

Commonwealth of Massachusetts Department of Public Health



Listening Session on Determination of Need Equipment and Services Proposed Revision to Determination of Need Regulation, 105 CMR 100.000

**Tuesday, November 1, 2016
2:00pm**

MA Department of Public Health
Public Health Council Room
250 Washington Street, 2nd Floor
Boston, MA 02108



Listening Session Format and Flow

1. Brief overview of Proposed Revision of 105 CMR 100.000, *Determination of Need*, DoN-Required Equipment and Services
2. Outlining questions for consideration related to DoN-Required Equipment and Services sub-regulatory guidelines
3. Gathering input/comments from participants
4. Wrap up
 - Any final comments
 - Please provide written comments by no later than **5PM, Monday, 11/7** to: [**dph.don@state.ma.us**](mailto:dph.don@state.ma.us)

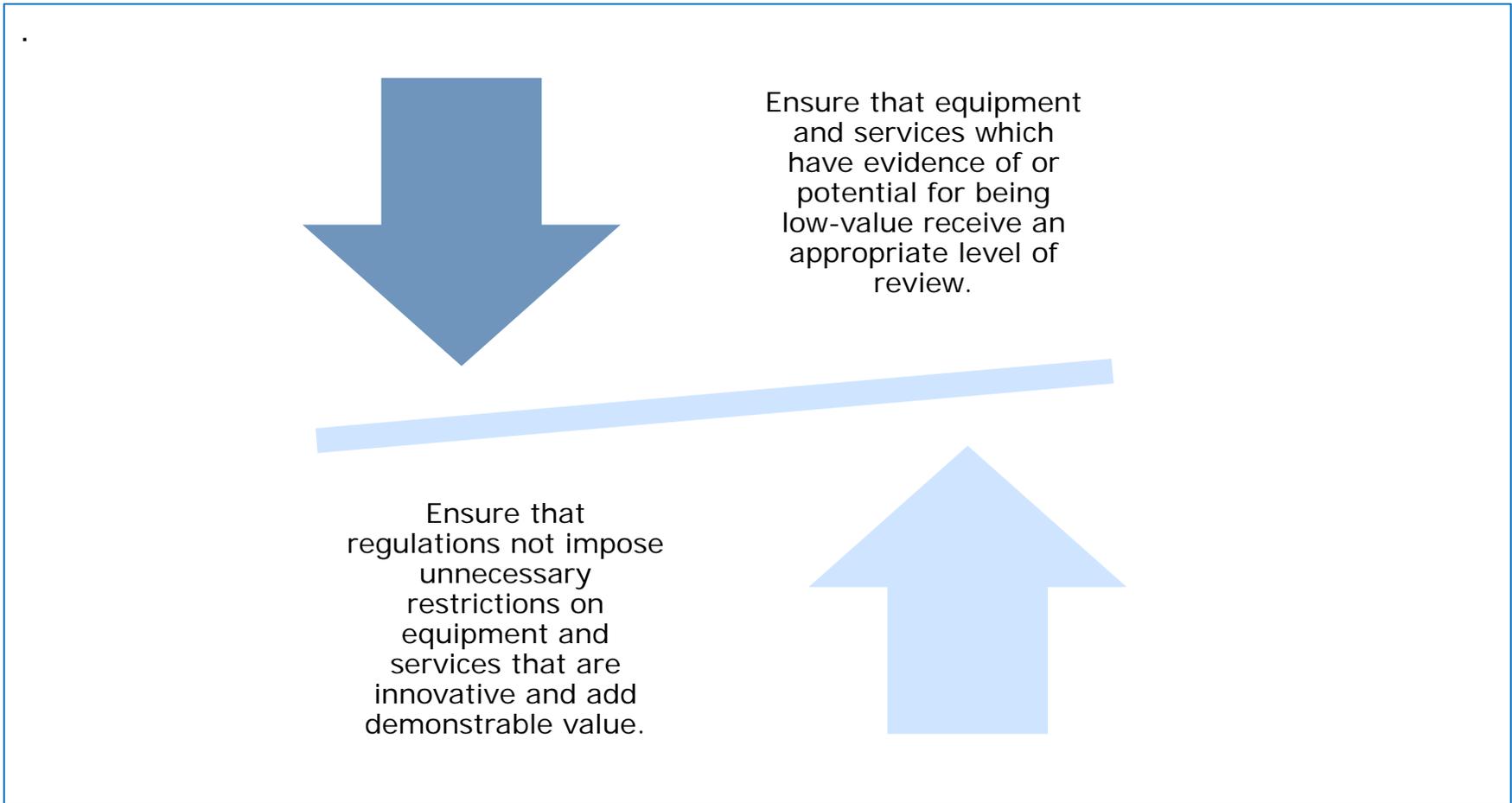


Introduction

- On August 23rd, the Massachusetts Department of Public Health (DPH) proposed a draft revision of 105 CMR 100.000, *Determination of Need* to the Public Health Council
- To accompany this proposed revision of the Determination of Need (DoN) regulation, the DoN program is also revising the DoN sub-regulatory guidelines that list equipment and services that require DoN review.
- To support completion of this work, DPH has contracted with John Snow Inc. (JSI) to conduct expert interviews and gather public input to inform the development of a DoN-Required Equipment and Services guideline.



DPH seeks critical balance for revising the Required Equipment and Service guideline





Definition for DoN Required Service and DoN Required Equipment Pursuant to Proposed DoN Revision

DoN-Required Service

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) 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.

DoN-Required Equipment

At a minimum, DoN-Required Equipment shall include magnetic resonance imagers and linear accelerators, as well as any equipment and services for which the Commissioner has determined 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.



Purpose of New Guidelines

- To constitute a new and updated list of DoN-Required Services and Equipment, specifying equipment and services for which DoN review is required.
 - **NOTE:** Health care services or equipment added to this list does *not* represent a moratorium or prohibition; rather, inclusion indicates that evidence exists for purposes of quality, access, cost, or health systems sustainability, that a service or equipment requires a case-by-case review *in the context* of the proposed DoN project.
- To further define the following two proposed regulatory terms “DoN-Required Service” and “DoN-Required Equipment” found in the proposed revision of 105 CMR 100.000 by establishing criteria by which DPH evaluates services and equipment for inclusion on the list.
- To establish a process and framework by which the list is annually reviewed and by which requests for consideration are submitted to the Department



Framework for Inclusion for DoN Review:

Evidence that the equipment or service does *not* lead to one or more of the following:

- **Quality**: Improved patient health outcomes
- **Access**: Increased access, including but not limited to a decrease in price
- **Cost**: Reduction in the Commonwealth's Total Health Care Expenditure

And takes into consideration **Health Systems Sustainability**: Financial viability of providers that are important access points for underserved residents



Gathering Input from Listening Session Participants



DoN regulations, guidelines, and policy advisories have historically defined equipment and services needing review. The current list includes:

Equipment

Positron Emission Tomography (PET)

Extracorporeal Shock Wave Lithotripter (for gallstones)

Magnetic Resonance Imager (MRI)*

Linear Accelerator*

** Proposed for inclusion in DoN revised regulation*

Services

Air Ambulance

Extracorporeal Membrane Oxygenation (ECMO)

Invasive Cardiac Services (Open Heart Surgery and Left Ventricular Assist Devices)

Neonatal Intensive Care Units

Organ Transplantation

Megavoltage Radiation Therapy



Referring to the list of those currently on DoN list ([see Handout](#)), please provide input on following questions:

- Which equipment and services currently requiring DoN review should remain on the list? What is the rationale for doing so?
- Which ones should removed from the list? What is the rationale for removing?



Published research and input from JSI expert interviewees suggest additional equipment and services potentially merit DoN review. For instance:

- **Computerized Tomography (CT) Scan**
 - Combines series of images to create detailed cross-sectional images
 - **Cardiac Catheterization**
 - Medical diagnostic or therapeutic procedure used to perform various studies and/or procedures in the heart
 - **3-D Imaging**
 - Extracts data from CT and MRI data to create anatomical visualizations
 - **Stand Alone Urgent Care**
 - Category of walk-in clinic focused on ambulatory care outside of the emergency room
 - **Limited Service Clinics**
 - Walk-in, retail health clinics offering evaluation of minor health care issues (common family illnesses, preventive screenings, prescriptions, minor wounds, common immunizations)
-



Referring to the list of possible additions ([see Handout](#)), please provide input on following questions:

- Which of the equipment and/or services identified in the literature review and expert interviews should be required to have DoN review? What is the rationale for including?
- Which ones should not be subjected to DoN review? What is the rationale for excluding?
- Are there others not listed that should be? If so, what are they and why should they be included?



Framework for Evaluation Tenets

- The framework needs to achieve the critical balance that DPH seeks and must be transparent and robust.
- The framework must take into consideration cost, quality, access and market sustainability – and the relationship among those criteria to ensure high value services for Massachusetts residents while achieving total health care expenditure targets.
- Identifying DoN-Required Services and DoN Required-Equipment is based on broad population research.
- Reviewing individual DoN requests is based on the applicant provider's patient panel needs and experience.



Example frameworks for evaluation from published research and input from engaged thought leaders

Inclusion of Equipment and Services on the DoN Required List

- Institute for Clinical and Economic Review (ICER)
- Choosing Wisely
- National Institute for Health and Care Excellence (NICE)
- Claims and quality indicator analysis (regional/statewide)

DoN Review

(use individually or collectively)

- Patient registries with corresponding cost (total health care expenditures) and quality metrics
- Pricing across the region/state
- Mapping for equitable access
- Market impact assessment
- Performance under risk based contracts



Framework for Evaluation

- What framework(s) could DPH employ to determine what is on the DoN-Required list?
- What framework(s) can DPH employ to evaluate individual applications for DoN approval?



Process for updating Equipment and Services list going forward

- How can DPH keep abreast of new equipment and services being introduced to the market?
- What methods and metrics could be employed to indicate an update is needed?
- What should be format and process for updates?



Overarching questions:

1. Which equipment and services currently requiring DoN review should remain on the list? Which ones should be removed? Why?
2. What other equipment and services should be added to the list for DoN review? Why?
3. Going forward, what framework(s) could DPH employ to best identify new equipment and services being introduced to the market and determine if they should be added to the list of DoN-Required Equipment and Services?
4. What framework(s) can DPH employ to evaluate individual applications for DoN approval of a DoN-Required piece of equipment or service?



Thank You!

Please send further comments to:
dph.don@state.ma.us

Comments accepted through
Monday, November 7, 2016, 5:00pm