

CLIENT ALERT: February 23, 2009

PROPOSED AMENDMENTS TO DPH HOSPITAL & CLINIC/ASC REGULATIONS

(Implementing Certain Provisions of Chapter 305 of the Acts of 2008: An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care & Other Items)

On February 11, 2009, the Public Health Council (“PHC”) approved for release for public comment proposed amendments to the 105 CMR 130.000 AND 105 CMR 140.00, the hospital and clinic licensure regulations (the “Amendments”). A copy of the Amendments, DPH staff summary and public hearing notice are available at the following links:

http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_clinics&csid=Eeohh

http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_hospital_licensure&csid=Eeohhs2

The Hospital Amendments would, among other things: (1) require hospitals licensed by the Department to report serious reportable events (SREs) to the Department and prohibit hospitals from charging or seeking reimbursement for SRE-related services, as well as redefining serious incidents; (2) require hospitals to report healthcare associated infections (HAIs) to the Department; (3) require hospitals to establish a patient and family advisory council (PFAC); (4) require hospitals to develop a patient rapid response method (PRRM); and (5) amend requirements for retention of hospital records to allow creation and maintenance of records in electronic format, shorten the retention period from 30 to 20 years, require notification to patients of record retention policies and require notification of DPH before records may be destroyed. In addition, the proposed amendments to 105 CMR 130.000 update requirements for (6) licensed cardiac catheterization services, and (7) make technical corrections to the newborn and maternal services section of the regulation.

The Clinic/ASC Amendments would, among other things: (1) require all Medicare-certified Ambulatory Surgery Centers (ASCs) to be licensed as clinics and allow the Department to grant “deemed-by accreditation” licensure to a Medicare-certified ASC that is accredited by one of three nationally-recognized accrediting bodies; (2) require ASCs to report SREs and prohibits ASCs from charging or seeking reimbursement for SRE-related services; (3) requires ASCs to report HAIs; and (4) includes comparable amendments concerning retention of clinic records; (4) makes technical changes to 105 CMR 140.000 to implement new Determination of Need requirements for ASCs; and (5) requires notification of the Department of clinic closures and temporary interruption

of service. Please note that the Department also has convened a task force to consider revisions to the ASC DoN guidelines, some of which overlap with the clinic regulations.

The Department is particularly interested in comments regarding: (1) what information relating to hospital/ASC reporting of SREs and HAIs should be available on the Department's website; and (2) what factors should hospitals consider in determining membership of PFACs.

A public hearing is scheduled in Boston for March 23rd and in Springfield for March 30, and DPH intends to return to the PHC with final regulations in May or June, 2009 after processing any public comments. Please let us know if we can be of assistance in interpreting the Amendments or preparing testimony.