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MEMORANDUM

TO: Commissioner Monica Bharel, MD, MPH and Members of the Public Health Council

FROM: Nora Mann, Director, Determination of Need Program

CC: Elizabeth Chen, PhD, MBA, MPH, Assistant Commissioner

RE: Informational Briefing on Proposed Revision of 105 CMR 100.000: Determination of Need

DATE: September 12, 2018

The purpose of this memorandum is to provide an informational briefing on proposed amendments to 105 CMR 100.000, *Determination of Need*, to be put forth for public comment.

I. Background and Summary of Proposed Changes

The purpose and objective of this regulation, as redrafted and promulgated in January 2017, “is to encourage competition and the development of innovative health delivery methods and population health strategies within the health care delivery system to ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost, advancing the Commonwealth’s goals for cost containment, improved public health outcomes, and delivery system transformation.” (*See*: 105 CMR 100.001)

In operationalizing the revised regulation, the Department of Public Health (“DPH”, “Department”) has identified several clarifying and substantive changes designed to improve implementation of the regulation for both DPH staff and regulated parties, as well as better achieve the regulation’s goals of cost containment, improved public health outcomes, and delivery system transformation. A summary of these changes is included below.

- **Consolidated Determination of Need (DoN) Projects (100.100, 100.715)**: Currently, the regulation defines and prohibits “disaggregation” of proposed capital expenditure project elements for the purpose of keeping a proposed project below the substantial capital expenditure minimum, with the intention of requiring proposed projects over a period of time be consolidated into a single DoN application, and to prevent applicants from dividing up projects to keep them below the minimum cost trigger to avoid DoN. However, given that the definition of “disaggregation” is predicated on an applicant’s intentional division of project elements, DPH believes the aim of the regulation may be unclear to regulated parties.

The Department proposes several amendments to the regulation to clarify DPH’s goal of and expectation for receiving consolidated DoN applications:

- 100.100, Definitions: Changes are proposed for several definitions in this section relative to consolidated projects and applications:
 - The definition of “disaggregation” has been deleted, to clarify that consolidated DoN applications are meant to be forward looking and to eliminate any confusion going forward. “Disaggregation” is a historic DoN concept that predates the 2017 revision; keeping this terminology in the regulation may detract from the goals of the consolidation process.
 - The definition of “proposed project” was amended to clarify that a proposed project includes 1) substantial capital expenditures and substantial changes in service, or any combination thereof, or 2) any original license or transfer of ownership subject to DoN review (i.e., application types that are not otherwise subject to consolidation).
 - “Substantial capital expenditure” would now be defined as the total of all capital expenditures by a health care facility that, when added over a single federal fiscal year (FFY), exceed the expenditure minimum. The DoN regulation defines “health care facility” as a facility licensed by a government agency, including hospitals, clinics, and long term care facilities; this definition also includes any satellite locations listed on the health care facility license.
- 100.715, Substantial Capital Expenditure and Substantial Change in Service: Amendments to this section complement and build upon those definitional changes in 100.000 related to consolidation.
 - *Substantial Capital Expenditure*: Amendments would require any health care facility whose planned capital expenditures when totaled over a single FFY exceed the expenditure minimum, submit a single, consolidated DoN application for all such capital expenditures and all proposed substantial changes in service consolidated over the same FFY.

Changes also recognize the law establishes a separate expenditure minimum for outpatient projects, and provides a mechanism for hospitals or comprehensive cancer centers to submit a single, consolidated DoN application that aggregates all outpatient-specific substantial capital expenditures and substantial changes in service across all locations listed on

the health care facility license.

- *Substantial Change in Service:* Amendments would require any health care facility that is not required to submit an application for Substantial Capital Expenditure to submit a single, consolidated DoN application for all proposed substantial changes in service consolidated over a single FFY.

Changes also recognize that hospitals or comprehensive cancer centers may submit a single, consolidated DoN application that aggregates all outpatient-specific substantial changes in service across all locations listed on the health care facility license.

- **Definitions for Filing Date and Submission Date (100.100):** Current regulation defines the filing date as the date an application is filed with the Department, whereas the submission date is the date an application is deemed substantially complete. M.G.L. c. 111 § 25C requires DPH to take final action on a DoN application within four months after the application was filed with the Department, provided DPH may on one occasion delay final action for two months.

In implementing the revised regulation, it has been DPH's experience that there can be significant delay between when an application is filed and deemed substantially complete, as those terms are defined now. To ensure DPH has the fullest extent of its statutory mandated review timeframe available to review complete applications, "filing date" is now defined as the date an application is deemed substantially complete, whereas "submission date" is now defined as the date an application is filed with DPH.

- **Definition for Patient Panel (100.100):** Current regulation defines "patient panel" as those patients seen by an applicant or DoN holder over the course of the last 36 months.

In implementing the revised regulation, regulated parties have brought to the Department's attention that an applicant or DoN holder itself may not always have a "patient panel"; for example, the holder may be the parent corporation of one or more health care facilities. To better operationalize this definition, in keeping with the actual practice, amendments add that:

- health system applicants must use the aggregate patient panel from each of its affiliated health care facilities, and
 - applications for new facilities with no existing patient panel must use the anticipated patient panel; and
 - for transfers of ownership, the patient panel includes both the applicant and facility/entity being acquired.
- **Amendments to Approved Projects (100.100, 100.635):** For the purposes of requesting amendment to a previously issued DoN, 100.100 defines Immaterial Change, Minor Change, and Significant Change. These definitions are consistent with those in place prior to the 2017 revision. 100.635 lays out the process through which a Holder must notify DPH of its request for amendment. The level of staff and public review during the amendment approval process

increases based on the amendment category; currently, all three amendment types must be approved by the Department.

Updates to 100.100 and 100.635 consolidate the definition for Minor Change into the definition of Immaterial change, and exclude such Immaterial Changes from DPH review and approval because such changes do not increase the maximum capital expenditure approved by the Department for a project, nor do such changes alter the scope of a project approved by the Department. Significant changes would still require DPH review and Commissioner or PHC approval. These changes focus DPH review of amendments to those that have a material impact on the previously issued DoN approval.

- **Determination of Need Factors (100.210)**: In addition to organizational changes to this section, the revised regulation also subjects transfers of ownership seeking a determination of need to Factor 2, Health Priorities (currently, transfers of ownership are exempt from this factor). Factor 2 requires the applicant to “sufficiently demonstrate the Proposed Project will meaningfully contribute to the Commonwealth’s goals for cost containment, improved public health outcomes, and delivery system transformation”.
- **Standard Conditions (100.310)**: Currently, the regulation contains 17 standard conditions.

In furtherance of the regulation’s goal to advance the Commonwealth’s goals related to cost containment, amendments to the regulation include a new standard condition that would require any holder of a DoN who is asked to file a Performance Improvement Plan (PIP) with the Health Policy Commission (HPC) to 1) report on its implementation of the PIP and 2) should the HPC determine the holder has not fully complied with the requirements of the PIP implementation, report to DPH why the holder should be found in compliance with the terms and conditions of its DoN approval.

This standard condition would apply to all transfers, substantial capital expenditures, and substantial changes in service. The language emphasizes the state’s existing process to address those increases in health status adjusted total medical expenses by Health Care Entities considered excessive and threaten the ability of the state to meet the health care cost growth benchmark established under M.G.L. c. 6D, § 9, and complements the DoN Factor 3 requirement that Applicants be in compliance with all applicable state and federal laws, and emphasizes the Holder’s obligations as they relate to Massachusetts cost containment and accountability.

The DoN program expects this condition will have limited impact on smaller and/or independent providers, but will be a useful tool in monitoring compliance of larger health systems.

- **Waivers and Special Exemptions (100.815)**: Current regulation provides a process to submit requests for waiver of any requirement in the DoN regulation. This section also authorizes the Commissioner to exempt certain Proposed Projects from any provision in the DoN regulation, subject to any terms and conditions deemed appropriate.

Proposed amendments remove the special exemption process, leaving reference to a waiver process only. The special exemption process in the current regulation simply describes how the waiver process operates for this regulation and across DPH. Consideration and approval of any request for waiver submitted would require the requestor provide rationale for the waiver request, and would allow the Commissioner to attach terms and conditions to the approval of any such request.

- **Organizational Changes (throughout)**: Current regulation includes the applicability of certain DoN factors, standard conditions, other conditions, and any exclusions in sections specific to the type of DoN application being discussed. For example, 100.735, *Transfers of Ownership*, includes subsections listing a subset of factors applicable to this application type, and a subset of the standard conditions applicable to this application type, whereas all standard conditions are described earlier in the regulation at 100.310.

The updated regulation makes organizational changes throughout, such as including the applicability of factors and standard conditions by application type in the DoN Factor and DoN Standard Conditions sections of the regulation, so the information is in a single place. These changes will help program staff, regulated parties, and other interested stakeholders more easily understand how certain application types are scrutinized under this regulation.

II. Next Steps

Staff will conduct a public comment period on the proposed changes to the regulation, and will return to the PHC to report on testimony and any recommended changes to the proposed amendments. Following final action by the PHC, the Department will file the final amendment with the Secretary of the Commonwealth.

The proposed amendments to 105 CMR 100.000 are attached to this memorandum.