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November 7, 2016

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

**105 CMR 100.000: Determination of Need  
Sub-regulatory Guidelines on Equipment and Services**

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 (DoN) sub-regulatory guidelines related to equipment and services. We are grateful for the thoughtful approach the Department has taken and process developed for soliciting input from the hospital community.

Pending revisions to the underlying determination of need regulation in many instances reflect the changes that have taken place in health care delivery and payment in the past decade. These changes are particularly pertinent to the application of the determination of need regulations to equipment and services. As payments systems continue to move away from traditional fee for service arrangements, the likelihood that providers will invest significant capital expenditures for a piece of equipment or a new service relying on simple volume to justify the investment is lessened significantly. Just as it did in revising the underlying regulation, the Department must balance the need for review thorough review and justification for pending projects with the need for providers to adjust and respond to changing patient and market needs. We believe our comments below help achieve that balance.

**Current List of DoN Regulated Services and Equipment and Suggestions for Addition**

Because of the many changes in the regulations and determination of need process that Department staff and the provider community will have to deal with after the promulgation of final regulations, we recommend that the existing list remain unchanged for at least a full year after the effective date of the new regulations and no additions made.

**Delegated Review for Expansion of MRI and megavoltage radiation therapy services**

We recommend that the guidelines reflect the current practice of allowing expansion of approved MRI and megavoltage radiation therapy services to be subject to delegated review. This is reflected in current guidance ("Discussion" section of Factor Two). Explicit inclusion of these services in the current regulation's delegated review section 100.505 (A)(9) and (10) has been deleted, the proposed regulation allows. However the proposed regulation 100.630 (A)(6) allows the Commissioner to allow delegated review for "project categories designated by the Department, including certain DoN-Required Services or DoN-Required Equipment." We recommend that this be reflected in the guidance.

## Process for Review

We recommend that changes to the list of DoN regulated services and equipment be revised no more frequently than annually. However, we would support a more frequent meeting of stakeholders to help inform and guide that annual revision and provide information and metrics on emerging technology and services, trends in other parts of the country and updated research on the efficacy of emerging technologies.

Thank you for the opportunity to provide input on these proposed guidelines. I look forward to continuing to work with you and Department staff on the new Determination of Need regulations.

Sincerely,

A handwritten signature in black ink that reads "John Erwin". The signature is written in a cursive style with a large, prominent initial "J".

John Erwin  
Executive Director