

September 30, 2016

## Massachusetts Determination of Need Proposed Regulations

On August 23, 2016, the Massachusetts Department of Public Health (“DPH”) proposed a major revision of its Determination of Need (“DoN”) regulations, 105 CMR 100.00, and held the first of two public hearings on the proposed amendments on September 21, 2016. A copy of the proposed amendments and related materials may be accessed by clicking [here](#). In its memorandum to the Public Health Council, DPH staff highlight that the proposal cuts the length of the current regulations by more than half, consolidates separate project approval processes, aligns the DoN regulations with DPH’s mission and the Commonwealth’s public health goals, and recalibrates DPH’s review of proposed mergers and acquisitions to permit review “through a public health lens.” Among many other changes, the proposed regulations establish a new enforcement regime by requiring providers to fund projects designated by DPH in the amount of 2.5% of the total Capital Expenditure of projects (or up to 5% of the Total Value of acquired facilities) if conditions in an approval are not satisfied for a period of five years. This significantly expands the enforcement provisions of the statute and existing regulations, which permit fines of no more than \$500 per day or revocation of a party’s license. Other proposed changes will materially affect the way in which DoNs are obtained.

### Broadened DoN Factors

The proposed regulations meaningfully broaden the criteria that an applicant must satisfy to obtain a DoN. For example, applicants must make a clear and convincing demonstration that thirteen specific requirements are met, including, among others, that the project “will add measurable public health value in terms of improved health outcomes and quality of life of the Applicant’s existing patient panel, while providing reasonable assurances of health equity;” “will meaningfully contribute to the Commonwealth’s goals for cost containment, improved public health outcomes, and delivery system transformation;” and “will compete on the basis of price.” There is no transition rule, so it is not clear how DPH will process DoN applications filed under the existing rules but not approved prior to the targeted effective date of the revised regulations, estimated in late 2016 or early 2017.

Not all of the thirteen factors will apply to every category of project. Most significantly, a “Conservation Project”—a newly defined term that captures facility restorations other than upgrades or expansions of existing services or functionalities—is exempt from nine of the thirteen criteria, including the items described above. In addition, under the current regulations, only certain renovation projects are eligible for delegated review by the Commissioner of Public Health (the “Commissioner”). The new regulations will make all Conservation Projects that exceed the applicable expenditure minimum eligible for delegated review.

### Ongoing Compliance Obligations and Expanded Enforcement

The proposed regulations broaden the required compliance conditions for maintenance of a DoN, as well as DPH’s ability to rescind a DoN and enforce continuing obligations. The current regulations require that DoN holders expend over a five-year period an amount “reasonably related” to the cost of the project for the provision of primary and preventive health care services for underserved populations and file reports detailing compliance with their approved DoN plan and an evaluation of health effects. In contrast, the proposed regulations bind the holder of a DoN to comply with various conditions for a period of five years following receipt of a DoN, including (a) expenditures of at least 5% (2.5% for Conservation Projects) of the total Capital Expenditure of the project, for projects other than transfers of ownership, to fund “Health Priorities” (DPH-designated goals for cost containment, improved public health outcomes and delivery system transformation); (b) mandatory participation (if eligible) in MassHealth; and (c)

at least annual reporting of measures relating to the project's achievement of the DoN factors required as part of the application. If DPH determines that the applicant has failed to comply with any of the conditions, the applicant must fund additional Health Priorities in an amount equal to 2.5% of the total value of a Capital Project, or up to 5% of the Total Value of the project of the acquired facility.

### **Removal of Alternate Process for Changes of Ownership**

For change of ownership of hospitals and freestanding ambulatory surgery centers ("ASCs"), the regulations currently allow an alternate review process with only four, objective factors. The proposed regulations eliminate the alternate process, and expressly condition each DoN approval on completion of the Health Policy Commission's review process; require that the facility to be acquired obtain a "Significant Change" amendment for each unimplemented DoN approval it holds at the time of DoN approval for the change of control; and subject the project to periodic reporting and enforcement standards, as described above.

### **Ambulatory Surgery Growth Limited to Acute Care Hospitals**

The proposed regulations limit DoNs for ASCs to those located on the main campus of an acute care hospital and those licensed as clinics that are either affiliated with, or constitute joint ventures with, existing acute care hospitals. This will prohibit independent clinics and other organizations not affiliated with acute care hospitals from establishing ASCs.

### **Removal of Major Movable Exemption**

The proposed regulations remove a number of provisions that hospitals have long relied upon in structuring projects and transactions. For example, the longstanding exemption for major movable equipment has been removed. Under the current regulations, acquisition by an acute care hospital of major movable equipment that was not defined as a new technology or an innovative service did not require a DoN and was not included in the calculation of the expenditure minimum. The proposed regulations will require such equipment acquisitions to be included in expenditure calculations and to be subject to DoN approval.

### **Health Policy Commission Alignment**

Under the current regulations, DPH has discretion to require applicants (now defined as registered "Provider Organizations," consistent with the Health Policy Commission's regulatory terminology) to provide an independent cost analysis demonstrating that the proposed project is consistent with the health care cost containment goals of the Commonwealth and the Health Policy Commission. Further, the Health Policy Commission is already a party of record with the right to review and comment upon any pending DoN application, supporting documentation, and independent cost analyses. The proposed regulations further align the DoN process with the Health Policy Commission's priorities by broadening the DoN factors as described above, and, for changes of ownership, deferring DoN effectiveness until completion of the Health Policy Commission's review, pursuant to which the Commissioner is allowed to rescind a DoN.

### **Other Material Changes**

Beyond these major changes, we note the following new provisions, which may be material, depending on the project:

- Added concepts of "Disaggregation" and "Reasonably Related Projects" (it is not clear whether this is an intent-based definition, nor is it clear whether this will effectively repeal the many years of advisory rulings on Disaggregation);
- Shell space fit-out constitutes a "Significant Change" subject to the significant change amendment process; and

- Addition of a “Silver Level” LEED-Healthcare, or an equivalent, nationally recognized best practice standard approved by DPH.

### Public Hearings, Listening Sessions, and Comment Period

The public comment period on the proposed regulations runs through October 7, 2016, and comments may be submitted to [Reg.Testimony@state.ma.us](mailto:Reg.Testimony@state.ma.us). DPH held the first public hearing on September 21, 2016 to a standing-room-only crowd. DPH will hold another public hearing on the proposed amendments on September 26, 2016 in Northampton. In addition to the public hearings, DPH expects to conduct listening sessions across the state in October and November 2016.