



Kathleen E. Toomey, M.D., M.P.H., Commissioner / Brian Kemp, Governor

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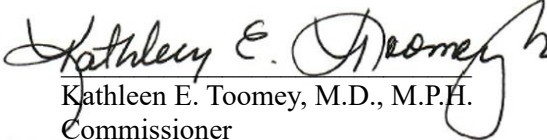
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NOTICE OF ADOPTION OF REGULATIONS
Revisions to Chapter 511-5-5
"Testing for Inherited Disorders in the Newborn"

The Department of Public Health hereby adopts amendments to Rule 511-5-5, "Testing for Inherited Disorders in the Newborn," as provided in the Notice of Proposed Rulemaking issued on July 25, 2024. This action is taken pursuant to the Department's authority under Georgia Code Sections 31-2A-6, 31-12-5 through 31-12-7.

In accordance with Georgia Code Section 31-5-1, the above-listed amendments will take effect on October 10, 2024.

This 10th day of September, 2024.


Kathleen E. Toomey, M.D., M.P.H.
Commissioner
Georgia Department of Public Health

We protect lives.



RESPONSE TO PUBLIC COMMENTS

Revisions to Chapter 511-5-5

“Testing for Inherited Disorders in the Newborn”

The Georgia Department of Public Health received written comments to the invitation for public comments included in the Notice of Proposed Rulemaking issued on July 25, 2024. Each comment received was reviewed and considered by Department staff and the Commissioner of Public Health.

The Commissioner elected to adopt the rules as proposed on July 25, 2024, and the new rules will become effective on October 10, 2024.

Although the Department is not required to respond to public comments, a brief discussion of the issues presented is provided below.

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1. One commenter proposed that the Department revise its Proposed Rules to allow a hospital or birthing center to have the option refer a newborn to the outpatient primary care physician for cytomegalovirus testing prior to twenty-one days of age. The commenter further proposes that, if the cytomegalovirus test ordered by the hospital or birthing center is pending at the time of discharge, the hospital or birthing center will notify the outpatient primary care physician, who would then be responsible for following up on the result and notifying the parents/legal guardians and the Department.
 2. One commenter requested clarification regarding process for circumstances where a parent/legal guardian refuses cytomegalovirus testing.
 3. One commenter requested clarification as to whether the cytomegalovirus test may be reported directly by a laboratory to the Department, and whether the Department could then notify the parents/legal guardians of the newborn and the outpatient primary care physician.

The comments received highlight several critical points regarding the practical implementation of these regulations, particularly within the context of inpatient care and the transition to outpatient primary care providers. Due to the time-sensitive nature of this testing, the Department emphasizes the importance of testing infants for cytomegalovirus prior to hospital discharge. Such testing must be completed within the first twenty-one days of life to ensure accurate diagnosis and timely intervention. Delaying testing until after discharge significantly increases the risk of loss to follow-up. This loss to follow-up could result in missed opportunities



for early diagnosis and treatment, which are critical to mitigating the long-term effects of congenital cytomegalovirus, including hearing loss and developmental delays.

Regarding circumstances where the guardian/legal guardian refuses testing, the Department intends to provide birthing facilities with detailed guidance on how to handle such refusals, including a standardized refusal form that can be utilized to document the guardian's decision.

Finally, with respect to reporting of results by the laboratory directly to the Department, the Department confirms that, where laboratories are utilizing the electronic lab reporting system, the cytomegalovirus test result will be reported to the Department automatically. Infants tested for cytomegalovirus prior to twenty-one days of age and who test positive will be linked to our newborn screening follow-up provider. The newborn screening follow-up provider will then notify the outpatient primary care provider and provide next steps. The outpatient provider will then assume responsibility for appropriate follow-up including routine and specialty care.

**RULES OF THE
DEPARTMENT OF PUBLIC HEALTH**

**CHAPTER 511-5
HEALTH PROMOTION**

**511-5-5
TESTING FOR INHERITED DISORDERS IN THE NEWBORN**

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Rule 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) Krabbe disease as a pilot program beginning September 21, 2021;
- (p) long-chain acyl-CoA dehydrogenase deficiency;
- (q) maple syrup urine disease;
- (r) medium-chain acyl Co-A dehydrogenase deficiency;
- (s) methylmalonic acidemia;
- (t) mucopolysaccharidosis type 1;
- (u) multiple carboxylase deficiency;
- (v) phenylketonuria;
- (w) pompe disease;
- (x) propionic acidemia;
- (y) severe combined immunodeficiency (SCID);

- (z) sickle cell hemoglobinopathies;
- (aa) spinal muscular atrophy;
- (bb) trifunctional protein deficiency;
- (cc) tyrosinemia;
- (dd) very long-chain acyl-CoA dehydrogenase deficiency;
- (ee) x-linked adrenoleukodystrophy;
- (ff) 3-methylcrotonyl-CoA carboxylase deficiency; and
- (gg) 3-OH 3-CH₃ glutaric aciduria.

(2) Unless otherwise noted in subparagraph (1) above, testing for conditions (1)(c) through (gg) 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 31-12-7.

Rule 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) If the baby does not pass the initial or final inpatient newborn hearing screening test, in cases where a second test is performed, in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual, the hospital or birthing center shall conduct cytomegalovirus testing before hospital discharge or 21 days of age, whichever occurs earlier;

(e) 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 and cytomegalovirus test, as indicated in subsection 3(d) of this Rule, is completed.

(4) The results of the hearing 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.

5) The results of the cCMV test shall be included in the baby's clinical record, and the status of the cCMV test shall be provided to the baby's physician or healthcare provider and the parent or legal guardian, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

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

Rule 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) In the event of an abnormal test for cCMV, the provider administering the cCMV test shall notify the Department. The appropriate 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.

(5) 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 31-12-7.