



SOUTH CAROLINA  
DEPARTMENT OF  
PUBLIC HEALTH

## Regulation 60-80 Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies

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**Statutory Authority:**

S.C. Code Section 44-37-30

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## **Section A – Purpose and Scope**

This regulation establishes rules implementing provisions of Section 44-37-30 of the South Carolina Code of Laws, 1976, as amended, regarding testing of newborn children for inborn metabolic errors and hemoglobinopathies. The Department of Public Health has been given the legislative mandate to promulgate rules and regulations for screening for inborn metabolic errors and hemoglobinopathies and to ensure compliance with the screening of every child born in South Carolina. The responsibilities of the various agencies, institutions and persons involved in the screening process are defined. Procedures for storage and use of blood specimens and maintenance of confidentiality are included.

## **Section B – Definitions**

1. Inborn Metabolic Errors—shall mean inborn errors of metabolism.
2. Hemoglobinopathy—shall mean a hematologic disorder or carrier state caused by alteration in the genetically determined molecular structure of hemoglobin which may result in overt anemia as well as clinical and other laboratory abnormalities.
3. Identifying Information—shall mean child’s legal name, sex, race, birth date, time of birth, place of birth, birth weight, current weight, feeding type; parent’s or legal guardian’s complete name, complete address and telephone number; mother’s Social Security Number.
4. Attending Physician—shall mean the physician who has entered into an agreement to provide care during and/or after delivery for the mother and/or her child. The physician listed on the laboratory form will be assumed to be the attending physician until notification to the contrary is received in accordance with Official Departmental Instructions.
5. Department—shall mean the South Carolina Department of Public Health.
6. Laboratory—shall mean the South Carolina Department of Public Health Laboratory.
7. Bureau of Maternal and Child Health—shall mean an organizational unit of the South Carolina Department of Public Health.
8. Official Departmental Instructions—shall mean detailed instructions approved by the Director of the South Carolina Department of Public Health or his designee under which the public and private health care providers, including hospitals, laboratories, clinics, physicians and their staffs screen all children born in South Carolina for designated Inborn Metabolic Errors and Hemoglobinopathies.

## **Section C – Testing**

1. The Laboratory shall perform all screening tests for inborn metabolic errors and hemoglobinopathies using procedures compliant with the Clinical Laboratories Improvement Act of 1988, as amended, and approved by the Food and Drug Administration. If any result is abnormal, the appropriate test shall be repeated and confirmatory tests performed in accordance with Official Departmental Instructions.
2. The Laboratory, in conjunction with the Bureau of Maternal and Child Health, shall adopt standards for the quality assurance and interpretation of approved tests and for the collection of specimens.
3. Confirmation and repeat specimen testing are available from the Laboratory at no charge to patients suspected or diagnosed as having one of the diseases if the analysis is completed at the Laboratory.

4. Test results and identifying information are to be reported and recorded in accordance with Official Departmental Instructions.

## **Section D – Collection of Specimen**

1. A specimen shall be collected from every child born in South Carolina for the purpose of screening for inborn metabolic errors and hemoglobinopathies.

### **2. Births in a Hospital**

a. The attending physician is responsible for the collection of the specimen from every child born in the hospital in accordance with Official Departmental Instructions and is responsible for submission of the specimen to the Laboratory on the day of collection.

b. Under the direction of the attending physician, the specimen shall be collected under the most favorable conditions following the procedures specified in the Official Departmental Instructions. The brochure produced by the Department that explains newborn screening for inborn metabolic errors and hemoglobinopathies and blood specimen storage options shall be given to the parent or legal guardian of the child.

c. A specimen shall be collected from every child born in the hospital prior to release from the hospital (except when the parents object due to religious convictions) in accordance with the procedure specified in the Official Departmental Instructions. If the parent objects to the screening on the basis of religious convictions, the parent shall complete the procedure specified in the Official Departmental Instructions.

d. If for some reason the specimen is not collected at the hospital, the hospital shall then be responsible for notifying the Bureau of Maternal and Child Health as specified in the Official Departmental Instructions.

e. The Hospital shall review the patient record for each child born in the hospital no later than ten (10) days after delivery to ensure that a specimen was collected and submitted to the Laboratory.

### **3. Births Outside a Hospital**

a. The attending physician is responsible for the collection of the specimen from every child in accordance with the Official Departmental Instructions and for submission of the specimen to the Laboratory on the day of collection.

b. Under the direction of the attending physician, the specimen shall be collected under the most favorable conditions following the procedure specified in the Official Departmental Instructions. The brochure produced by the Department that explains newborn screening for inborn metabolic errors and hemoglobinopathies and blood specimen storage options shall be given to the parent or legal guardian of the child.

c. If the parents object to the screening on the basis of religious convictions, the parents shall complete the procedure specified in the Official Departmental Instructions.

d. If for some reason the specimen is not collected within three (3) days of delivery by the attending physician, this physician shall notify the Bureau of Maternal and Child Health as specified in the Official Departmental Instructions.

e. If there is not an attending physician, then the person in attendance is responsible for the collection of the specimen. If there is no other person in attendance, then the parents or legal guardian shall notify the Health Department in the county in which the child resides within three (3) days of delivery so that a specimen may be collected.

## **Section E – Assurance of Diagnosis and Follow-up**

1. Information obtained as a result of the tests conducted for screening for inborn metabolic errors and hemoglobinopathies is confidential and may be released only to the infant's physician or other staff acting under the direction of the physician, the child's parent or legal guardian, and the child when he/she is eighteen years of age or older.

2. Normal and abnormal test results will be forwarded by the Laboratory and/or Bureau of Maternal and Child Health to the attending physician who shall be responsible for informing the parents or legal guardian of test results.

3. If the child is not under the care of the attending physician, as specified in the Official Departmental Instructions, the person in attendance shall notify the Bureau of Maternal and Child Health. The Department will then notify the parents or legal guardian of the test results.

4. Upon notification that a specimen was insufficient or that it is necessary for a test to be repeated, the attending physician shall collect and submit a second specimen to the Laboratory in accordance with Official Departmental Instructions.

5. The attending physician shall initiate appropriate medical follow-up and diagnosis when abnormal test results occur. If that is not possible, the Bureau of Maternal and Child Health shall be notified as specified in the Official Departmental Instructions.

6. The attending physician shall notify the Bureau of Maternal and Child Health of all children born in South Carolina who are diagnosed as having inborn metabolic errors or hemoglobinopathies.

7. Appropriate genetic counseling should be offered to all families of children with abnormal test results as outlined in the Official Departmental Instructions.

## **Section F – Storage of Specimen**

1. Hospital staff or other persons who collect blood specimens for the purpose of screening for inborn metabolic errors and hemoglobinopathies shall inform each child's parent or legal guardian of the blood specimen storage options.

2. Hospital staff or other persons who collect these blood specimens shall give the brochure produced by the Department that explains newborn screening for inborn metabolic errors and hemoglobinopathies to the parent or legal guardian as a means of informing them of the benefits of screening and blood specimen storage. Hospital staff or other persons who collect these blood specimens shall indicate that the brochure was given to the parent or legal guardian by documenting in the appropriate space on the Blood Sample Storage Options Form.

3. The Laboratory shall store all specimens at minus 20° Centigrade and may release specimens for purposes of confidential, anonymous scientific study unless prohibited by the parents, legal guardians, or children from whom the specimens were obtained when the children are eighteen years of age or older.

4. Hospital staff or other persons who collect these specimens shall ensure that the parent's or legal guardian's storage choice is documented on the Blood Sample Storage Options form if the parent or legal guardian does not agree to have their child's blood specimen stored and potentially released for confidential, anonymous scientific study. In these instances, the Laboratory shall maintain all such specimens based upon the storage option chosen by the parent or legal guardian as documented on the Blood Sample Storage Options form.

## **Section G – Use of Stored Specimen**

1. Stored blood specimens may be released for the purposes of confidential, anonymous scientific study unless prohibited by the parent, legal guardian, or child from whom the specimen was obtained when he/she is eighteen years of age or older.

2. The Department's Institutional Review Board shall approve all scientific studies that use stored blood specimens before the specimens are released.

3. Blood specimens released for scientific study shall not contain information that may be used to determine the identity of the children from whom they were obtained by the person(s) to whom the specimens are released. The Department shall code the specimens before releasing them so that the Department can identify the children from whom the blood specimens were obtained if necessary.

4. If any such scientific study identifies genetic or other information that may benefit the children from whom the specimens were obtained, the Department may confidentially provide this information to the parents, legal guardians or children from whom the specimens were obtained when the children are eighteen years of age or older.

## **Section H – Forms**

1. Newborn Screening Program Parental Statement of Religious Objection (Religious Objection Form): The Religious Objection Form shall be completed if the parents refuse newborn screening for inborn metabolic errors and hemoglobinopathies for their child based upon religious convictions.

2. Authorization to Release Information Relative to Newborn Screening for Inborn Metabolic Errors and Hemoglobinopathies (Information Release Form): The Information Release Form may be completed as needed for release of information regarding newborn screening for inborn metabolic errors and hemoglobinopathies to persons other than those specified elsewhere in this regulation.

3. Blood Sample Storage Options, Screening for Inborn Metabolic Errors and Hemoglobinopathies (Blood Sample Storage Options Form): The Blood Sample Storage Options Form shall be completed if the parents or legal guardians do not agree to have their child's specimen stored and potentially released for confidential, anonymous scientific study.

## **Section I – Enforcement Provision**

### **1. Constitutionality**

If any part or provision of these regulations is legally declared unconstitutional or if the application thereof to any persons or circumstances is held invalid, the validity and constitutionality of the remainder of these regulations shall not be affected thereby.

### **2. Penalties**

Violation of these regulations shall be punishable in accordance with Section 44-37-30 of the Code of Laws of South Carolina, 1976, as amended.