GEORGIA DEPARTMENT OF PUBLIC HEALTH

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

200 Piedmont Avenue, SE
Atlanta, Georgia 30334

dph.ga.gov

October 7, 2025

NOTICE OF PROPOSED RULEMAKING

Chapter 511-5-5
"Testing for Inherited Disorders in the Newborn"

The Department of Public Health proposes revisions to the rules located in Chapter 511-5-5, "Testing for Inherited Disorders in the Newborn" pursuant to its authority under Georgia Code Sections 31-2A-6, 31-12-5 through 31-12-7.

The purpose of the proposed rulemaking is to add Guanidinoacetate Methyltransferase Deficiency (GAMT) and Mucopolysaccharidosis Type II (MPS-II) to the conditions list and to update the newborn screening fee.

The proposed rules are posted on the Department's website at http://dph.georgia.gov/regulationsrule-making. Interested persons may submit comments on these proposed revisions in writing addressed to:

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Written comments must be submitted on or before October 30, 2025. Oral comments may be presented online or via phone at a public meeting scheduled for 2 p.m. on October 29, 2025. To join the public meeting:

- To join by computer:
  - https://gapublichealth.webex.com/gapublichealth/j.php?MTID=mfd864d5f3a9ba4207744fa4da610e79f
  - Meeting Number: 2535 814 1799
  - Meeting Password: Arjzf9h4pC8

- To join by phone:
  - +1-415-655-0001 US Toll
  - Access Code: 2535 814 1799

The Commissioner of Public Health will consider the proposed rules for adoption on or about November 6, 2025, to become effective on or about December 7, 2025.

Jeff Rickman

Jeffrey Rickman
General Counsel
Georgia Department of Public Health

RULES
OF
GEORGIA DEPARTMENT OF PUBLIC HEALTH

CHAPTER 511-5
HEAL TH PROMOTION

SUBJECT 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) guanidinoacetate methyltransferase deficiency (GAMT)
(~~m~~n) homocystinuria
(o~~n~~) isovaleric acidemia
(p~~o~~) Krabbe disease
(~~p~~q) long-chain acyl-CoA dehydrogenase deficiency
(r~~q~~) maple syrup urine disease
(s~~r~~) medium-chain acyl-CoA dehydrogenase deficiency
(~~s~~t) methylmalonic acidemia
(u~~t~~) mucopolysaccharidosis type 1
(v) mucopolysaccharidosis type II
(w~~u~~) multiple carboxylase deficiency
(x~~v~~) phenylketonuria
(y~~w~~) pompe disease
(z~~x~~) propionic acidemia
(aa~~y~~) severe combined immunodeficiency (SCID)
(bb~~z~~) sickle cell hemoglobinopathies
(cc~~aa~~) spinal muscular atrophy
(dd~~bb~~) trifunctional protein deficiency
(ee~~cc~~) tyrosinemia
(ff~~dd~~) very long-chain acyl-CoA dehydrogenase deficiency
(gg~~ee~~) x-linked adrenoleukodystrophy
(hh~~ff~~) 3-methylcrotonyl-CoA carboxylase deficiency
(ii~~gg~~) 3-OH 3-CH3 glutaric aciduria

(2) Unless otherwise noted in subparagraph (1) above, testing for conditions (1)(c) through (iigg) 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.

Rule 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 an 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:

1. All information requested on the NBS Card shall be legibly and accurately collected;
2. 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;
3. 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;
4. If an NBS Card does not reach the Public Health Laboratory within ten (10) 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 $88.3396.13 per baby, for screening, patient retrieval and diagnosis, in order to meet or defray the Department's actual 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.