



11 Beacon Street, Suite 710
Boston, MA 02108
Phone: 617-723-6100
Fax: 617-723-6111
www.cobth.org

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Monica Bharel, M.D., MPH
Commissioner, Department of Public Health
250 Washington St.
Boston, MA 02108-4619

105 CMR 100.000: Determination of Need

Dear Commissioner Bharel:

On behalf of the Conference of Boston Teaching Hospitals (COBTH) and its member hospitals, I would like to thank you and Department staff for this opportunity to provide comments on the proposed Determination of Need Regulations. In making these comments, we recognize and appreciate the significant amount of effort and thought the Department staff have put into the proposed amendments. We commend the Department for the process of soliciting input prior to the release of the proposed regulations and the willingness to hear and consider different approaches to achieving our common goals.

We are pleased that many of the suggestions that we and others in the hospital community made have been incorporated into the proposal. We appreciate that the Department has attempted to streamline the process through an allowance for concurrent plan review and Determination of Need review. Previous requirements that an application could only be submitted at certain times of the year have been eliminated which is also a welcomed change. The new category of project "Conservation Project" takes into account the fact that some projects which still may exceed minimum cost thresholds may not require the same degree of scrutiny as other projects.

We strongly support of the approach that the Department has taken with respect to ambulatory surgical centers. The controlled approach that the Department has proposed is prudent and in line with the goals outlined by the Department. In addition, we are pleased that the new category of project "Conservation Project" takes into account the fact that some projects which still may exceed minimum cost thresholds may not require the same degree of scrutiny as other projects.

Comments below fall into either of two categories, those that seek clarification and those that recommend a change to the proposed regulation. Comments are ordered as the section appears in the proposed regulation.

100.100 - Definitions - Conservation Project

We appreciate that the Department recognizes that some proposed projects, while exceeding the minimum threshold, may not require the scrutiny of larger projects which seek to expand current facilities or services. However as currently drafted, we believe this category is too narrow and would not include any modernization projects. We recommend that some modernization projects be included in this conservation project category and the definition be amended in the first paragraph and paragraph (3) as follows:

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

(3) ~~Modernization means the alteration, Addition, Expansion, or replacement of all, or part of a Health Care Facility or service to accommodate new or increased functionality, or to replace components of a Health Care Facility or service beyond that necessary to sustain or restore said facility or service.~~ in response to AIA or other regulatory guidelines

Examples of such modernization projects would be:

- conversion of semi-private rooms to private rooms
- updating infusion suites
- adding toilet rooms to existing patient rooms
- modernizing existing private rooms for bariatric patients with appropriate structural changes to improve patient safety and reduce staff injuries
- modernizing existing ED treatment rooms to be “safer” for the increasing behavioral patient population
- modernization of existing Pharmacy clean room / compounding space to meet the new FDA, USP and MGL standards.

In the alternate, we recommend that the definition of "restore" include allowance for changes required by accreditation organizations such as The Joint Commission.

100.100 - Definitions - DoN-Required Service or Innovative Service and DoN-Required Equipment or New Technology

We appreciate that the Department has proposed a process for regular input into and review of what services and technologies should be included and require a Notice of Determination of Need. Current guidance in this area is very outdated and a cause of frustration for many. However, we find the definitions as proposed quite confusing and suggest several changes below in track mode to clarify the definitions.

DoN-Required Service or Innovative Service means a new clinical service or procedure that for reasons of quality, access, cost, or health systems sustainability is determined by the Commissioner to require a Notice of Determination of Need. At a minimum, DoN-Required Services shall include services or procedures for which the Commissioner has determined ~~that there is evidence that the service(s) or procedure(s) to~~ (1) be a substantially high cost; and (2) is of low to moderate clinical utility or efficiency. ~~do not lead to one or more of the following: improved Patient Panel health outcomes; increased access, including, but not limited to a decrease in price; or, a reduction in the Commonwealth's Total Health Care Expenditure.~~ The Commissioner shall issue a list of DoN-Required Services in the form of Guidelines. Said Guidelines shall be reviewed and evaluated annually. Persons may submit to the Commissioner requests that a certain service(s) or procedure(s) be considered for inclusion or exclusion from said Guidelines.

DoN-Required Equipment or New Technology means new clinical equipment or services that for reasons of quality, access, cost, or health systems sustainability is determined by the Commissioner to require a Notice of Determination of Need.

At a minimum, DoN-Required Equipment shall include magnetic resonance imagers and linear accelerators, as well as any new equipment and services for which the Commissioner has determined to (1) be a substantially high cost; and (2) is of low to moderate clinical utility or efficiency. ~~that there is evidence that the equipment or service(s) do not lead to one or more of the following: improved Patient Panel health outcomes; increased access, including, but not limited to a decrease in price; or, a reduction in the Commonwealth's Total Health Care Expenditure.~~ The Commissioner shall issue a list of DoN-Required Equipment in the form of Guidelines. Said Guidelines shall be regularly reviewed and evaluated annually. Persons may submit to the Commissioner requests that certain new equipment or service(s) be considered for inclusion or exclusion from said Guidelines.

100.100 - Definitions - Health Priorities

We realize that health priorities will be addressed in sub regulations through a process that will begin shortly. However, that work will be guided by the underlying definition of health priorities which we believe is too narrow as currently drafted. We recommend that the definition be amended to allow for health care priorities defined by entities in addition to the Health Policy Commission and the Department, including other state and federal agencies and also through community health needs assessments undertaken by hospitals and others.

100.100 - Recommended Definition - Site Planning and Preparation

Many large projects require extensive site preparation, such as the relocation of utilities, removal of asbestos, or demolition of no-longer occupied buildings. In many instances, post approval construction work could be completely more quickly and efficiently if this work were done prior to approval of the project. We recommend inclusion of a definition for Site Planning and Preparation and appropriate language that allows the Department to permit such work while a DoN application is under review. The applicant would conduct such work at their own risk and the cost would be included in the total capital cost of the project if it is approved.

100.210: Determination of Need Factors

100.210(A)(1)(a)(b)(c) - Applicant Patient Panel Need, Public Health Value and Operational Objectives

Much of the focus of factor one is on the applicant's existing patient panel. While in many cases the need for and impact upon the applicant's existing patient panel may appropriately be the primary focus for evaluation, there are many instances where this would be too narrow. The focus on the patient panel, seemingly to the exclusion of others, would not take into account instances where an applicant may be proposing a project that seeks to meet an unmet need and serves persons that are not currently in its patient panel or new and emerging models of care delivery. For instance, if a particular community lacks access to a needed service, an applicant may be seeking to fill that need. We recommend that this section be amended to include language which allows for instances where existing patient panel may not be applicable.

100.210(A)(1)(f) - Applicant Patient Panel Need, Public Health Value and Operational Objectives

The proposed provision requires the applicant to demonstrate that the proposed project will "compete on the basis of price". Leaving aside the issue of how price may be determined or interpreted and with whom the applicant may be competing, the project's cost containment impact and merit are addressed in other factors, two and five, respectively. We recommend that this section be deleted. Hospitals are not the sole determinant of price: It is set by the insurance companies as to how much they will pay providers for services.

100.210(A)(2)(a) - Health Priorities

The proposal requires the applicant to demonstrate that the project meaningfully contributes to "improved public health outcomes, and delivery system transformation". To require such demonstration appears not to recognize the limits that one provider, regardless of size, may have on "public health outcomes." Therefore we suggest a clarification on what is meant or delete this reference. In addition, as described above we recommend that the health priorities established by other entities, including hospitals through their community needs assessment process be recognized in the process by which health priorities are determined.

100.210(A)(4) - Financial Feasibility and Reasonableness of expenditures and Costs

We appreciate that the Department has tried to streamline the determination of need process. However, there is no limitation on when during this process the Department may require an independent cost analysis. Such a cost analysis is a costly and time consuming undertaking, and can add delay to the review process and the start of a project. We recommend that any determination to require a cost analysis be made within 30 days of the initial filing of an application.

We also encourage the Department to include a standard that in no case shall an independent cost analysis delay the staff report beyond 6 months from the date an application is complete. Similar to the concurrent review of plans, there is no reason why the Department should be unable to continue its DON review while the analysis is underway.

100.310(F)(4): Standard Conditions

This provision requires that "all new construction" meet or exceed certifiable silver or the equivalent level of the Leadership in Energy and Environmental Design-Health Care (LEED-HC) Green Guide for Healthcare (GGHC). While such a requirement may be appropriate for an entirely new facility or building, many proposed projects will be for construction within an existing building. It may be difficult or impossible for older buildings to be retrofitted to meet these standards and such retrofitting if possible at all may be cost prohibitive. This provision should not apply to renovations within an existing building as LEED-HC standards are dependent on base building infrastructure items which in most cases would require temporarily ceasing building operations.

100.310(L) and 100.310(M): Standard Conditions

We understand that in order for the Determination of Need process to function as intended, commitments made by both parties must be monitored and adhered to. However, as currently written, all approved projects, regardless of size, will be subject to at least annual reporting and monitoring. This requirement has the potential to require significant resources of not only the certificate holder, but the Department itself. We recommend an approach that requires monitoring and reporting commensurate with the size and complexity of the approved project.

We propose a redraft of conditions L and M to read as follows:

The Holder shall report to the Department, at mutually agreed upon intervals beginning after project completion as evidenced by issuance of a certificate of occupancy. Such reporting may include, but not be limited to, the reporting of measures related to the project's achievement of the Determination of Need Factors, as directed by the Department pursuant to 105 CMR 100.210 in a mutually agreed upon format.

If it is determined by the Department that the Holder has failed to sufficiently demonstrate compliance or progress toward compliance with all Standard and Other Conditions, the Department and Holder shall develop a performance improvement plan with specific measures and timeframes for compliance. The Holder shall have the opportunity to demonstrate that good cause exists, which did not exist at the time of approval, to not fulfill a Standard and Other condition. If the Department determines that the Holder has: (i) willfully neglected to file a performance improvement plan ; (ii) failed to file an acceptable performance improvement plan in good faith with the Department; (iii) failed to implement the performance improvement plan in good faith; or (iv) knowingly failed to provide information agreed to in the conditions, the Department may assess a civil penalty to the health care entity which shall fund projects which address Health Priorities set out in the Department's Guidelines.

100.405(A): Filing of Applications for Determination of Need

100.405(A) reads that "all materials related to an application for Determination of need....shall be made publicly and readily available." We recommend that the regulation be amended to mirror the Health Policy Commission's approach to the confidentiality of information gathered during their cost and market impact review process as detailed in 958 CMR 7.09.

100.405(D): Filing of Applications for Determination of Need

Current statute (M.G.L. c. 111, § 25C(h)) allows the Department to require an applicant to commission an independent cost analysis. Such a cost analysis is a costly and time consuming undertaking and has the potential to delay the determination of process considerably. The Department has made streamlining the process a priority. We recommend that this section be amended to require that any request for a cost analysis be made within 30 days after the initial filing of the application, to read:

(D) Pursuant to M.G.L. c. 111, § 25C(h)), at its discretion, but no later than 30 days after Applications' Filing Date, the Department may require the Applicant to provide an independent cost-analysis.....

100.715(C)(a): Substantial Capital Expenditure and Substantial Change in Service

This section requires projects that fall into the Conservation Project category to comply with standard condition (J) and pay 2.5% of total capital expenditure for community health initiatives. The impact of a conservation project on the larger community is very limited and should not require a community health initiative payment. This new category of project, and its streamlined review process, has been explained in part as a way to encourage those facilities that have deferred maintenance to undertake these needed projects. Imposing an additional 2.5% on the project's cost could serve as a disincentive to undertaking the types of projects the new category is intended to encourage.

100.735: Change of Ownership

This section states that the Commissioner may rescind an approved notice if the Health Policy Commission (HPC) "issues a recommendation" that the Notice of Determination of Need should not go into effect. There is currently no statutory role for the HPC in the Determination of Need Process through its cost and market impact review (CMIR) authority. 958 CMR 7.00, which governs the cost and market impact review (CMIR) process, provides the HPC with only two options after completing a CMIR, either refer it to the Attorney General or take no action. We recommend that this be reflected in the regulation.

(b) Notwithstanding 105 CMR 100.735(D)(1)(A)(2), the Commissioner may rescind an approved Notice of Determination of Need ~~if the HPC issues a recommendation that the Notice of Determination of Need should not go into effect on the basis of adverse findings~~ a referral to the Attorney General pursuant to MGL c. 6D, section 13(e) and (f) in the completed Cost and Market Impact Review. If a Notice of Determination of Need is duly rescinded by the Commissioner ~~based on the HPC's recommendation~~, the Person for which the rescinded Notice of Determination of Need was issued must file a new Application for Determination of Need, if so desired. Such Application must satisfy 105 CMR 100.210 and shall account for the concerns expressed by the HPC within their findings.

This section empowers the Department to fine a certificate holder if it is determined that it has failed to comply with all standards and other conditions. The fine as proposed would be 5% of the total value of the approved project. Total value is defined as the "total valuation of the proposed Health Care Facility to be acquired" which could vary widely. We recommend a process similar to what we have recommended above for 100.310(L) and 100.310(M).

100.740(A) Other Determination of Need Required Categories - (A) Ambulatory Surgery

COBTH and its members strongly support the approach that the Department has proposed as it relates to ambulatory surgical centers and appreciates the considerable effort to develop a proposal that strikes the appropriate balance as it relates to access, cost and quality. We do have some a suggested revision and a request for clarification in this area..

100.740(A)(1)(a)(i-iii) describes three cases where a determination of need for ambulatory surgery would be considered. 100.740(A)(1)(a)(i) requires that the

proposed facility be on the **main** campus of a licensed hospitals. Given the policy goal described by the Department, we believe that this is too restrictive and recommend that the language be amended as follows:

(i) Ambulatory Surgery capacity located on the ~~main campus, only,~~ of an existing Acute Care Hospital licensed pursuant to M.G.L. c. 111, § 51; or,

While section 100.740(A)(1)(a)(i-iii) are consistent with the description of allowing controlled growth at the hospital level or hospital joint venture level, 100.740(A)(1)(c) appears to allow proposed projects which are neither by existing hospitals or by joint ventures with existing hospitals. We seek clarification on the intent of 100.740(A)(1)(c) as well as a distinction the Department sees between "joint venture" and "affiliate".

We commend the Department for the thoughtful and thorough review and revision of this important regulation. We look forward to working with the Department on these proposed amendments as well as the sub-regulatory guidance being developed that will guide the community-based health initiative process.

Sincerely,

A handwritten signature in black ink that reads "John Erwin". The signature is written in a cursive, flowing style.

John Erwin
Executive Director
Conference of Boston Teaching Hospitals