

THOUGHT LEADERSHIP

LEGAL UPDATES

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New Legislation Revises Massachusetts' Determination of Need Statute

On January 8, 2025, Massachusetts Governor Maura Healey signed into law “An Act Enhancing the Health Care Market Review Process.” Part of this sweeping healthcare oversight law includes changes to the Determination of Need (DoN) statute that give the Massachusetts Department of Public Health (DPH) an opportunity to make substantive changes to the DoN review process for the first time since DPH’s 2017 revision to the DoN regulation.

Health planning

Although not a direct change to the DoN statute, changes to the state’s health planning efforts will affect DPH’s review of DoN applications. The act moves the responsibility for developing a state health resource plan to the Health Policy Commission (HPC), creating a new Health Resource Planning Council responsible for developing the plan. The council must submit the first five-year state health resource plan to the governor and General Court by January 1, 2026. The plan must identify existing healthcare resources and anticipated healthcare needs and include recommendations for the supply and distribution of healthcare resources on a state-wide or regional basis. Importantly, the council must consider not only cost containment goals but also focus on health equity and health disparities in the commonwealth. DPH is required to consider the state health plan in all DoN decisions.

Determination of Need factors

An applicant for DoN must demonstrate that the proposed project meets each applicable factor of review. For the first time, the DoN statute directs DPH to take certain specific factors into account when reviewing a DoN application. These are:

1. The state health resource plan;
2. The commonwealth's cost containment goals;
3. The proposed project's impacts on:

the applicant's patients, including considerations of health equity, the workforce of surrounding healthcare providers, and other residents of the commonwealth; and

4. Comments and relevant data from Center for Health Information and Analysis (CHIA), HPC, and any other state agency.

DPH will likely update the DoN regulation to reflect these required considerations or may instead issue guidance or an updated application form, directing applicants to include these factors in their applications. By including these factors in the statute but not including all of the current regulatory factors, the legislature may be indicating the relative importance of these specific factors. Therefore, DoN applicants should expect to see an even greater emphasis on cost containment, health equity, and consideration of how proposed projects affect their community and region. To address this, applicants should, beginning in the planning stages of a new project, consider these areas of potential impact and how the project can address them.

Independent cost analysis

The act also gives DPH additional decision-making authority over any independent cost analysis. If DPH requires an applicant to provide an independent cost analysis, DPH may choose the entity that conducts the analysis from a list of three entities provided by the applicant.

Codification of timeframes

The statute codifies existing regulatory language regarding timeframes for review when there is an independent cost analysis, or the holder of a DoN is subject to a cost and market impact review (CMIR) by HPC. In addition, the act adds a delayed approval process for any DoN issued to a holder that is subject to a performance improvement plan (PIP). Further, HPC may rescind this determination at any time prior to successful completion of the PIP. This means that even if an applicant is implementing a PIP when it applies for DoN approval, if HPC determines that the holder is not appropriately implementing the PIP, HPC action could delay the approval of a DoN until the HPC is satisfied with the holder's activities under the PIP.

DoN process for ambulatory surgery centers

The act adds a new section MGL c. 111, §25C^{1/4}, which codifies and clarifies regulatory requirements for construction of ambulatory surgery centers (ASCs).

The statute adds some definitions that are relevant to the section. These include:

An independent community hospital is defined as a hospital that is designated by the HPC as an independent community hospital in the year in which the DoN application is filed or one that was eligible for enhanced Medicaid payments in 2021 because it was an independent acute care hospital with a statewide relative price less than \$0.90 and a public payer mix equal to or greater than 60%.

Party of record for this section also includes an independent community hospital whose primary service area (PSA) overlaps with the PSA of the proposed project.

Primary service area is defined as the contiguous geographic area from which a healthcare facility draws 75% of its commercial discharges, as measured by the zip codes closest to the facility by drive time, and for which the facility represents a minimum proportion of the total discharges in a zip code, as determined by the department in consultation with the health policy commission and based on the best available data using a methodology determined by the department in consultation with the health policy commission.

For any application for DoN for which the PSA of the proposed project overlaps with the PSA of an existing independent community hospital, the applicant must obtain a letter of support for the project from the independent community hospital's CEO and board chair, or the project must be a joint venture with the independent community hospital. DPH will not review an application for an ASC that is not in compliance with this section. Further, if a proposed project does not meet these requirements and DPH fails to dismiss the application, the independent community hospital may bring a civil action in superior court to require that DPH dismiss the application.

This statutory language provides much needed clarity to the definition of primary service area. The current regulatory definition is overly broad and defers to nonexistent guidelines for further information. The new definition will increase the predictability and transparency of DoN analysis when reviewing ASC DoN applications.

What this means to you

These changes represent the continued evolution of the utilization of DoN to implement the commonwealth's goals for healthcare access, equity, and cost containment. We will continue to monitor the implementation of these statutory changes and their practical impact for providers. There may be opportunities for public input during the regulation making process.

Contact us

If you have any questions about the new DoN rules or other issues, contact Crystal Bloom, Rebecca Rodman, or another member of our Massachusetts-based Healthcare team.