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October 19, 2018

William Anderson  
Office of the General Counsel  
Department of Public Health  
250 Washington Street  
Boston, MA 02108

**Attention: 105 CMR 100.000**

***RE: Proposed Changes to Determination of Need Regulations, 105 CMR 100.000***

Dear Mr. Anderson:

The Conference of Boston Teaching Hospitals (COBTH) welcomes this opportunity to comment on the proposed changes to 105 CMR 100.000, *Determination of Need*.

COBTH is an organization of twelve Boston-area teaching hospitals that works to advance policies critical to the core mission of academic medical centers: advancing medical education, funding biomedical research, improving patient care and serving vulnerable populations.

We appreciate that the Department has proposed a number of changes that correct errors, provide clarification and better organize the regulation. Our comments below focus on those proposed changes which we see as more substantial and problematic. Several provisions in the proposed regulation would impose an onerous burden on hospitals pursuing capital improvements, and in some cases would deter or delay hospitals from making capital investments that enhance access to care and the quality of care available to patients.

The following items reflect COBTH's recommendations in regards to key proposals in the amended DoN regulations:

- **Definition of Filing Date:** COBTH understands that the process undertaken by the Department in reviewing a DoN application is exhaustive and may require the full statutory review period of four months. However, we do have some concerns regarding the proposed changes to the Department's procedure for reviewing DoN applications. Capital improvements are undertaken by our member hospitals to enable them to better meet the complex and changing needs of their patient panels. Certainty and timeliness are crucial in the execution of any capital project, and our member hospitals have expressed concern with the new definition of "filing date" put forth in the proposed regulation. By altering the definition of filing date to the date on which the Department determines the DoN application to be "substantially complete," we worry that the DoN review process will become less predictable. The proposed regulation contains no set time by which the Department is to make the determination that an application is "substantially complete." We recommend that the final regulation include specific parameters by which each DoN application would be judged to be complete and suggest that a limit of ten business days is reasonable.

- Consolidated Determination of Need Projects:** The proposed consolidation provision would require that a provider's projects across all licensed locations be combined for purposes of determining if a capital expenditure threshold will be exceeded. These thresholds are set by statute, recognizing that not all projects should require DoN review. However, by requiring a provider to consolidate expenditures during a fiscal year, the proposed regulation effectively eliminates the statutory thresholds for some projects that, absent this new requirement, would not require DoN approval, while allowing smaller, stand-alone projects to proceed without DoN approval. As a result, the application of the law will be inconsistent as the same types of projects may or may not be subject to review depending on the budget a provider has for capital expenditures in a fiscal year. For example, any provider that plans a large project that exceeds the threshold will now need to obtain DoN approval for other unrelated projects that would not be considered a substantial capital expenditure under DoN regulations but for the consolidation requirement. Similarly, a collection of small unrelated expenditures would require DoN approval due to consolidation, if collectively the expenditures meet the statutory threshold. This outcome is more likely with the consolidation of projects across licensed locations. From a practical perspective, if multiple sites must be combined into one DoN filing, it is possible that a provider's ability to meet the needs of its patient panel will be delayed significantly as not all projects in a fiscal year are at the same stage of planning and a DoN application cannot be submitted unless it incorporates all planned projects. This will result in increased inefficiency and waste in the capital improvement process, and will deprive hospitals of the flexibility required to make informed and timely capital investment decisions to better meet patient needs.

It is not clear from the proposed regulation if conservation projects must be included in consolidated DoN filings. If such projects are to be included in the consolidated filings, the Department will have approval authority over a hospital's **entire** capital budget. We strongly recommend that - should the consolidation requirement be retained - the Department clarify that conservation projects not be included in this new requirement.

- Amendments to Approved Projects:** COBTH has concerns with the Department's proposed changes to the DoN amendment process. Defining any change in capital expenditure over 10% as a significant change warranting review seems a low threshold, particularly in light of the proposed DoN consolidation requirements. Spending \$30m on a projected \$27 million capital improvement project due to unforeseen labor, materials, or time costs is not a case where the magnitude, scope, or purpose of the project has changed, and yet under these proposed regulations this scenario would be considered a significant change requiring an application to amend the original DoN and a Department review.
- Performance Improvement Plan Compliance Requirements:** Under existing regulations, any health care entity seeking approval for a DoN by DPH must be found to be in compliance with all other state regulations and statutes. As such, it is duplicative to require that health care entities undergoing the Performance Improvement Plan (PIP) process report on PIP implementation to DPH in addition to the Health Policy Commission (HPC). Additionally, while the HPC is constrained by strict confidentiality requirements in overseeing the PIP process, DPH is not, potentially compromising proprietary and confidential information of a health system's implementing a PIP. Also of concern is that HPC regulations governing the PIP process could be changed at any time, potentially resulting in new and burdensome requirements imposed on health care facilities seeking DoN approval outside of DPH oversight.
- Transitional Period:** The proposed amendments include language requiring the consolidation of projects that will occur in Federal Fiscal year (FFY) 2019 even though such projects would not be subject to DoN review under the current regulations. FFY2019 has already commenced, but the proposed amendments, including the requirement to consolidate projects across sites, have not yet been promulgated. This

retroactive application of the consolidation requirement will halt or delay projects that are currently underway until DoN review is complete. For example, under the proposed regulations, if a provider filed a DoN in FY2018 that will not be approved until FY2019, the provider must wait for DoN approval and then file for a significant change to obtain approval for any other project that will occur at any licensed location, regardless of the amount of the expenditure. As a result, that project which would be captured by retroactive application of the new regulations will be delayed a minimum of 4 months due to the time it takes to prepare a request for amendment and to complete the DoN review period. Providers have relied on the current DoN requirements in planning projects that must begin in FFY2019 and it would be unfair to change the rules without significant notice. Accordingly, the consolidation requirement should not become effective until FFY2020 at the earliest.

Thank you for the opportunity to comment on these proposed amendments to 105 CMR 100.000. COBTH looks forward to continuing to work with the Department on these important regulations.

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