approved pursuant to 105 CMR 100.551, in which case an amendment request must be submitted prior to the expiration of the extension.

(3) the figures submitted representing the costs of construction and financing shall be documented by the provision of executed construction contracts and financing agreements;

(4) the Program Director may require the provision of further documentation relating to any or all expenses of the project prior to the approval of an inflation adjustment;

(5) the Program Director shall, unless otherwise provided, approve an adjustment for inflation from the date of application to the date of issuance of final approved project costs (or phase thereof, if approved under 105 CMR 100.551(G)), which shall include an adjustment for the amount of equity required, if any; and

(6) the final approved project cost shall be submitted by the Commissioner or his or her designee to the Division of Health Care Finance and Policy and other appropriate third parties. Should the

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holder fail to submit firm figures specifying the actual capital cost of the project pursuant to 105 CMR 100.551(I)(1) through (5), final approved project costs shall be deemed to be those set forth in the Notice of Determination of Need issued for the project, with the addition of inflation to the date of final plan approval.

(7) no additional increases in the maximum capital expenditure, inflationary or otherwise, shall be approved for convalescent, nursing, rest home, clinic or hospital projects beyond 12 months after the initial licensure of beds and opening of the facility or service.

(J) For all projects other than long term care projects, unless the Program Director has waived, in whole or in part, the primary/preventive health care services and community contributions review factor, pursuant to 105 CMR 100.533(B)(9),

(1) the holder shall expend, over a five-year period (or other period approved by the Department) an amount reasonably related to the cost of the project, for the provision of primary and preventive health care services necessary for underserved populations in the project's service area (or other area approved by the Department) and reasonably related to the project, in accordance with a plan submitted as part of the application process (see 105 CMR 100.533(B)(9)) and approved by the Department; and

(2) the holder shall file reports with the Department detailing compliance with its approved plan and, to the extent practicable, an evaluation of the health effects thereof. The frequency, content and format of such reports shall be established by the Department.

(K) The determination, if made for magnetic resonance imaging equipment for location other than in a health care facility, shall be subject to the following conditions:

(1) In no event shall the holder refer or influence any referrals of patients to said equipment, unless the holder is a physician providing services with that equipment. For purposes of 105 CMR 100.551, no public advertisement shall be deemed a referral or influence of referrals.

(2) Any person who has an ownership interest in said equipment, whether direct or indirect, shall disclose said interest to patients utilizing said equipment in a conspicuous manner.

(L) The determination, if issued for acquisition of medical equipment used to provide an innovative service or which is a new technology, for location other than in a health care facility, shall be subject to the following condition:

The holder shall submit annually to the Department information and data in connection with utilization and volume rates of said equipment on a form or forms prescribed by the Department.

100.552: Terms and Conditions Discretionary with Department

(A) When making a determination of need, the Department may prescribe, in addition to the conditions under 105 CMR 100.551, any other conditions reasonably related to the scope of the project and within the control of the applicant and consistent with the objective of making adequate health care services reasonably available to every person within Massachusetts at the lowest reasonable aggregate cost.

(B) If any conditions are prescribed, pursuant to 105 CMR 100.552(A), the holder shall, unless otherwise provided, file a progress report on its meeting such conditions with the Program Director annually for the first two years after implementation of the project has commenced. The Program Director may require additional reports if deemed necessary.

100.560: Notice of Preliminary Action

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Whenever the Council takes preliminary action upon an application for determination of need, it shall be the responsibility of the Program Director, within 14 days of such action to send appropriate notice in writing to each party of record. Such notice shall, in every instance, set forth the action taken and the rights and duties of each such party and agency with respect to said action.

100.561: Notice of Final Action

(A) Whenever the Department takes final action upon an application for determination of need, it shall be the responsibility of the Program Director to send appropriate notice in writing to each party of record within 21 days of final action. Such notice shall in every instance set forth the final action taken and the reasons therefore, the terms and conditions of any determination of need, the reasons for any rejection of a timely and proper specific recommendation, and the rights and duties of each person and agency notified with respect to said action.

(B) Unless otherwise stated therein, a determination shall not take effect until notice thereof is received by the affected applicant, except that if such determination was made pursuant to, or was comparable with an application filed under M.G.L. c. 111, § 25C, and was treated as a category # 2 application (*see* 105 CMR 100.515), such determination shall not take effect until 20 days after receipt of notice.

(C) Such notice, when signed by the Commissioner or by the Secretary of the Public Health Council with his or her approval, shall constitute the official record of any action taken by the Department and shall be included with the minutes of the Council meeting kept by the Secretary. Such records shall be public and shall be kept on file with the Department.

(D) The Program Director may, within his or her discretion, seek clarification from the Council, if he or she is unsure as to the Council's action on an application. If such clarification is sought, the Program Director shall, at least seven days prior to the Council meeting, send notice to all parties of record of the date of the Council meeting at which the clarification will be considered. Each party of record shall be provided an opportunity to make a brief presentation to the Council.

100.600: Review for Change of Ownership of Hospitals and Freestanding Ambulatory Surgery Centers

Under the authority of M.G.L. c. 111, §§ 51 through 53, no person shall be issued an original license for a hospital or freestanding ambulatory surgery center in which there has been a change in ownership, unless the Department has determined that there is need for such facility at the designated location. 105 CMR 100.600 through 100.603 provide an alternate process, in addition to the process set forth at 105 CMR 100.300 *et seq.*, by which the Department may, in the case of a change of ownership of an existing hospital or freestanding ambulatory surgery center licensed under M.G.L. c. 111, §§ 51 through 53, determine that there is need for the facility at the designated location. Persons seeking determination of need approval under 105 CMR 100.600 through 100.603 are advised to review 105 CMR 100.000 carefully. Persons unable to meet the standards set forth in 105 CMR 100.602 should not submit an application hereunder, but instead should save time and resources by applying, in the first instance, for determination of need approval under the procedures set forth at 105 CMR 100.300 *et seq.* and the objectives, factors, and criteria set forth at 105 CMR 100.001 and 105 CMR 100.533 through 100.541.

100.601: Application Process for Change of Ownership Pursuant to 105 CMR 100.600

(A) Submission. An application in an original and two copies shall be submitted to the Program Director.

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(B) Filing Date and Fee. An application may be filed on any business day and no filing fee shall be required.

(C) Affidavit of Truthfulness. The application shall include an affidavit of truthfulness and proper submission pursuant to 105 CMR 100.324, certifying the truthfulness of the facts contained in the application.

(D) Notice. The applicant shall cause notice of the application to be published prior to the filing of such application in accordance with 105 CMR 100.332. Said notice shall identify the applicant by name and address, the name and address of the hospital or freestanding ambulatory surgery center involved, shall describe the project briefly and shall state the capital expenditure associated with the proposed change. Said notice shall also contain the following statement:

“Persons who wish to comment on the application must submit written comments within (20 days of the filing date or publication date, whichever is later) to the Department of Public Health, Attention: Program Director, Determination of Need Program, (at its current address). The application may be inspected at such address.”

(E) Content. The application shall be made on such form as the Department may require and shall contain, in addition to any information required on such form, the following:

- (1) The names of the current owners of the hospital or freestanding ambulatory surgery center including all partners, shareholders, members, directors, trustees, and officers. If the shareholders, members, or partners are not all individuals, the names of the individuals who directly or indirectly own the partnership interests or shares, or control the members;
- (2) The names of the proposed owners of the hospital or freestanding ambulatory surgery center including all partners, shareholders, members, directors, trustees, and officers. If the shareholders, members, or partners are not all individuals, the names of the individuals who directly or indirectly own the partnership interests or shares, and who control the members;
- (3) A copy of the agreement setting forth all the terms of the proposed transfer;
- (4) A description of any capital expenditures contemplated as part of the transfer;
- (5) A description of any changes in the services of the hospital or freestanding ambulatory surgery center contemplated as a result of the proposed transfer;
- (6) The relationship, if any, of the applicant to an existing hospital or freestanding ambulatory surgery center; and
- (7) Documentation sufficient to demonstrate the compliance with the standards set forth in 105 CMR 100.602.

(F) Completeness Review. Each application shall be subject to a review for completeness by the Program Director who shall, within 30 days of submission, determine and send written notice of such determination to the applicant. The application shall be considered incomplete if the contents of the application do not conform with the requirements of 105 CMR 100.601(C), (D), or (E). The Program Director shall reject an incomplete application, provided, however, that he or she may, within his or her discretion, give the applicant a reasonable opportunity for correction. If such opportunity is provided, the Program Director shall subsequently either accept or reject the application and send written notice of his or her determination to the applicant. An application which initially is found incomplete but subsequently is corrected shall be deemed to have been filed on the day the corrections are received at the Determination of Need Program office. Notwithstanding any failure of the Program Director to reject an application, the existence of any of the defects set forth in 105 CMR 100.601(F) shall constitute grounds for dismissal under 105 CMR 100.531.

100.602: Standards Applied

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The Department shall grant determination of need approval under 105 CMR 100.603 when the applicant demonstrates that it is in conformance with each of the following standards:

(A) Individuals residing in the hospital's or freestanding ambulatory surgery center's primary service area or health systems area comprise a majority of the individuals responsible for the following decisions:

- (1) approval of borrowings in excess of \$ 500,000;
- (2) additions or conversions which constitute substantial changes in service;
- (3) approval of capital and operating budgets; and
- (4) approval of the filing of an application for determination of need;

(B) Evidence that consultation has taken place with the Division of Medical Assistance, prior to submission of the application, regarding access problems of Medicaid recipients to medical services in the facility's primary service area. In the event access problems are identified during the course of such consultation, the applicant shall submit with its application a plan, developed in conjunction with the Division of Medical Assistance, to resolve the identified access problems;

(C) Neither the applicant nor any health care facility affiliates of the applicant have been found to have engaged in a pattern or practice of violating the provisions of M.G.L. c. 111, § 51(D);

(D) If the application is for a transfer of ownership of a hospital, then the applicant is a hospital licensed by the Department or is an affiliate of a hospital licensed by the Department.

100.603: Action on Applications

(A) No action shall be taken until the application shall have been on file for at least 20 days

(B) A public hearing shall be scheduled upon the request of residents of the applicant's service area. Any such request shall be in writing, include the signatures of at least ten residents of the applicant's service areas, and filed with the Program Director within 20 days of the filing of the application. The public hearing shall be scheduled and conducted in accordance with the provisions of 105 CMR 100.410(C) through (E).

(C) The application shall be considered at the Public Health Council. Notice shall be sent to the applicant, persons testifying at the public hearing held pursuant to 105 CMR 100.603(B), and the persons who commented, of the date of the Council meeting at which the application shall be considered. Said notice shall be sent at least seven days prior to the Council meeting. The applicant and the persons who filed comments or testified at the hearing shall be afforded the opportunity to make a brief presentation to the Council prior to the Council taking action on the application. If the Council votes to deny the application, the applicant may, if it so chooses, file an application in accordance with the procedures set forth at 105 CMR 100.300 *et seq.* and the objectives, factors, and criteria set forth at 105 CMR 100.001 and 100.533 through 100.541. Denial of an application filed pursuant to 105 CMR 100.600 *et seq.* shall be without prejudice to a subsequent application filed pursuant to 105 CMR 100.300 *et seq.*

100.604: Review of Conversions of Acute Care Beds to Non-acute Care

Under the authority of M.G.L. c. 111 § 25C, an acute care hospital may initiate a substantial change in service through the conversion of acute care beds to non-acute care services, upon written certification by the Department that the criteria for conversion to non-acute care services in underbedded areas have been met. The non-acute care services for this alternate process shall include skilled nursing, rehabilitation, acute psychiatric and substance abuse when provided as inpatient services. For conversion to each of these non-

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acute care services, the Department shall establish and update guidelines. 105 CMR 100.604 through 100.607 provide the process by which acute care hospitals converting existing acute care bed capacity to non-acute care services may apply for certification, as an alternative to the process set forth at 105 CMR 100.300 *et seq.* A certification pursuant to 105 CMR 100.604 through 100.607 shall not be deemed a determination for purposes of M.G.L. c. 111, § 25E. Applicants whose applications for certification have been denied shall retain the right to submit the application under 105 CMR 100.300 *et seq.*

Acute care hospitals seeking certification under 105 CMR 100.604 through 100.607 are advised to review 105 CMR 100.000 and Department guidelines carefully. Acute care hospitals unable to meet the criteria set forth in 100.606 should elect not to submit an application under this part and should submit an application under 105 CMR 100.300 *et seq.*

100.605: Application Process for Conversions of Acute Care Beds to Non-Acute Care

(A) Submission. An original and two copies of the application shall be submitted to the Program Director, and one copy each filed with the Regional Health Office, the Division of Health Care Finance and Policy, and other appropriate government agencies as set forth in 105 CMR 100.152 and 100.153.

(B) Filing Date and Fee. An application pursuant to the certification process shall be unique and is subject to the terms of 105 CMR 100.302(A) and 100.323.

(C) Affidavit of Truthfulness. The application shall include an affidavit of truthfulness and proper submission pursuant to 105 CMR 100.324, certifying the truthfulness of the facts contained in the application.

(D) Notice. The applicant shall cause notice of the application to be published prior to the filing of such application in accordance with 105 CMR 100.330 and 100.331(A) and shall submit an affidavit of publication of notice in conformance with 105 CMR 100.332.

Said notice shall identify the applicant by name and address, the name and address of the facility involved, shall describe briefly the proposed conversion and shall state the capital expenditure and operating costs associated with the proposed project. The notice shall contain also the following statement: "Persons who wish to comment on the application must submit written comments within ten days of date of filing or publication date, whichever is later to the Department of Public Health, Attention: Program Director, Determination of Need Program, (at its current address). The application may be inspected at such address, and also at (name and address of appropriate Department of Public Health Regional Health Office)."

(E) Content. The application shall contain the following information:

- (1) The names of the current owners of the facility including all shareholders, members, directors, trustees, officers, and partners. If the shareholders, members, or partners are not all individuals, the names of the individuals who directly or indirectly own the shares or partnership interests or control the members.
- (2) A description of any capital expenditures or operating costs associated with the proposed project; and,
- (3) Documentation sufficient to demonstrate compliance with Department guidelines for the non-acute care service desired.

(F) Completeness Review. Each application shall be subject to a review for completeness by the Program Director who shall within 20 days of submission review the application for completeness and send written notice of acceptance or rejection to the applicant. The application shall be considered incomplete, shall be

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rejected and the filing fee returned if the contents of the application do not conform with the requirements of 105 CMR 100.605. An applicant whose application is rejected as incomplete may reapply without prejudice, under 105 CMR 100.605 or under the process set out at 105 CMR 100.300 *et seq.*

100.606: Criteria Applied

The Department shall grant certification for conversion to inpatient non-acute care services when the applicant demonstrates that it conforms with the requirements of 105 CMR 100.606(A) through (G):

- (A) The hospital conforms with each of the criteria contained in Department guidelines for the specific service(s) for which application is made;
- (B) The acute care hospital has consulted with the Division of Medical Assistance prior to submission of the application regarding access problems of Massachusetts Medicaid recipients to the relevant non-acute care service(s) in the proposed service area. The applicant shall demonstrate that it will satisfy the Medicaid access requirements established by the Department's conversion guidelines applicable to its project and that patient selection and scheduling will not be based on a patient's source of payment;
- (C) Neither the applicant nor any health care facility affiliates have been found to have engaged in a pattern or practice of violating the provisions of M.G.L. c. 111, § 51(D);
- (D) The acute care hospital agrees to meet the Department's licensure standards for the non-acute care service(s) for which application is made;
- (E) The acute care hospital has agreed to provide the Department with at least six months notice of cessation of the non-acute care service(s), if approved under 105 CMR 100.607, for the purpose of reconverting to the former acute care services(s). A plan for reconversion shall be developed and approved by the Department prior to cessation of the non-acute care service;
- (F) The applicant has agreed to make substantial and continuing progress toward implementing the project within the 18-month authorization period for conversions to non-acute care services approved under 105 CMR 100.607. Failure of the applicant to make substantial and continuing progress toward implementing the project shall result in the Program Director revoking the certification pursuant to 105 CMR 100.700, unless a request for an immaterial, minor, or significant change to the certification is filed, pursuant to 105 CMR 100.751 through 100.756, within the first 15 months of the authorization period.

For acute care conversions to non-acute care services approved under 105 CMR 100.607, substantial and continuing progress shall be demonstrated by the following:

 - (1) in the case of a conversion to non-acute care services involving no substantial capital expenditure for renovation, a request to the Department for delicensure of the acute care beds requested for conversion and the licensure of the non-acute care service;
 - (2) in the case of a conversion to non-acute care services which involves a substantial capital expenditure for renovation, completion of the renovation and a request to the Department for delicensure of the acute care beds requested for conversion; and,
- (G) Unless it is for a long term care project, the application includes:
 - (1) a plan for the provision of primary and preventive health care services in accordance with applicable regulations (*see* 105 CMR 100.551(J)).
 - (2) documentation of any such community services and contributions currently provided by the applicant in its service area.

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Evaluation of this criterion may take into account the applicant's existing commitment to primary and preventive health care services as well as community contributions. The Program Director may waive this requirement, in whole or in part, at the request of an applicant which has provided or, at the time the application is filed, is providing, substantial primary/preventive health care services and community contributions in its service area.

100.607: Action on Applications for Certification

(A) Prior to recommending final action on an application, the Program Director shall consider any comments submitted pursuant to 105 CMR 100.605. No action shall be taken until the application has been on file for at least 20 days. The Program Director shall be authorized to seek whatever additional information he or she deems appropriate in order to make a decision on the application.

(B) The Commissioner is hereby delegated the authority as set forth at 105 CMR 100.504 to approve or deny the application based on the criteria set forth at 105 CMR 100.606. The certification shall be valid authorization for 18 months.

(C) Unless it is for a long term care project, each certification approved pursuant to 105 CMR 100.607 shall be subject to the conditions set out at 105 CMR 100.551 (C), (G), (I) and (J), except that architectural plans and specifications must be filed within nine months, and if not so filed, the certification shall lapse except as provided by 105 CMR 100.551(G)(2).

(D) If the Commissioner denies the application, the applicant may file an application in accordance with the procedures set forth at 105 CMR 100.300 *et seq.* and the objectives, factors, and criteria set forth at 105 CMR 100.001 and 105 CMR 100.533 through 100.541. Denial of an application filed pursuant to 105 CMR 100.604 *et seq.* shall be without prejudice to a subsequent application filed pursuant to 105 CMR 100.300 *et seq.*

100.608: Exemption for Long Term Care Facilities in Urban Underbedded Areas

Under the authority of M.G.L. c. 111, § 25C½(a)(4) a long term facility, including an infirmary maintained in a town, a convalescent or nursing home, a rest or charitable home for the aged, currently located in or proposed for an urban area which is underbedded for nursing home beds, shall be exempted from the Determination of Need process to add beds or construct a freestanding facility pursuant to 105 CMR 100.608 through 100.611 if it is demonstrated that the criteria of 105 CMR 100.610 and the criteria established in Department guidelines are satisfied.

Applicants for long term care facilities which seek exemption are advised to review 105 CMR 100.000 and Department guidelines carefully. Proposals for long term care facilities which are unable to satisfy the criteria set forth in 105 CMR 100.610 should not be submitted under 105 CMR_100.608, and should be submitted pursuant to 105 CMR 100.300 *et seq.*

100.609: Application Process for Exemption Pursuant to 105 CMR 100.608

(A) Submission. An original and two copies of the application for exemption shall be submitted to the Program Director, and one copy each filed with the Division of Health Care Finance and Policy, the Division of Medical Assistance, the Department of Elder Affairs, and the appropriate Department of Public Health Regional Health Office.

(B) Content. An application for exemption shall describe the proposed project for construction or addition of long term care beds, including the exact number of beds to be added, the address of the facility, shall

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demonstrate how the facility satisfies the criteria set out at 105 CMR 100.610 and shall provide documentation sufficient to demonstrate compliance with Department guidelines.

(C) Filing Date and Fee. An application for exemption filed pursuant to 105 CMR 100.609 shall be unique and has no filing fee (*see* 105 CMR 100.302(A)).

(D) Affidavit of Truthfulness. The application shall include an affidavit of truthfulness and proper submission pursuant to 105 CMR 100.324, certifying the truthfulness of the facts contained in the application.

(E) Notice. The applicant shall cause notice of the application for exemption to be published prior to the filing of such application in accordance with 105 CMR 100.331(A) and shall submit an affidavit of publication of notice in conformance with 105 CMR 100.332. Said notice shall identify the applicant by name and address, the name and address of the facility involved, or proposed, shall state that the applicant seeks exemption from the determination of need process pursuant to M.G.L. c. 111, § 25C½(a)(4), shall describe briefly the proposed addition of long-term care bed capacity, or construction of a long-term care facility and shall state the capital expenditure and operating costs associated with the proposed project. The notice shall contain also the following statement: "Persons who wish to comment on the application must submit written comments ten days of the date of proposed filing or publication date, whichever is later, to the Department of Public Health, Attention: Program Director, Determination of Need Program, (at its current address). The application may be inspected at such address, and also at (name and address of appropriate Regional Health Office)."

100.610: Criteria Applied to Applications Pursuant to 105 CMR 100.609

The Department shall approve an application for exemption from determination of need if the applicant demonstrates that it conforms with the following criteria:

(A) The existing or proposed long term care facility conforms with each of the criteria contained in Department guidelines;

(B) The long term care facility is, or will be located in an underbedded urban area;

(C) If an existing long term care facility, such facility provides at least 70% of its services to residents who are enrolled in Title XIX of the Federal Social Security Act; and

(D) If not an existing long term care facility the applicant shall file an affidavit which states that the facility will provide at least 70% of its services to residents whose costs are reimbursed through Title XIX of the Federal Social Security Act.

100.611: Action on Applications Pursuant to 105 CMR 100.609

(A) Prior to issuing an exemption, the Program Director shall consider the comments filed within ten days of the application's filing. No action shall be taken until the application has been on file for at least 20 days. The Program Director shall be authorized to seek whatever additional information he or she deems appropriate in order to determine that the proposal satisfies the requirements for exemption.

(B) The Program Director shall issue an exemption for a specific number of beds; that exemption shall be valid authorization for three years. If substantial and continuing progress toward completion is not made during the three year exemption period, the exemption shall expire if not extended by the Department for good cause shown. Any request for an extension must be filed within such period of authorization. *See* 105 CMR 100.551(E), 100.551(E½), and 100.756. Substantial and continuing progress is defined by 105 CMR

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100.551(E)(3) through (5). All construction must conform to the licensure requirements of the Department, and cannot be started without written, final plan approval issued by the Division of Health Care Quality.

100.700: Revocation Procedure

The Department shall be authorized to revoke a determination of need for failure of a holder to comply with all terms and conditions of the determination of need. If the Program Director has reason to believe that a determination of need should be revoked, he or she shall comply with the following procedures:

(A) He or she shall make whatever preliminary inquiry of the holder of the determination of need he or she deems appropriate in order to clarify whether a term or condition has been complied with and whether such a failure to comply is justifiable.

(B) If in his or her judgment no reasonable explanation is forthcoming, he or she shall cause the matter to be placed on the agenda of a Council meeting for its consideration.

(C) He or she shall send written notice of the action he or she intends to recommend to the holder, the Division of Health Care Finance and Policy, and each party of record to the original application at least 21 days prior to the Council meeting at which the matter will be considered. The notice shall specify the reasons for the Program Director's recommendation and indicate that the holder will be afforded an opportunity to address the Council concerning its recommended action.

(D) At its meeting the Council shall afford an opportunity to speak to the holder, and to each party given notice. The Council shall take such action as it deems fair and appropriate.

100.710: Transfer of Ownership Procedure for Unimplemented Projects

Whenever a holder of a determination of need (or such person as may have obtained control over the conduct of an approved project) seeks to transfer ownership of an approved but not yet implemented determination of need authorization, in accordance with 105 CMR 100.551(B), the following procedures shall apply, provided that no application for a transfer of ownership shall be accepted or approved in any instance where:

- (1) a holder of a determination of need proposes a transfer of fewer than 100% of the approved number of beds to any single transferee; or
- (2) the approved DoN is for the expansion or addition of a service at a health care facility already licensed at the time of the approval.

(A) The holder(s) of the Determination of Need shall submit a request for transfer of ownership to the Program Director. Copies of the request shall be filed on the same day by certified mail, return receipt requested, or by delivery in hand, with the Division of Health Care Finance and Policy, the Department of Elder Affairs if relevant pursuant to 105 CMR 100.152, the Department of Mental Health if relevant pursuant to 105 CMR 100.153, and the appropriate state licensure authority. The statement shall be signed under the pains and penalties of perjury by a person qualified to sign an affidavit of truthfulness and proper submission under 105 CMR 100.324 and shall contain:

- (1) A brief description of the project as approved, including the project number, date of approval, precise terms of approval, and identity of the original owners. To the extent that this information is contained in the Department's Notice of Determination of Need for the project for which a transfer of ownership is requested, this requirement may be fulfilled by attaching a copy of such notice to each copy of the request for transfer;

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- (2) A brief description of progress of the project to date, including a specification of all expenditures incurred to date and the purpose thereof;
- (3) A copy of the agreement setting forth the terms of the proposed transfer;
- (4) The reason for the proposed transfer;
- (5) The following information, depending on the type of business entity with respect to the proposed transferee:
 - (a) If a partnership, the name, address, and ownership share (expressed as a percentage), and legal status (general or limited) of each partner;
 - (b) If a for-profit corporation, the address, and ownership share of each shareholder who directly or indirectly owns or controls 5% or more of any class of shares of the corporation, if a non-profit corporation, the name and addresses of all its members, and in both cases the name, address, and corporate title of each officer and director. In addition, copies of all documents of incorporation filed with the Massachusetts Secretary of the Commonwealth shall be filed with the Department; or
 - (c) If a sole proprietorship or any other form of business entity, the name, address, title, and ownership share (expressed as a percentage) of each person with a financial interest therein, and the name, address, and title of every person who controls, directs or operates the business entity;
- (6) The name and location of each health care facility, whether located in Massachusetts or elsewhere, in which the transferee(s) had an ownership interest or was employed in a management capacity within the previous five years;
- (7) A description and date of every proceeding in the United States within the previous five years in which the transferee(s) was involved, the result of which was a limitation on or a suspension, revocation, or refusal to grant or renew a health care facility license, certification for Medicaid or Medicare, or contract for participation in Medicaid or Medicare; and
- (8) A description of every criminal proceeding within the previous five years of the date of the application in which the transferee(s) has been convicted of, or a *nolo contendere* plea accepted in regard to, a criminal offense related to the operation, management, or ownership of a health care facility or institution.

(B) An applicant for transfer of ownership shall cause notice of its request to be published prior to the filing of such request in conformance with 105 CMR 100.330 and 105 CMR 100.331(A). The notice shall identify the applicant by name and address, the proposed transferee by name and address, the name and address of the health care facility involved, the date on which the request will be filed, and shall contain the following statement: "Persons who wish to comment on the proposed transfer must submit written comments within 20 days of the filing date of the request to the Department of Public Health, Attention: Program Director, Determination of Need Program, (at its current address). The request for transfer of ownership may be inspected at such address." No request for transfer of ownership shall be accepted for filing unless the applicant submits an affidavit of publication in conformance with 105 CMR 100.332.

(C) Persons who wish to comment on the proposed transfer must submit their comments, in writing, to the Program Director within 20 days of the filing date of the request.

(D) The Program Director shall be authorized to obtain whatever additional information he or she shall deem necessary, including but not limited to, the operating record of any facility in which any transferee had an ownership interest or was employed in a management capacity within the previous five years, and information regarding the financial capability of the transferee(s) to undertake the project.

(E) The Department shall consider the following in acting upon transfer requests:

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- (1) whether financial resources of the transferee(s) appear adequate to complete the proposed project and to provide staff, services, and the physical environment sufficient to comply with state law and regulations;
- (2) the progress of the project to date;
- (3) whether a substantially consistent and adequate level of care, as measured by compliance with state licensing standards and other pertinent evidence, is being or was rendered by the transferee(s) in each institution in which the transferee(s) exercises or exercised ownership, management, or operational functions; and
- (4) whether the transferee(s) is a person who is clearly not suitable for the ownership of the determination of need authorization, including evidence of adverse action as described in 105 CMR 100.710(A)(7) or criminal prosecution described in 105 CMR 100.710(A)(8).

(F) The Program Director shall take no action for 20 days after the submission of a complete request hereunder. If no comments objecting to the proposed transfer are filed within the 20 day period, the Program Director shall be authorized to approve the request.

(G) If the Program Director proposes to deny the request or if objections to the proposed transfer are filed, the Program Director shall notify the person requesting the transfer, the persons identified in 105 CMR 100.710(A), and the persons who commented pursuant to 105 CMR 100.710(C), of the date of the Council meeting at which the proposed transfer will be considered at least seven days prior to said meeting. The person requesting the transfer and the other persons shall be afforded the opportunity to make a brief presentation to the Council prior to its taking action with regard to the proposed transfer.

100.720: Transfer of Site Procedures

Subject to the following standards and procedures, the Department shall grant a transfer of site for any project approved under 105 CMR 100.530 or a change in location (premises) for any duly licensed health care facility, provided that any such change in location(s) of a duly licensed hospital other than an acute care hospital may be granted for a number of licensed beds that is no greater than the maximum number of beds that have been in service pursuant to 105 CMR 130.000 for the period six months prior to the date the request is filed with the Department, and provided further, that any series of such changes in location of licensed beds may not result in a total number of beds that exceeds the total number of beds in service at the time of the first transfer of site. A transfer granted to a licensed health care facility pursuant to 105 CMR 100.720 or pursuant to 105 CMR 100.754 shall constitute a determination of need for the purpose of original licensure pursuant to M.G.L. c. 111, §§ 51 through 52.

(A) The holder of the determination of need or licensee shall submit a written request for transfer of site to the Program Director and shall simultaneously file by certified mail, return receipt requested, or by hand delivery, one copy each to the Department of Elder Affairs if relevant pursuant to 105 CMR 100.152, and the Department of Mental Health if relevant pursuant to 105 CMR 100.153. The request shall contain at least the following information:

- (1) A brief description of the current and proposed new site including a comparison of the area (gross square feet) associated with licensed services in both sites, the current and proposed service area, and the reasons for the request;

Licensees of long term care facilities:

- (a) whose facilities are currently located in an underbedded urban area, as defined in Department guidelines and that meets the criteria in 105 CMR 100.535(D); and
- (b) who are unable to secure a suitable site for transfer in the urban area, shall provide written documentation of the unavailability of a site within the city or town.

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- (2) A signed affidavit of truthfulness and proper submission, in accordance with 105 CMR 100.324;
- (3) A detailed statement of all expenditures to be incurred as a result to the transfer of site and, in the case of an approved project not yet licensed by the Department (or not yet in operation if no license by the Department is required), an itemized statement detailing the effect of the site transfer upon the approved maximum capital expenditure; and
- (4) In the case of an approved project not yet licensed by the Department (or not yet in operation if no license by the Department is required), 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 100.306.

(B) An applicant for transfer of site shall cause notice of its request to be published prior to the filing of such request in conformance with 105 CMR 100.330 and 105 CMR 100.331(A). The notice shall identify the applicant by name and address, the name of existing and proposed addresses of the health care facility involved, the date on which the request will be filed, and shall contain the following statement: "Persons who wish to comment on the proposed transfer must submit written comments within 20 days of the filing date of the request to the Department of Public Health, Attention: Program Director, Determination of Need Program, (at its current address). The request for transfer of site may be inspected at such address." No request for transfer of site shall be accepted for filing unless the applicant submits an affidavit of publication in conformance with 105 CMR 100.332.

(C) Persons who wish to comment on the proposed transfer must submit their comments, in writing, to the Program Director within 20 days of the filing date of the request.

(D) The Program Director shall be authorized to obtain whatever additional information he or she may deem necessary.

(E) The Program Director shall take no action for 20 days after the submission of a complete request under 105 CMR 100.720. If no comments objecting to the transfer are filed within the 20 day period, the Program Director shall be authorized to approve the request so long as it meets the requirements of 105 CMR 100.720(H) and 100.720(I). The Program Director may approve the request subject to reasonable conditions related to the proposed transfer of site or change in location.

(F) If objections are filed within the 20 day period, or if the Program Director proposes to deny the request, the Program Director shall send notice to the person requesting the transfer, the persons identified in 105 CMR 100.720(A), and the persons who commented pursuant to 105 CMR 100.720(C), at least seven days in advance of the date of the Department meeting at which the request will be considered. The Department shall afford the person requesting the transfer and the other persons the opportunity to make brief a presentation to the Department prior to acting upon the request.

(G) Except as provided in 105 CMR 100.720(H) and 100.720(I), the Department shall grant a request for transfer of site or change in location unless it finds that transfer of the project or facility to the site proposed would likely violate the objectives of the determination of need process stated at 105 CMR 100.001. The Department may approve the request subject to reasonable conditions related to the proposed transfer of site or change in location.

(H) With respect to a project approved pursuant to 105 CMR 100.530 and not yet licensed (or not yet in operation, if no license by the Department is required), a request for a transfer of site under 105 CMR

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100.720 shall be approved if the Department determines that no substantial change in service or substantial capital expenditure will result and one of the following applies:

- (1) The proposed transfer will not substantially change the population served by the facility defined as the population residing in the cities and towns whose patients when ranked ordinally contribute cumulatively 75% of the facility's total discharges; provided that the transfer of site request shall not be approved if the proposed site of the transfer is a city or town that ranks higher on the 75% discharge list of another facility that provides the same services than it does on the 75% list of the facility proposing the transfer, unless there has been demonstration that the proposed transfer will not result in the duplication of services; or
- (2) The proposed transfer will significantly increase access to the service for the population residing in the cities and towns of the new site, and will not result in a corresponding decrease in access to the service at the original site; or
- (3) For a long term care project, the proposed transfer will not result in relocation of more than 25 miles from the original approved site, unless it has been demonstrated that access to services will be significantly improved, and will not result in a corresponding decrease in access to the service at the original site.

(I) With respect to a facility duly licensed pursuant to M.G.L. c.111, §§ 51 through 53, a request for a transfer of site under 105 CMR 100.720 shall be approved if the Department determines that no substantial change in service or substantial capital expenditure will result and one of the following applies:

- (1) The proposed transfer will not substantially change the population served by the facility, defined as the population residing in the cities and towns whose patients when ranked ordinally contribute cumulatively 75% of the facility's total discharges; provided that the transfer of site request shall not be approved if the proposed site of the transfer is a city or town that ranks higher on the 75% discharge list of another facility that provides the same services than it does on the 75% list of the facility proposing the transfer, unless there has been demonstration that the proposed transfer will not result in the duplication of services; or;
- (2) The proposed transfer will significantly increase access to the service for the population residing in cities and towns of the new site, and will not result in a corresponding decrease in access to the service at the original site; or
- (3) For a long term care facility, the proposed transfer will not result in a change in the service area of the facility as defined by 105 CMR 100.535, or if the proposed transfer is outside the service area of the facility will significantly increase access at the new site, and will not result in a corresponding decrease in access to the service at the original site.

100.750: Amendment of Approved Projects

After a determination of need has been issued no changes in the project may be made except as herein provided.

(A) Changes or modifications which are immaterial shall not require approval but shall be reported to the Department in accordance with the procedures set forth in 105 CMR 100.754.

(B) Changes or modifications which are minor shall not be made unless the Program Director or Council approves such modifications in accordance with the procedures set forth in 105 CMR 100.755. The review shall be limited to determining whether the changes or modifications are minor, whether they fall within the scope of the project as initially approved, and whether the changes are reasonable.

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(C) Changes or modifications which are significant shall not be made unless the Department approves such changes in accordance with the procedures set forth in 105 CMR 100.756.

(D) It shall be within the Program Director's discretion to determine, in accordance with the criteria set forth at 105 CMR 100.751 through 100.753, whether the requested changes or modifications are immaterial, minor, or significant.

100.751: Immaterial changes

The following are immaterial changes:

(A) Increases or decreases in cost allocation among or between architectural costs, construction contract, fixed equipment, and site services which do not result in any increase in the maximum capital expenditure (other changes from one category to another, including changes from financing to construction, shall be considered minor or significant changes);

(B) Changes in the proposed method of financing which do not result in any increase in the maximum capital expenditure or operating costs for interest in any year;

(C) Changes in the maximum capital expenditure to the extent of the inflation adjustment provided for in 105 CMR 100.551(I)(5);

(D) Increases in bed capacity of the project or the beds allocated to a specific service by 12 or fewer beds with respect to health care facilities other than acute-care hospitals;

(E) Changes in the architectural design which do 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 changes in the architectural design shall be subject to the Department's architectural plan approval as provided for in 105 CMR 100.551(G).

100.752: Minor Changes

The following are minor changes:

(A) Increases or decreases in the spatial allocation among different components of the project which result in increases or decreases of up to 25% of the originally approved gross square footage for that component, provided that such changes do not result in any changes in the aggregate gross square footage, bed capacity, or maximum capital expenditure (unless approved hereunder). Any such increases or decreases in the spatial allocation of the project's different components shall also be subject to the Department's architectural plan approval as provided for in 105 CMR 100.551(G);

(B) Increases or decreases in the aggregate gross square footage up to 15% of the approved space or 2000 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 approved hereunder);

(C) Deletions from the originally approved project which the Program Director determines to be minor in nature;

(D) Increases in the maximum capital expenditure of up to 10% of the inflation adjusted originally approved total expenditure and decreases in the maximum capital expenditure. Increases shall be allowed only for contingencies which could not have been reasonably foreseen, which are not reasonably within the control of the holder and for which the inflationary adjustment contained in 105 CMR 100.551(I)(5) is not appropriate; and

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(E) Changes in the type of equipment which the Program Director determines not to be technologically different from that approved, provided that such a change does not result in any increase in the maximum capital expenditure (unless approved hereunder) or any increase in the likely operating costs.

100.753: Significant Changes

The following are significant changes:

(A) Changes, modifications, or deletions of the approved determination of need which are not expressly set forth at 105 CMR 100.751 or 100.752;

(B) Modifications or deletions of any condition set forth in the approved determination of need;

(C) Extensions of the authorization period of an approved determination of need or an exemption from determination of need for long term care facilities in underbedded areas granted pursuant to 105 CMR 100.611; and

(D) Build out of any shell space in the project that was subject to determination of need review by the Department.

100.754: Procedure for Immaterial Changes

The holder, prior to implementing any immaterial change, shall submit to the Program Director a written description of the proposed changes, with two copies of the proposal. A copy of the proposal shall be filed at the same time with the Division of Health Care Quality. The proposal shall contain a narrative comparison of the approved project and the proposed immaterial changes. Within 60 days of receipt of the proposed immaterial changes, the Program Director shall determine whether such proposed changes, as defined at 105 CMR 100.751, are immaterial. The Program Director, may within this time period, request further information from the holder in order to assess whether the proposed changes are immaterial. If additional information is requested, the Program Director shall have 20 days from the receipt of such additional information to determine whether the changes are immaterial. If the Program Director determines that a proposed change is not immaterial, he or she shall order the holder to follow the procedures set forth at 105 CMR 100.755 or 100.756. No immaterial change may be implemented prior to the expiration of 60 days after the submission of a complete description of the proposed changes. The Program Director may waive the 60 day waiting period by written notice. If the Program Director does not respond within 60 days of receipt of the proposed immaterial changes, the holder shall be authorized to make the proposed changes.

100.755: Procedure for Minor Changes

(A) The holder, prior to implementing any minor change, shall submit to the Program Director a written request for an amendment to an approved determination of need together with two copies of the request. The request shall contain a narrative comparison of the approved project and the proposed changes, and the rationale for the proposed changes.

(B) The request shall include a certificate of truthfulness and proper submission pursuant to 105 CMR 100.324, certifying the truthfulness of the facts contained in the request, and that the requisite number of copies have been sent by mail or delivered by hand to the Program Director.

(C) The Program Director shall take no action on the request until such request has been on file with the Department for at least 20 days, except that if the Program Director finds that the request proposes a significant change, he or she shall require the holder to follow the procedures set forth at 105 CMR 100.756.

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The Program Director may request such additional information from the applicant which he or she deems necessary. After said 20 days, the Program Director shall be authorized to act on the request. The Program Director shall send written notice of his or her decision to the holder. If the Program Director denies the request, the holder may have the Program Director's decision reviewed by the Council by filing a written request for review within 14 days of receipt of the notice, together with a statement of objections to the Program Director's decision. The Program Director shall notify the holder of the date of the Council meeting at which his or her decision will be reviewed at least seven days prior to said meeting.

100.756: Procedure for Significant Changes

(A) The holder, prior to implementing any significant change, shall submit to the Program Director a written request for an amendment to an approved determination of need together with two copies of the request. A copy of the request shall also be filed at the same time with the appropriate Regional Health Office, the Division of Health Care Finance and Policy; the Department of Elder Affairs if necessary under 105 CMR 100.152; and the Department of Mental Health if necessary under 105 CMR 100.153. The request shall contain a detailed description and comparison of the approved project with the proposed change, a description of the cost implications, and the rationale for the proposed change.

(B) The request shall include a certificate of truthfulness and proper submission pursuant to 105 CMR 100.324, certifying the truthfulness of the facts contained in the request and that the requisite number of copies have been sent by mail or delivered by hand to the parties specified in 105 CMR 100.756(A).

(C) The applicant shall cause notice of the proposed amendment to the approved determination of need to be published prior to the filing of such request in accordance with 105 CMR 100.330 and 100.331(A). Said notice shall identify the applicant by name and address, the name and address of the facility involved, shall describe the approved project and proposed changes to the project, and shall state the capital expenditures associated with the proposed change. Said notice shall also contain the following statement: "Persons who wish to comment on the proposed amendment must submit written comments within 20 days of the filing date of the request to the Department of Public Health, Attention: Program Director, **Determination of Need Program**, (at its current address). The request for amendment may be inspected at such address and also at the (name and address of appropriate Regional Health Office)." No request for amendment shall be accepted for filing unless the applicant submits an affidavit of publication in conformance with 105 CMR 100.332.

(D) Persons who wish to comment on the proposed amendment must submit their comments, in writing, to the Program Director, within 20 days of the filing date of the request.

(E) The Department shall take no action on the request until the request has been on file with the Department for at least 20 days.

(F) If the request relates to a project which was originally approved pursuant to the delegated review process, as set forth at 105 CMR 100.504 through 100.506 or the procedure for exemption from determination of need for long term care facilities in underbedded areas as set forth in 105 CMR 100.608 through 100.611, and if no comments objecting to the proposed amendments are filed within the 20 day period set forth at 105 CMR 100.756(D), then the Commissioner shall be authorized to act on the amendment request.

(G) If the request is not eligible for action pursuant to 105 CMR 100.756(F), then the Program Director shall prepare a written staff report for the Council. This report shall summarize the proposed changes to the project, and the comments if any, of the persons set forth at 105 CMR 100.756(A) and the comments

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submitted by persons in accordance with 105 CMR 100.756(D). Said staff report shall also contain the recommendations of staff regarding the proposed amendment to the original determination of need.

(H) Where the staff report recommends approval of the proposed amendment and is consistent with all specific comments submitted in writing, the Program Director shall send copies of the staff report to the person requesting the amendment and the parties identified in 105 CMR 100.756(A) and 100.756(D) and notice to such persons of the date of the Council meeting at which the proposed amendment will be considered at least seven days prior to the Council meeting.

(I) Where the staff report recommends denial of the proposed amendment or where it is inconsistent with a specific recommendation submitted in writing, the Program Director shall send copies of the staff report to the person requesting the amendment and the parties identified in 105 CMR 100.756(A) and 100.756(D) and notice to such persons of the date of the Council meeting at which the proposed amendment will be considered at least 21 days prior to the Council meeting. The person requesting the amendment and the other parties set forth at 100.756(A) and 100.756(D) shall be afforded the opportunity to submit written reactions to the staff report and to make a brief presentation to the Council prior to the Council taking action with regard to the proposed amendment.

100.757: Effect of Amendment on Authorization Period

The issuance of an amendment to an approved determination of need shall not, unless otherwise provided, result in the extension of the period during which the applicant must make substantial progress toward completion, as required by 105 CMR 100.551(D) and 105.551(F).

100.758: Effect of Significant Change to a Project That Was Below the Expenditure Minimum

Any party that did not submit an application for a project that was below the expenditure minimum but subsequently involves the build out of shell space must submit a request for an advisory ruling pursuant to 105 CMR 100.120 for a determination by the Department of whether the project in its entirety exceeds the expenditure minimum and requires DoN approval.

100.970: Health Facilities Appeals Board Jurisdiction

Any determination of need made pursuant to M.G.L. c. 111, § 25C, is subject to administrative review by the Health Facilities Appeals Board in the manner and under the terms set forth in M.G.L. c. 111, § 25E. The Board shall review any determination of need which was not made pursuant to M.G.L. c. 111, § 25C where the determination of need was made with respect to an application designated comparable to, and considered at the same time as, an application for which a determination of need review was conducted pursuant to M.G.L. c. 111, § 25C. Proceedings before the Board are governed by rules of procedures adopted by the Board and available at the Board offices. The Department advises every applicant and party of record that whenever such person, agency, or group is not satisfied with an action of the Program Director, Commissioner, or Department during the pendency of an application, it should make its objection in writing to the Program Director prior to final action otherwise, upon appeal, the Department will argue that complaint on such ground has been waived by the appellant's failure to raise its objections with the Department and to allow the Department an opportunity to respond thereto. Communication to the Department with regard to an appeal shall be directed to its General Counsel.

100.980: Availability of Departmental Review

Proposed additions appear in **bold**
Proposed deletions are ~~stricken~~

Administrative review shall be available under 105 CMR 100.000 within the Department with respect to:
(1) dismissal of an application under 105 CMR 100.531, except where preceded by a formal hearing under M.G.L. c. 30A pursuant to 105 CMR 100.531(B); or

(2) revocation of a determination of need under 105 CMR 100.700.

100.981: Departmental Review Procedures

Departmental review, where available under 105 CMR 981.000, may be claimed and conducted as follows:

(A) The person claiming aggrievement, not later than 14 days after receipt of written notice of the action, shall file with the Commissioner a petition for administrative review which details the reasons for the request. If the petitioner desires an evidentiary hearing for any purposes, request therefore shall be set forth in the petition, together with the basis for the request.

(B) Upon receipt of a timely and proper petition, the Commissioner shall designate an impartial Department employee as a referee to review the allegations and claims set forth in the petition, and to report to the Department whether legal error was committed such as to require different action by the Department. Where the Commissioner determines that an evidentiary hearing is required under M.G.L. c. 30A, the employee designated shall be a hearing examiner of the Department, and the proceeding shall be subject to 801 CMR 1.01: Adjudicatory Rules of Practice and Procedure.

REGULATORY AUTHORITY

105 CMR 100.000: M.G.L. c. 111, §§ 3, 5, 25B through 25G, 51 through 53, 71 and 72.