

October 19, 2018

Monica Bharel, M.D., MPH

Commissioner

Department of Public Health

250 Washington St.

Boston, MA 02108-4619

Re: Proposed Revisions to Determination of Need (105 CMR 100.000)

Dear Commissioner Bharel,

The Massachusetts Health & Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates the opportunity to submit comments on the proposed amendments to the Department of Public Health (DPH) Determination of Need (DoN) regulations. We commend DPH for taking into consideration the issues the provider community has raised regarding needed clarification on several requirements.

As DPH is well aware, the DoN and subsequent licensure processes are very complex, requiring compliance with various state agency’s regulatory requirements and expectations, local zoning and certification standards, and coordination of the project with current clinical practices, existing financial resources, and the availability of construction and architectural teams. As the 2017 revisions required extensive time and discussions, we ask that DPH consider additional time for a stakeholder group to develop guidance for implementation of the issues identified in this letter, prior to promulgation of the regulations.

With the passage of Chapter 208 of the Acts of 2018, it is important to note that acute care hospitals with psychiatric units may be required to go through duplicative DoN reviews for both DPH and the Department of Mental Health (DMH). The hospital community strongly supported passage of Chapter 208, as we share the goals of the Governor and the Legislature to improve clinical and operational practices to address the opioid crisis in our state. Given potential complications with duplicative DoN reviews, we would request that DPH consider developing a joint working group with DMH and the hospital community to consider how to eliminate unnecessary duplication of administrative filings and the resulting increased costs. This may also require that DPH or DMH waive or exempt changes that are being considered within a psychiatric unit of an acute care hospital so those changes would not impact a DoN filing under the proposed DPH regulatory changes.

While we provide comments regarding the specific proposed amendments, we also ask DPH to consider the issues that our members have raised, which are included in this letter. MHA and our members share your goal of having regulations that promote cost containment, improve health outcomes, and deliver system transformation; however, we also want to ensure that any regulatory requirements reduce duplication of staff time and resources for both the state and the provider community.

If you have any questions about our comments, please do not hesitate to contact me at (781) 262-6034 or agoel@mhalink.org.

Sincerely,

Anuj K. Goel, Esq.

Vice President, Legal and Regulatory Affairs

**MHA Concerns and Request for Reconsideration of Proposed Amendments to Determination of Need Regulations**

**October 19, 2018**

**Proposed Changes to Filing and Submission Date:**

MHA is very concerned with the proposed changes to the definition of “filing” and “submission” dates as this will impact the four-month period for the DPH approval of an application. We appreciate that this change is intended to provide clarification to ensure flexibility for approving applications. However, without further clarification as to how DPH deems an application to be “substantially complete” there is a concern that applications may be unreasonably delayed. Any delays will result in increased costs to providers while also affecting statewide tax revenues when jobs and construction/equipment purchases are put on hold. As a result, we strongly urge DPH to consider issuing guidelines that will further clarify what is considered “substantially complete” for an application filing to be deemed complete. Further, we ask that the state set a deadline (for example 14 days from the submission date) for all required documentation to be submitted. MHA also recommends that DPH meet with a smaller group to review and consider these approaches prior to finalizing the regulations so that all stakeholders understand the new requirements, are clear on expectations, and can ensure an efficient implementation of this new change.

**Proposed Changes to Amendments to Approved Projects:**

MHA strongly supports the overall concept and goal of streamlining the terms “immaterial”, “minor”, and “significant” changes. We supported changes to these terms during the review of proposed regulations in 2017, and thought they should reflect that many providers seek to make changes to facilities in non-patient areas to improve the overall operations of a facility and to meet the access needs of patients and communities. While our members agree that the focus of a DoN application should be on projects that meet a significant change, the amendment’s proposed “consolidation” changes present several unintended consequences. For example, minor projects that are under the defined threshold of immaterial changes will be reviewed based on the proposed consolidation rule changes. While we appreciate that the Commissioner or DPH (through the Public Health Council) has the ability to approve projects that are deemed significant changes, we also request that the regulations provide the Commissioner with authority to determine if changes deemed “immaterial” will be exempt from the consolidation proposed changes. We further request that DPH meet with a stakeholder group to discuss what should constitute immaterial changes and should not be part of a DoN and consolidation.

**Proposed changes to Standard Conditions**

MHA is opposed to the proposed addition of the requirement that a performance improvement plan (PIP) will require additional DoN reviews. As drafted, this proposal would be in direct contradiction to Governor Baker’s Executive Order 562, which requires executive branch agencies to review current regulations and policies that are duplicative and to assess whether they need to be revised or removed. Requiring DoN holders to submit duplicative paperwork to DPH, HPC, and CHIA regarding efforts surrounding a PIP adds unnecessary costs and administrative burdens on providers and the state. HPC already has authority to review and work with a provider to address specific issues raised in the PIP. The DoN regulations also already require a provider to be in compliance with applicable laws and regulations. Further, as they are both state agencies, DPH should be able to develop an interagency agreement with HPC to obtain relevant filings with HPC regarding a PIP to determine a possible impact on an existing or ongoing DoN. We feel that this proposal is an unnecessary, administratively burdensome, and duplicative requirement that should be removed.

**Proposed Amendments to Consolidated DoN Projects:**

MHA generally supports the overall concept and approach to remove the antiquated term and process for disaggregation of projects into the proposed new terminology and process of “Consolidation.” However, we have concerns with the application and implementation of this proposal. A potential issue is the application of a regulation’s future terms to all applications submitted in the current federal fiscal year that began on October 1, 2018. From a public policy perspective, we are concerned that the state’s actions, except perhaps in special cases as we propose to occur below, may be in violation of the state administrative procedures act (Chapter 30A, section 6), which prohibits applying a proposed/future regulation to a prior period. It is not fair to apply a proposed or final rule to projects that are in compliance with existing regulatory requirements at the time that they are filed. If there is a significant concern with a current project in a specific service area, we believe that the Commissioner should have the ability to review such issues on a case-specific basis. As a result, we would request that the proposed regulations be changed to remove the retroactive application and instead provide for a Commissioner review on a case-specific basis.

We are also concerned that, as drafted, the proposed regulations would incorrectly bring into consideration smaller projects (immaterial, conservation, or others) that generally would not have been subject to DoN reviews. We strongly urge DPH to again pull together a smaller stakeholder group to discuss the application of consolidation rules, prior to promulgation of final changes. We believe that DPH will need to issue clarifying guidelines to help providers determine what should and should not be included in an application or revised application. By having to now consider multiple projects over various locations, providers may have to delay necessary updates to clinical services, facility improvements, and more. The overall delays to projects that do not require a DoN review will result in unnecessary costs and duplication of efforts by administrative staff. As a result, we strongly urge DPH as part of our proposed stakeholder group, to develop waivers or exemptions for projects that were never intended to be consolidated as part of the DoN application. Any hospital project has the desired effect of adding jobs, affecting tax revenues, and more importantly improving patient access and/or ability to provide services to our communities.

**Requested changes to current regulatory requirements to provide further clarity on DoN applications**

1. *Technical amendment to “Capital Expenditure”*

We urge DPH to clarify the *“Capital Expenditure”* term so that staff is able to better allocate known and upcoming costs for a project. To that effect, we request DPH remove throughout the definition the term “any expenditure or obligation to make an expenditure past, present, or future.” It is not realistic or possible for any staff to know the full extent of any and all costs related and unrelated to the project at the time of the application. In its place, we would request that DPH replace the terms with the following: “an expected expenditure or obligation for the Proposed Project…”

We further ask that DPH remove the terms “fair market value” within the second subpart (2) in the definition. We believe the inclusion of this term as currently drafted will increase costs and erect barriers to the development of innovative delivery models of care in community settings. Many providers are offered locations below market value depending on their planned use and arrangements. Many times this is done to ensure use of property or locations that are not being developed or in use by local cities or towns. Therefore we request the removal of the words “fair market value” and in their place add the words: “based on appropriate and reasonable valuation for leased space given the expected use and the current arrangement for such use”

1. *DoN-Required Equipment*

While we do not have a specific concern with the definition in the regulations, we strongly urge DPH to reconvene its DoN Required Equipment and Services Advisory Committee to consider the issues several providers raised to remove Computerized Tomographer (CT) from the list of equipment that requires a DoN review. This was a new service added when the regulations were revised in 2017, with little discussion with the advisory committee or other interested stakeholders. From a public health and health equity perspective, there is no basis for including this equipment (that was never part of the DoN equipment review prior to 2017).

1. *Expenditure Minimum*

We strongly support the addition of the words “similarly reliable national index” and urge DPH to consult with stakeholders as to an applicable index to be used. We know that currently the state uses the Marshall and Swift index, but we believe that the commonwealth should also consider current federal CPI for medical services or a rate that is based on current construction cost rate increases within a certain area. (This is often many times greater than any CPI or inflationary index.) We urge DPH to consider such changes in guidelines to update the requirements to standards used by the provider community.

1. *Patient Panel*

While we appreciate and support the overall definitional changes to a patient panel, we are very concerned with the requirement that the review be based on a 36-month period by the applicant or holder, especially given the new requirements to consider anticipated patients. We strongly urge DPH to amend the time frame for the review from a “36-month period” to a “12-month period”. This would reflect how providers may be changing their services in the near future to develop integrated delivery models of care that would target different patients (who may not be part of the existing patient panel) or are developing services in areas that may not be adequately served and that are also not part of the existing patient panel.

1. *DoN Factors (100.210)*

While MHA supports the six factors, we urge DPH to consider amending various terms that would allow providers to better demonstrate how they are meeting existing federal and state goals of innovation, cost effectiveness, and integrated care design. To that end we would request the following changes:

1. Factor 1 - Objectives

We request that the words “sufficient need/evidence” in parts (a) and (b) of this factor be removed and replaced with “reasonable basis.” The overall goal is to develop a project based on what is known at the time the application is being developed and based on the goals of the facility to meet expected patient needs. Requiring information at a level of “sufficient” requires the provider to meet a level of expectation on projects that is neither feasible nor realistic.

We also request that Part (e) be clarified to reflect realistic community engagement expectations by removing the words “community coalitions statistically representative of the Applicant’s existing Patient Panel” and replacing it with “community groups that are identified in a provider’s community health needs assessment or which are known to represent the Applicant’s Patient Panel.”

We also request that part (f) be removed. This provision is duplicative to the financial feasibility requirements in Factor 4 where the applicant must demonstrate the cost analysis of meeting cost containment. Adding a requirement here that is vague and not reflective of the requirements of Factor 4 is confusing and should be removed.

1. Factor 3 – Compliance

MHA is very concerned with the wording in this specific factor as it is broad and unrealistic for a facility to attempt to document that it is in compliance with *all* government agencies. As worded, this requirement is related to the applicant or facility and not to a proposed project; this requirement will add to the overall cost of a project in order to have a detailed legal review and lengthy submission completed.

We would instead urge DPH to consider the following revised language for this factor to ensure that any compliance review is based on the actual project, which would also be consistent with other licensure requirements:

*The Applicant has provided documentation attesting to compliance with any applicable and known laws and regulations related to the Proposed Project, including but not limited to construction standards of the state building code, the Facility Guidelines Institute’s Guidelines for Design and Construction of Health Care Facilities, the Life Safety Codes as specified in 42 C.F.R. 482.41(b), and other accreditation requirements applicable to the Proposed project.*

1. Factor 6 – Community Based Health Initiatives

MHA requests serious re-consideration regarding the cost requirement for a CHI project. While we are not opposed to the requirement in general, we are concerned with the cost that this adds to a project by having an amount greater than or equal to the percentage. Instead, we request that DPH amend the percentage to be an amount “*up to 5%”*. Allowing the factor to be an amount higher than 5% significantly increases the costs and would stifle any project that may be necessary in many non-urban communities. Also there is no recognition that operational costs associated with DON related community-based health initiatives are in included in the “up to 5%”.