

# Massachusetts Proposes Amendments to Hospital and Clinic Licensure Regulations

On February 11, the Division of Health Care Quality (DHCQ) proposed amendments to Massachusetts' hospital licensure and licensure of clinics regulations. The proposed regulations seek to increase safety and improve quality of care by: (i) bringing greater transparency to the health care system; (ii) prohibiting hospitals and clinics from seeking payment for certain adverse events; and (iii) requiring hospitals and clinics to form patient councils and to develop methods to respond to a deterioration in a patient's condition. These proposed regulations are the latest in a series of regulations required by An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (the Act), signed by Governor Deval Patrick on August 10, 2008.

## Hospital Licensure

The following list highlights a few of the changes implemented by the proposed hospital licensure regulations:

- **Serious Reportable Events (SREs):** The proposed regulations prohibit hospitals from charging or seeking reimbursement for SREs unless the hospital demonstrates that the SRE was not preventable, not within its control, and not the result of a system failure caused by hospital policies and procedures. Within seven days of any SRE on its premises, the hospital must file a report with the Department of Public Health (DPH), provide a copy of this report to any responsible third-party payer, and notify the patient involved. The DPH will publish the SRE data it receives on the Health Care Quality and Cost Council (HCQCC) consumer health information website.
- **Healthcare-Associated Infections (HAIs):** Although hospital licensure regulations currently require the reporting of HAIs to DPH, the proposed regulations clarify this requirement by defining HAI. Like SRE data, HAI data will be published on the HCQCC consumer health information website.
- **Patient and Family Advisory Councils (PFACs):** The proposed regulations require hospitals to establish PFACs on or before September 1. PFACs will advise hospitals on various matters, including patient and provider relationships, quality improvement, and patient education about safety and quality.
- **Patient Rapid Response Method (PRRM):** Under the proposed regulations, acute care hospitals must adopt a PRRM to provide health care staff, patients, and family members with 24-hour access to specially trained individuals who can assist when a patient's condition deteriorates.
- **Patient Record Retention:** The changes to the patient record retention requirements implemented by the proposed regulations include a shortening of the record retention period from 30 to 20 years, a requirement that hospitals notify DPH before destroying records, and a requirement that hospitals inform patients of their record retention and destruction policies.

## Licensure of Clinics

The proposed changes to the clinic licensure regulations mirror the proposed changes to the hospital licensure regulations in the areas of SREs, HAIs, and patient record retention. Additionally, the proposed amendments would require physician-owned, Medicare-certified ambulatory surgery centers to submit to Determination of Need (DoN) review and obtain a clinic license. The Act exempts from DoN review ambulatory surgery centers that were in operation or under construction as of August 10, 2008. These DoN exempt ambulatory surgery centers, however, are not exempt from having to obtain a clinic license, and they must submit their clinic license applications no later than six months after the effective date of the proposed regulations.

DHCQ will hold two public hearings on the proposed regulations. The first hearing will be held at the DPH offices in Boston at 9 a.m. on Monday, March 23. The second hearing will be held at the Springfield City Hall at 11 a.m. on Monday, March 30. DHCQ intends to bring the final regulations before the PHC for approval in either May or June.

For further information, please contact your usual Ropes & Gray attorney or [Michele M. Garvin](#), [Timothy M. McCrystal](#) or [Anne Phillips Ogilby](#).

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