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Document No. 4429

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44‑37‑70 et seq.

61-123. Critical Congenital Heart Defects Screening on Newborns

**Synopsis:**

South Carolina Act No. 0064, effective September 11, 2013, enacted the Emerson Rose Act, S.C. Code Section 44‑37‑70 et seq. The Act, at 1976 Code Sections 44‑37‑70 et seq., directed the Department to promulgate regulations to perform a pulse oximetry screening tests, or another approved screening to detect congenital heart defects, on every newborn in its care, when the baby is twenty‑four to forty‑eight hours of age, or as late as possible if the baby is discharged from the hospital before reaching twenty‑four hours of age. This regulation will comply with the Act by mandating congenital heart defect screening on newborns. See sectional discussion below and Statements of Need and Reasonableness and Rationale herein.

A Notice of Drafting for this regulation was published in the *State Register* on September 27, 2013.

Sectional Discussion of New Regulation

Section 100 provides the purpose and scope of the regulation and definitions of key terms in the regulation.

Section 200 addresses screening criteria and procedures.

Section 300 addresses religious objections.

**Instructions:** Add new R.61- 123, Critical Congenital Heart Defects Screening on Newborns, to Chapter 61 regulations.

**Text:**

61-123. Critical Congenital Heart Defects Screening on Newborns.

 Statutory Authority: 1976 Code Section 44‑37‑70 et seq.

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SECTION 100. Purpose and Scope; Definitions.

SECTION 200. Screening Criteria and Procedures.

SECTION 300. Religious Objection.

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.

**Fiscal Impact Statement:**

The regulation will have no substantial fiscal or economic impact on the state or its political subdivisions.

**Statement of Need and Reasonableness:**

This statement was determined by staff analysis pursuant to S.C. Code Ann Section 1‑23‑115 C(1)‑(3) and (9)‑(11).

DESCRIPTION OF REGULATION: New R.61-123, Critical Congenital Heart Defects Screening on Newborns.

Purpose: This regulation will implement the provisions of the Emerson Rose Act, S.C. Code Section 44‑37‑70 et seq.

Legal Authority: Emerson Rose Act, S.C. Code Section 44‑37‑70 et seq.

Plan for Implementation: Upon approval from the S.C. General Assembly and publication as a final regulation in the South Carolina State Register, copies of the regulation will be available electronically on the South Carolina Legislature Online website, and the Department regulation development website (<http://www.scdhec.gov/regulatory.htm>). Printed copies will be available for a fee from the Department’s Freedom of Information Office. Staff will educate the regulated community on the provisions of the Act and the requirements of the regulation.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The regulation is needed and reasonable because it will satisfy a legislative mandate to implement the provisions of the Emerson Rose Act. The regulation allows for intended benefits of the Act regarding critical congenital heart defect screening.

DETERMINATION OF COSTS AND BENEFITS:

Internal Costs: Implementation of this regulation will not require additional resources beyond those allowed for in the Act. There is no anticipated additional cost by the Department or State government due to any inherent requirements of this regulation.

External Costs: There will be a cost to the licensees of birthing facilities of purchasing and maintaining equipment. There will be no cost to the public for implementation of the regulation.

External Benefits: Congenital heart defects are the leading cause of infant death due to birth defects. According to the United States Secretary of Health and Human Services’ Advisory Committee on Heritable Disorders in Newborns and Children, congenital heart disease affects approximately seven to nine of every thousand live births in the United States and Europe. Pulse oximetry is a noninvasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen. When performed on a newborn when the baby is twenty‑four to forty‑eight hours of age, or as late as possible if the baby is discharged from the hospital before reaching twenty‑four hours of age, pulse oximetry screening is often more effective at detecting critical, life‑threatening congenital heart defects which otherwise go undetected by current screening methods.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

There will be no effect on the environment.

The regulation will provide standards for pulse oximetry or other department approved screening to detect critical congenital heart defects in South Carolina newborns.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There would not be a detrimental effect on the environment. However, if the regulation is not implemented, critical congenital heart defects in newborns may go undetected by current screening methods.

**Statement of Rationale:**

The Department promulgated this regulation to implement the provisions of the Emerson Rose Act, S.C. Code Section 44‑37‑70 et seq.