TO: Chief Executive Officers, Acute Care Hospitals and Birth Centers

FROM: Deborah Allwes, BS, BSN, RN, MPH
Director, Bureau of Healthcare Safety and Quality

DATE: January 26, 2015

RE: Screening for Critical Congenital Heart Disease in Newborns:
Amendments to 105 CMR 130.000 (Hospital Licensure) and
105 CMR 142.000 (Operation and Maintenance of Birth Centers)

The purpose of this letter is to update hospitals with birthing and newborn services and birth centers in the Commonwealth about amendments to licensure regulations that address Critical Congenital Heart Disease (CCHD) screening for newborns using pulse oximetry. The amendments to 105 CMR 130.000, Hospital Licensure and 105 CMR 142.000 Operation and Maintenance of Birth Centers went into effect October 24, 2014. CCHD is defined in both regulations as “a group of defects that cause severe and life-threatening symptoms and require intervention within the first days or first year of life.”

The amended regulation requires screening for CCHD with pulse oximetry or other test approved by the Department as set forth in guidelines, unless the parent or guardian objects to the screening based on sincerely held religious beliefs. Until the Department issues additional guidance, the Department expects all facilities to screen newborns for CCHD using pulse oximetry in accordance with the regulations.

This regulation aligns with statute from March 6, 2014, when Governor Patrick signed into law Chapter 42 of the Acts of 2014. This law adds a new section 110C to Chapter 111 of the Massachusetts General Laws. Among its provisions is the requirement that hospitals that provide birthing and newborn services and birthing facilities adopt written protocols for pulse oximetry screening for congenital heart defects on all newborns prior to discharge, in accordance with Department regulations. The Department shall review the written protocols and the implementation of these protocols as part of its hospital licensure and birth center licensure review processes.

Attached are changes to the relevant sections of the hospital and birth center regulations.
Since May of 2013, the Department of Public Health (DPH) has recommended that hospitals with birthing and newborn services and birth centers in the Commonwealth use pulse oximetry to screen newborns for CCHD, using the guidelines recommended by the Secretary of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children and the American Academy of Pediatrics (AAP).

If you have any questions about the information in this correspondence, please contact Marlene Anderka, Director of the Massachusetts Center for Birth Defects Research and Prevention, at 617-624-6045 or at Marlene.Anderka@state.ma.us.

We request that you forward this circular letter to the following staff at your hospital, and any others as appropriate: Chief Medical Officer, Chief of Obstetrics, Chief of Pediatrics, Chief of Neonatology, Chief Nursing Officer, Director of Maternal and Child Health, and QA Director/Risk Manager.

Attachment:
Amended sections of the hospital licensure regulation and birth center regulation