

1 April 2014

NOTICE OF PROPOSED RULEMAKING
“Georgia Newborn Screening Program”
Revisions to Regulation Chapter 511-5-5

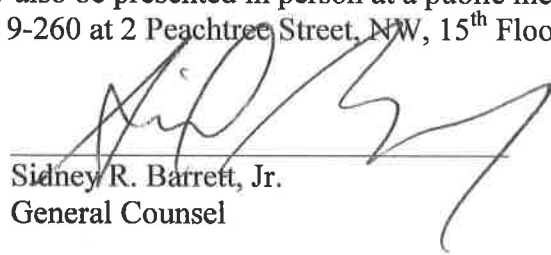
Please take note that the Department of Public Health proposes to revise the administrative regulations currently codified as Chapter 511-5-5 (“Testing for inherited disorders in the newborn”), pursuant to its authority under O.C.G.A. Sections 31-2A-4(12) and 31-2A-6. The proposed revised regulation is attached.

These revisions are intended to add new tests to the roster of required testing of newborn babies in Georgia; to clarify the role of private laboratories; and to incorporate testing standards to be published in the form of the Department’s “Georgia Newborn Screening Program Policy and Procedure Manual.”

Interested persons may submit comments on these proposed revisions in writing addressed to:

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Comment may also be presented in person at a public meeting scheduled for 1:30 p.m., 2 May 2014, in room 9-260 at 2 Peachtree Street, NW, 15th Floor, Atlanta GA.



Sidney R. Barrett, Jr.
General Counsel



**RULES
OF
DEPARTMENT OF PUBLIC HEALTH**

**CHAPTER 511-5-5
GEORGIA NEWBORN SCREENING PROGRAM**

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511-5-5-.01 Purpose

The purpose of these rules is to provide administrative details and procedures to ensure that all newborn babies in Georgia are promptly tested for certain conditions which pose a threat of severe illness, physical or developmental disability, or death.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7

511-5-5-.02 Definitions

- (a) "Abnormal test result" is a test result from blood testing or physiologic monitoring that is outside the screening limits set forth in the current edition of the Department's "Georgia Newborn Screening Program Policy and Procedure Manual";
- (b) "Adequate specimen" is a dried blood spot specimen that is properly collected in accordance with the current edition of the Department's "Georgia Newborn Screening Program Policy and Procedure Manual";
- (c) "Approved laboratory" is a laboratory licensed in Georgia which has been specifically approved by the Department to conduct laboratory analysis of dried blood spot specimens for the disorders specified in the Georgia Newborn Screening Policy and Procedure Manual;

- (d) "Automated auditory brainstem response" or "aABR" is a specific test method that measures the brainstem's response to acoustic stimulation of the ear, using equipment that automatically provides a pass/refer outcome;
- (e) "Automated Otoacoustic Emissions Testing" or "aOAE" is a specific test method that elicits a physiologic response from the outer hair cells in the cochlea, using equipment that automatically provides a pass/refer outcome;
- (f) "Birthing center" means any facility that is licensed by the Georgia Department of Community Health as a birthing center;
- (g) "Critical Congenital Heart Disease" or CCHD refers to a group of serious heart defects that are present from birth, including coarctation of the aorta, double-outlet right ventricle, D-transposition of the great arteries, Ebstein anomaly, hypoplastic left heart syndrome, interrupted aortic arch, pulmonary atresia, single ventricle, total anomalous pulmonary venous connection, tetralogy of Fallot, tricuspid atresia, and truncus arteriosus;
- (h) "Department" means the Georgia Department of Public Health;
- (i) "Hospital" means any facility that is licensed by the Georgia Department of Community Health as a hospital;
- (j) "Newborn Screening Specimen Card" or "NBS Card" means the current version of DPH Form 3491 used to collect information and blood specimen from a newborn baby;
- (k) "Newborn Hearing Screening Test" means the completion of an objective, physiological test or battery of tests administered to determine the infant's hearing status and the need for further diagnostic testing by an audiologist or physician in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual's approved instrumentation, protocols and pass/refer criteria;
- (l) "Newborn Screening and Genetics Advisory Committee (NBSAC)" is a multi-disciplinary group of professional and consumer representatives with knowledge and expertise in newborn screening programs appointed by the Commissioner of Public Health;
- (m) "Submitter" means any person or entity submitting a Newborn Screening Specimen Card for analysis;
- (n) "Unsatisfactory Specimen" is a dried blood spot specimen that is rejected by the laboratory because the quality of the specimen does not allow accurate testing, or because critical information is missing from the NBS Card which inhibits the laboratory's ability to accurately identify the baby or interpret the test results.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

511-5-5-.03 Testing Required of Newborn Babies

(1) It is the goal of the Department that every baby born alive in Georgia shall be tested for the following conditions, unless its parents or legal guardians object in writing on the ground that such tests and treatment conflict with their religious beliefs:

- (a) critical congenital heart disease (CCHD),
- (b) hearing impairment,
- (c) argininosuccinic aciduria,
- (d) beta-ketothiolase deficiency,
- (e) biotinidase deficiency,
- (f) carnitine uptake defect,
- (g) citrullinemia,
- (h) congenital adrenal hyperplasia,
- (i) congenital hypothyroidism,
- (j) cystic fibrosis,
- (k) galactosemia,
- (l) glutaric acidemia type I,
- (m) homocystinuria,
- (n) isovaleric acidemia,
- (o) long-chain acyl-CoA dehydrogenase deficiency,
- (p) maple syrup urine disease,
- (q) medium-chain acyl Co-A dehydrogenase deficiency,
- (r) methylmalonic acidemia,
- (s) multiple carboxylase deficiency,

- (t) phenylketonuria,
- (u) propionic acidemia,
- (v) severe combined immunodeficiency (SCID),
- (w) sickle cell hemoglobinopathies,
- (x) trifunctional protein deficiency,
- (y) tyrosinemia,
- (z) very long-chain acyl-CoA dehydrogenase deficiency,
- (aa) 3-methylcrotonyl-CoA carboxylase deficiency, and
- (bb) 3-OH 3-CH₃ glutaric aciduria.

(2) Unless otherwise noted in subparagraph (1) above, testing for conditions (1)(c) through (1)(bb) shall be conducted through laboratory analysis of the baby's blood on a Newborn Screening Specimen Card as provided in DPH Rule 511-5-5-.04.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

511-5-5-.04 Newborn Screening Specimen Cards and Laboratory Analysis

(1) It shall be the responsibility of the hospital, birthing center, physician's office or other healthcare facility in which the baby is born to ensure that a NBS Card is properly completed and submitted to the Department in accordance with these Rules, and that the parents are given a copy of DPH Form 5506 ("Georgia Newborn Screening Program: What Every Parent Should Know"). If the birth occurs outside a hospital, birthing center, or other healthcare facility, then it shall be the responsibility of the attending physician or midwife to do so.

(2) A Newborn Screening Dried Bloodspot Specimen (DBS) shall be completed 24 hours after birth, as follows:

(a) All information requested on the NBS Card shall be legibly and accurately collected;

(b) Specimens of the baby's blood shall be collected and placed on the DBS in accordance with the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual, and allowed to dry for at least three hours;

(c) The NBS Card shall be sent within 24 hours to the Department's Public Health Laboratory, using a courier service that ensures next business day delivery and allows the tracking of the package. A copy of the completed NBS Card shall be maintained with the baby's clinical records;

(d) If a NBS Card does not reach the Public Health Laboratory within seven days after the blood sample was drawn, the submitter shall repeat this process and submit a new Card for that baby.

(3) If the baby is admitted into a Neonatal Intensive Care Unit (NICU) or Special Care Nursery (SCN), the baby shall have up to three specimens collected in accordance with the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual.

(4) The Department shall charge a fee of \$50.00 per baby, for screening, patient retrieval and diagnosis to meet or defray Department cost. However, no parent shall be denied screening on the basis of inability to pay.

(5) If the Department or approved laboratory determines that the specimen is unsatisfactory, then the submitter shall obtain a second specimen and submit another Card as soon as possible, but before the baby reaches three to four weeks of age. If the baby has been discharged, then the submitter shall be responsible for contacting the baby's physician, healthcare provider, or parent or legal guardian to arrange for the second specimen.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

511-5-5-.05 Critical Congenital Heart Disease Screening

(1) All hospitals and birthing centers shall be equipped to conduct a CCHD screening test on newborn babies in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual.

(2) When a live birth occurs in any hospital, birthing center or in a facility that is equipped to conduct a CCHD screening test the test shall be conducted prior to the baby's discharge in accordance with the Georgia Newborn Screening Policy and Procedure Manual. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening.

(3) If the baby is admitted into a NICU or SCN, the baby shall have a CCHD screening test prior to discharge or once the baby is weaned from supplemental oxygen. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening.

(4) The person administering the test shall ensure that the CCHD screening test is conducted in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual.

(5) The results of the test shall be included in the baby's clinical record, reported to the Department, and given to the parents or legal guardians, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

511-5-5-.06 Hearing Screening

(1) All hospitals and birthing centers shall be equipped to conduct a newborn hearing screening test in accordance with these Rules.

(2) When a live birth occurs in a hospital or birthing center or in an office or facility that is equipped to conduct a newborn hearing screening test according to these Rules, a newborn hearing screening test shall be conducted prior to the baby's discharge.

(3) A newborn hearing screening test shall be conducted in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual as follows:

(a) If the baby is in the well-baby nursery, then the test shall be conducted by aOAE and/or aABR;

(b) If the baby is in a SCN or NICU, for greater than five days, then the test shall be conducted after 32 weeks gestational age and when the baby is medically stable, and must include an aABR;

(c) If the baby does not pass the initial newborn hearing screening test, then the submitter may perform a second newborn hearing screening test prior to hospital discharge in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual;

(d) In the event that a baby is transferred to another hospital or birthing center before the newborn hearing screening test has been completed, then it is the responsibility of the second facility to assure that a newborn hearing screening test is completed.

(4) The results of the test shall be included in the baby's clinical record, reported to the Department, and given to the parents or legal guardians along with any follow-up recommendations, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

511-5-5.07 Approved Laboratories

(1) A private laboratory may seek approval from the Department to conduct newborn screening laboratory analysis by showing to the Department's satisfaction that it is licensed in Georgia, that it holds a valid Certificate of Accreditation or Certificate of Registration from CMS to perform high-complexity testing of newborns for the conditions listed in DPH Rule 511-5-5-.03(c) through (bb), and that it can perform consistent and reliable testing in accordance with the Rules of the Department.

(2) Approved laboratories performing analysis of a Georgia Newborn Screening Specimen Card shall conduct testing for all of the conditions listed in DPH Rule 511-5-5-.03(c) through (bb), and shall report the results of the testing to the appropriate newborn screening follow-up provider and submitter on the day that testing is completed.

(3) Approved laboratories shall retain the Cards according to the retention schedule in the current Georgia Newborn Screening Program Policy and Procedure Manual.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

511-5-5.08 Abnormal Test Results

(1) In the event of an abnormal test result from the NBS Card, the appropriate newborn screening follow-up provider shall notify the baby's physician or healthcare provider, and the parent or legal guardian, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

(2) In the event of an abnormal test result for CCHD, an appropriate assessment or referral shall be made immediately, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

(3) In the event of a newborn not passing the newborn hearing screening test, the person administering the newborn hearing screening test shall notify the Department of Public Health (DPH) in accordance with the Georgia Newborn Screening Policy and Procedure Manual

(4) If the parents or legal guardians cannot be reached or are non-responsive, the Department or the parents' county health department should be contacted for assistance.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

511-5-5-.09 Reporting

Every licensed or permitted hospital, laboratory and physician confirming abnormal test results or clinical symptoms for the conditions listed in DPH Rule 511-5-5-.03 must report those findings to the appropriate follow-up provider and to the Department in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Authority: O.C.G.A. 31-12-2, 31-1-3.2

511-5-5-.10 Revisions to Newborn Screening Panel

The Commissioner of Public Health may from time to time change the roster of conditions for which testing is required. In determining which conditions are to be added or deleted from the newborn screening panel, the Commissioner may seek the advice and guidance of the Newborn Screening and Genetics Advisory Committee. Criteria to be considered in adding disorders shall include, without limitation, the following:

- (a) Whether the disorder has significant morbidity and mortality when not identified and not treated before symptoms appear;
- (b) Whether early clinical identification of the disorder is unlikely;
- (c) Whether the prevalence of the disorder in the population is frequent enough to justify screening an entire population;
- (d) Whether appropriate and effective technology and trained personnel are available to perform the additional tests;
- (e) Whether resources for follow-up and counseling are available;
- (f) Whether resources and efficacious treatment are available; and
- (g) Whether the disorder is recommended for screening by any national professional organization such as, but not limited to the Secretary's Advisory Committee on Heritable Disorders of Newborns and Children, The American Academy of Pediatrics and the National March of Dimes.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.