GEORGIA DEPARTMENT OF PUBLIC HEALTH

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April 16, 2019

NOTICE OF PROPOSED RULEMAKING

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

The Department of Public Health proposes the attached amendments to Rule 511-5-5-.03, "Testing Required of Newborn Babies"; Rule 511-5-5-.04, "Newborn Screening Specimen Cards and Laboratory Analysis"; and Rule 511-5-5-.07, "Approved Laboratories," pursuant to its authority under Georgia Code Sections 31-2A-6 and 31-12-5 through -7.

The purpose of the proposed rulemaking is to add four disorders (mucopolysaccharidosis type 1, pompe disease, spinal muscular atrophy, and x-linked adrenoleukodystrophy) to the panel of disorders for which Georgia newborns are tested under the Georgia Newborn Screening Program, as directed by the Commissioner of Public Health. The Department also proposes to increase the laboratory fee for newborn screening to accommodate the additional testing.

The proposed amendments have been posted to the Department's website at https://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 May 24, 2019. Comments may also be presented in person at a public meeting scheduled for 11:00 a.m. on May 14, 2019, in Room 9-260, at 2 Peachtree Street, NW, Atlanta, Georgia 30303. The Commissioner of Public Health will consider the proposed rules for adoption on or about May 31, 2019, to become effective on July 1, 2019.

Kristin L. Miller
General Counsel
Georgia Department of Public

RULES OF THE
DEPARTMENT OF PUBLIC HEALTH

CHAPTER 511-5-5
Testing for Inherited Disorders in the Newborn

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) mucopolysaccharidosis type 1;

(ts) multiple carboxylase deficiency;

(ut) phenylketonuria;

(v) pompe disease;

(wu) propionic acidemia;

(xv) severe combined immunodeficiency (SCID);

(yw) sickle cell hemoglobinopathies;

(zx) spinal muscular atrophy;

(aa) trifunctional protein deficiency;

(bby) tyrosinemia;

(ccz) very long-chain acyl-CoA dehydrogenase deficiency;

(dd) x-linked adrenoleukodystrophy;

(eeaa) 3-methylcrotonyl-CoA carboxylase deficiency; and

(ffbb) 3-OH 3-CH3 glutaric aciduria.

(2) Unless otherwise noted in subparagraph (1) above, testing for conditions (1)(c) through (1)(ffbb) 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 $~~63~~86.00 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.

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 (ff~~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 (ff~~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.