



REGULATION 61-123, CRITICAL CONGENITAL HEART DEFECTS SCREENING ON NEWBORNS

Effective June 27, 2014

**Bureau of Health Facilities Licensing
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201**

DISCLAIMER

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PREAMBLE

This regulation implements the provisions of the South Carolina Emerson Rose Act codified at Section 44-37-70 et seq., S.C. Code of Laws, 1976, as amended. This regulation will apply to each birthing facility licensed by the Department in South Carolina.

Regulation History

Promulgated pursuant to Section 44-37-70 et seq., S.C. Code of Laws, 1976, as amended

Added to Chapter 61 in the S.C. Code of Regulations by Document No. 4429 as published in S.C. State Register Volume 38 Issue 6, effective June 27, 2014

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SECTION 100. Purpose and Scope; Definitions.

101. Purpose and Scope.

The purpose of this regulation is to provide requirements regarding screening of newborns for critical congenital heart defects. Congenital heart defects are the leading cause of infant death due to birth defects. Some critical congenital heart defects can cause severe and life-threatening symptoms that require intervention within the first days of life. Newborns with abnormal pulse oximetry screening results require immediate confirmatory testing and intervention. Many newborn lives potentially could be saved by earlier detection and treatment of congenital heart defects. The South Carolina Birth Outcomes Initiative, established by the Department of Health and Human Services to improve care and outcomes for mothers and newborns, has acknowledged the value of pulse oximetry screening of newborns, and under this initiative all South Carolina birthing hospitals have committed to implementing this screening for newborns. The American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association recommend pulse oximetry screening for newborns.

102. Definitions.

A. Birthing facility. An inpatient or ambulatory health care facility licensed by the Department of Health and Environmental Control that provides birthing and newborn care services.

B. Department. The South Carolina Department of Health and Environmental Control.

C. Department Approved Screening. A critical congenital heart defects screening approved by the Department of Health and Environmental Control as an alternative to pulse oximetry screening 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.

D. Pulse Oximetry. Pulse oximetry is a noninvasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen.

SECTION 200. Screening Criteria and Procedures.

201. Screening Criteria.

Each birthing facility licensed by the Department shall 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.

202. Procedures.

A. When performing pulse oximetry screenings, licensed facilities shall use 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 two percent root-mean-square accuracy. Any pulse oximeter used for screening shall meet FDA recommendations.

B. If reusable probes are utilized, licensed facilities shall appropriately clean the probes between uses to minimize the risk of infection. 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.

C. Performing a pulse oximetry or Department approved screening does not replace a complete history and physical examination.

SECTION 300. Religious Objection.

If a parent or guardian 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 Section 44-37-70 of the South Carolina Code of Laws of 1976, as amended.