

KROKIDAS & BLUESTEIN

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CLIENT ALERT

CHAPTER 224 HEALTH CARE COST CONTAINMENT UPDATE #6: DEPARTMENT OF PUBLIC HEALTH FINALIZES AMENDMENTS TO DETERMINATION OF NEED REGULATIONS

On August 1, 2014, [final amendments](#) to the Determination of Need (“DoN”) regulations at 105 CMR 100.00 (with the final amendments, the “New DoN Regulations”) went into effect. The primary purpose of the final amendments was to incorporate the DoN-related changes enacted by Chapter 224 of the Acts of 2012 (“An Act Improving the Quality of Health Care and Reducing Costs Through Increased Transparency, Efficiency and Innovation”), which went into effect on November 5, 2012 (“Chapter 224”).

Our first Chapter 224 Client Alert of January 9, 2013 stated that the Massachusetts Department of Public Health (“DPH”) had issued interim guidance for the DoN program which was to be in effect until the DoN program regulations were amended consistent with Chapter 224. Presumably, this DPH interim guidance has been superseded by the New DoN Regulations. We note DPH has stated that it expects to further revise and amend the DoN regulations along with DoN guidelines, policies, and procedures in the near future as the various entities charged with implementing Chapter 224 continue to issue policies and directives that impact the DoN program.

The following is a brief overview of some of the more important changes to the DoN process resulting from the New DoN Regulations:

A. Health Policy Commission (“HPC”) and Expanded Center for Health Information & Analysis (“CHIA”) Involvement

The HPC is now defined as a “party of record” and as such is entitled to receive notice of DoN applications and copies of related documentation. This change means that the HPC may review and comment on any DoN application or supporting documentation, and may recommend that DPH require an independent cost-analysis from the DoN applicant (see below). An applicant must also notify DPH of certain interactions with the HPC, such as if the applicant is subject to filing a notice of material change and/or is subject to a performance improvement plan (M.G.L. Chapter 6D, Sections 10(d) and 13).

Although any party of record may comment on an application as it sees fit, CHIA was previously invited to comment particularly on the financial feasibility and cost ramifications of

applications and is now invited to also comment on issues related to access and competition in an applicant's primary and dispersed service areas.

B. New Role for the Attorney General ("AG")

DoN applicants must provide a copy of their newspaper notice of the application to the AG, which may review the application. Additionally, the AG may request a public hearing on any DoN application within 30 days after receipt of the notice, and may intervene in such a hearing, ask questions of any party choosing to speak at the hearing, and provide written comments to DPH. The AG may also review and comment on an applicant's independent cost-analysis.

C. Changes to the Timeline

The eight-month time limit within which DPH must complete its review has been replaced by a four-month limit. However, there are multiple ways this shorter time limit may be extended, including the following:

- DPH may, on one occasion, delay action on an application for up to two months after the applicant provides information reasonably requested by DPH;
- If DPH requests an independent cost-analysis, the time limit is stayed until the final cost-analysis is received; and
- A party of record, such as the HPC, may request postponement of consideration of the application until the HPC's next meeting.

D. Independent Cost-Analysis

DPH may now require DoN applicants to provide, at their own expense, an independent cost-analysis of a proposed transaction to demonstrate that the DoN application is consistent with the Commonwealth's cost-containment goals. The cost-analysis results are likely to be compared to the health care cost growth benchmark set annually by the HPC, and must be provided to the HPC and all other parties of record. DPH specifically rejected requiring an independent cost-analysis for each DoN application so as not to impose unnecessary costs on applicants for projects where a cost-analysis would be inappropriate (such as some changes not involving capital expenditures).

E. Updated Definitions of Innovative Service and New Technology; Ambulatory Surgery

The definition of "innovative service" has been amended to remove the list of specific services, and instead to provide for DPH to issue a list of services that it determines to be innovative for reasons of quality, access or cost. Although the definition of "new technology" still includes a list of examples, it also gives DPH discretion to provide its own list. DPH has stated that it will not provide new lists under these definitions until the State Health Plan is issued (see below), and that these lists will be included in annual informational bulletins.

The definition of "ambulatory surgery" now explicitly includes outpatient surgery performed both in freestanding ambulatory surgery centers and in hospitals. This means that hospitals are now subject to DoN approval for outpatient surgery projects that fall below the expenditure minimum, whether located on the main campus or at a satellite facility.

F. Section 308 Waiver Maintained

DPH declined to delete the longstanding regulatory waiver provision permitting DPH to allow exemptions in the DoN process in order to permit flexibility in unique circumstances.

G. Final Agency Action Clarified if No Health Facilities Appeals Board (“HFAB”)

The HFAB has not been constituted in many years, which has resulted in uncertainty as to the manner of appealing a DoN. The New DoN Regulations preserve the possibility of the HFAB being constituted in the future, but clarify that if none exists, the DoN would be considered a final agency action subject to review under M.G.L. c. 30A.

H. Filing Fee Increase

The filing fee for DoN applications is 0.2% of the proposed project’s total capital expenditure, doubling from 0.1% under the previous regulations.

I. State Health Plan

DPH expects further revision to the DoN regulations based on the Chapter 224-mandated State Health Plan, the plan to be developed and filed by DPH’s Health Planning Council pursuant to M.G.L. Chapter 6A, Section 16T (the “Plan”). The timing of issuance of the Plan is uncertain but anticipated on or about January 1, 2015, having passed the mandated January 1, 2014 release date. For its initial plan, the Health Planning Council is focused on health care services that have not traditionally been regulated by DoNs (behavioral and primary health care), although a review of long term care services appears to be contemplated for the next phase. Therefore, it may be a while before we see additional changes to the DoN Regulations, and instead, we may see additional DoN policy guidance issued in the form of circular letters. It is important to note, however, that the New DoN Regulations require that applications be consistent with the State Health Plan once such a Plan exists.

J. Sanctions

The New DoN Regulations codify the longstanding statutory enforcement and penalty provisions of M.G.L. c. 111, § 25G as a new section in the DoN regulations. This section states that DPH, the appropriate regional health planning agency, or any ten Massachusetts taxpayers may request court enforcement of the DoN regulations. In addition, violations of the DoN regulations may subject health care providers to fines of up to \$500 per day of violation, and may be used as grounds for licensure enforcement.

If you have questions about the New DoN Regulations, please contact Attorneys Jennifer Gallop (jgallop@kb-law.com), Robert Griffin (rgriffin@kb-law.com), or Emily Kretchmer (ekretchmer@kb-law.com).