



Catherine B. Templeton, Director

*Promoting and protecting the health of the public and the environment*

**DATE:** August 27, 2013

**PS-R016-20130827**

**MEMORANDUM**

**TO:** Administrators of Hospitals and Institutional General Infirmaries

**FROM:** Gwen C. Thompson, Chief, *Gwen C. Thompson*  
Bureau of Health Facilities Licensing

**SUBJECT:** Pulse Oximetry Screening Test on Newborns to Detect Congenital Heart Defects.

On June 13, 2013, the Governor signed into law the "Emerson Rose Act" mandating that "The Department of Health and Environmental Control shall require each birthing facility licensed by the department to perform on every newborn in its care a pulse oximetry screening test or other department-approved screening to detect critical congenital heart defects[.]" Pulse oximetry is a noninvasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen. Effective September 11, 2013, in accordance with the Act, birthing facilities shall perform on every newborn a pulse oximetry screen test or other department approved screening to detect critical congenital heart defects when the baby is twenty-four (24) to forty-eight (48) hours of age. Pulse oximetry screening for newborns shall be performed in the manner designated by the Department guidelines in the attached addendum.

If a parent of a newborn objects, in writing, to the screening, for reasons pertaining to religious beliefs only, the newborn is exempt from the required screening.

This memorandum applies immediately to all birthing facilities licensed by the Department. The Department will also promulgate regulations necessary to implement the Emerson Rose Act.

This memorandum relates solely to SC licensing standards. If there are any questions regarding pulse oximetry screening test on newborns, please contact Michell Hatcher (803) 545-4968.

GCT/dnf

**CC:** Terry L. English, DHEC  
Michell Hatcher, DHEC



Catherine B. Templeton, Director

*Promoting and protecting the health of the public and the environment*

## **EMERSON ROSE ACT**

### **GUIDELINES**

**September 11, 2013**

#### **SECTION I: Emerson Rose Act**

Pursuant to 1976 S.C. Code of Law, Section 44-37-70, “The Department of Health and Environmental Control shall require each birthing facility licensed by the department to perform on every newborn in its care a pulse oximetry or other department approved screening to detect critical congenital heart defects when the baby is twenty-four (24) to forty-eight (48) hours of age, or as late as possible if the baby is discharged from the hospital before reaching twenty-four (24) hours of age. A department approved screening must be based on standards set forth by the United States Secretary of Health and Human Services’ Advisory Committee on Heritable Disorders in Newborns and Children, the American Heart Association, and the American Academy of Pediatrics. If a parent of a newborn objects, in writing, to the screening, for reasons pertaining to religious beliefs only, the newborn is exempt from the screening required by this subsection.”

#### **SECTION II: Screening Technology**

Licensed facilities shall perform screenings with motion-tolerant pulse oximeters that report functional oxygen saturation, have been validated in low-perfusion conditions, have been cleared by the Food and Drug Administration (FDA) for use in newborns, and have a 2% root-mean-square accuracy. A new guidance document on the safety and effectiveness of pulse oximeters has been developed by the FDA. Any pulse oximeter used for screening shall meet FDA recommendations.

Licensed facilities may use pulse oximeters with either disposable or reusable probes. Reusable probes can reduce the cost of screening but must be appropriately cleaned between uses to minimize the risk of infection. Some probes have been developed to be partially reusable, which reduces the need to clean between uses and are less expensive than fully disposable probes. Probes with close coupling to skin (ie, taped rather than clamped) provide better performance for oximetry monitoring in newborns. Pulse oximeters are validated only with the specific probes recommended by the manufacturer; therefore, to optimize valid screening, licensed facilities shall use only manufacturer-recommended pulse-oximeter–probe combinations.

#### **SECTION III: Screening Criteria**

The facility shall perform on every newborn in its care a pulse oximetry screening test to detect critical congenital heart defects when the baby is twenty-four (24) to forty-eight (48) hours of age, or as late as possible if the baby is discharged from the hospital before reaching twenty-four (24) hours of age. Screening shall be accomplished based on standards set forth by the United States Secretary of Health and Human Services’ Advisory Committee on Heritable Disorders in Newborns and Children, the American Heart Association, and the American Academy of Pediatrics.

Performing a pulse oximetry screening does not replace a complete history and physical examination.

#### **SECTION IV: Religious Objection**

If a parent of a newborn objects, in writing, to the screening for reasons pertaining to religious beliefs only, the newborn is exempt from the required screening.