

KROKIDAS & BLUESTEIN
ATTORNEYS

CLIENT ALERT

**DPH PROPOSES REVISIONS TO HOSPITAL AND CLINIC LICENSURE
REGULATIONS**

**NOTICE OF HEARING FOR DPH'S PROPOSED DETERMINATION OF NEED
("DoN") REGULATIONS**

I. PROPOSED LICENSURE REGULATIONS

The Massachusetts Department of Public Health ("DPH") released proposed regulations governing the licensure of [hospitals](#) and [clinics](#) on September 14, 2016. The proposed regulations are described in [DPH's PowerPoints](#). The public hearing for the proposed hospital licensure regulations is scheduled for October 24, 2016, and the public hearing for the proposed clinic licensure regulations is scheduled for October 25, 2016. Both will take place at 9:30 A.M. in Room 417 at 239 Causeway Street in Boston, Massachusetts. DPH is accepting public comments until October 28, 2016.

Please note the following items of interest:

**A. PROPOSED HOSPITAL LICENSURE REGULATIONS (105 CMR
130.000)**

Transfer of Ownership. Two requirements in the proposed regulations appear to be inconsistent: 105 CMR 130.101 provides that applications for initial license must be submitted at least 60 days in advance, whereas 105 CMR 130.109 provides that the initial licensure application/notice of intent to transfer ownership must be submitted at least 90 calendar days prior to the anticipated date of such transfer. This needs to be clarified.

Notice Requirements for Closure of Essential Service. The proposed regulations significantly expand the existing notice requirements. A hospital must inform the parties listed below of its intent to close an essential service at least 120 days prior to the closure date. Thereafter, the hospital must submit its closure plan to DPH at least 90 days prior to the closure date.

- DPH;
- The hospital’s patient and family council;
- Each staff member of the hospital;
- Every labor organization that represents the hospital’s workforce during the period of the essential services closure;
- All members of the General Court who represent the city or town in which the hospital is located; and
- A representative of the local officials of the city or town in which the hospital is located.

Additionally, the proposed regulations expand the required content of the 90-day notice to DPH by mandating that it include “a detailed account of any community engagement and planning” that occurred before submission of the notice. A copy of the 90-day notice to DPH must be sent to the Health Policy Commission, Office of the Attorney General, Center for Health Information and Analysis, and Executive Office of Labor and Workforce Development.

Incident Reporting. The proposed regulations require reports of serious adverse drug events (“SADE”) and surgery/anesthesia-related complications that result in death, and update reporting requirements for serious incidents, serious reportable events (“SRE”), and healthcare-associated infections (“HAI”).

Cardiac Catheterization. The proposed regulations remove the current moratorium and permit any hospital to apply to provide cardiac catheterization as a licensed service, subject to annual renewal. They also eliminate the existing 300- procedure minimum caseload requirement, and replace it with a requirement to maintain a minimum annual caseload volume in accordance with guidelines and standards issued by DPH, the American College of Cardiology, the American Heart Association, and the Society for Cardiac Angiography and Interventions.

Mobile Services. The proposed regulations do not incorporate mobile services, which are currently addressed through special project status. This should be clarified.

B. PROPOSED CLINIC LICENSURE REGULATIONS (105 CMR 140.000)

Staffing. The proposed regulations require the clinic administrator and professional services director to be physically present at the clinic as necessary to perform their duties and ensure patient safety.

Incident Reporting. The proposed regulations require reports of SADE and surgery/anesthesia-related complications that result in death, and update reporting requirements for serious incidents, SREs, and HAIs.

Mental Health Outreach Programs. The proposed regulations eliminate the existing requirement that mental health outreach programs not participating in Medicaid meet all of the

requirements set forth in MassHealth's Mental Health Center Regulations (130 CMR 429.440). Additionally, the proposed regulations strike the current prohibition against outreach clients and visits comprising the majority of the clinic's overall client and visits.

Mobile/Portable Host and Satellite Sites. The proposed regulations require licensure of mobile services, something that was previously addressed through obtaining special project status. The regulations require that space leased by a clinic be licensed as a satellite location. The proposed regulations include limitations on storage of medications by mobile clinics in order to prevent diversion, both prohibiting a mobile/portable clinic from storing medications at any host site, and prohibiting the clinic from storing medications overnight in the mobile and/or portable unit.

Urgent Care. The proposed regulations add a definition of urgent care and clarify that urgent care facilities require licensure as a clinic. The proposed regulations require urgent care clinics to provide each patient with a copy of his or her medical record at the end of the visit, or as soon thereafter as possible, and to provide a copy of the medical record to each patient's primary care physician, with the patient's consent. All clinics must have a policy for calling 911 in case of emergency.

Physical Plant Requirements. The proposed regulations expand the types of clinics that are exempt from the requirement to provide a clean supply storage room and certain soiled holding areas. Where this exemption was previously limited to mental health services, the proposed regulations broaden the exemption to include small clinics with no more than two examination rooms. The regulations also allow limited service clinics and mobile and portable units located on the same premises as another entity to share toilet facilities.

II. PROPOSED DETERMINATION OF NEED REGULATIONS (105 CMR 100.000)

The changes in DPH's proposed [DoN regulations](#) are extensive. DPH is conducting two public hearings, which will take place on September 21, 2016 at 1:30 PM at 250 Washington Street in Boston, and on September 26, 2016 at 1:00 P.M. at 23 Service Center Road in Northampton. Written comments are due on October 7, 2016.

We will continue to monitor developments in these areas, and advise you when the final rules are released. In the meantime, if you have any questions or would like assistance in submitting comments to DPH on any of these regulations, please contact Jennifer Gallop (jgallop@kb-law.com) or Emily Kretchmer (ekretchmer@kb-law.com).