GEORGIA DEPARTMENT OF PUBLIC HEALTH

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

2 Peachtree Street, NW, 15th Floor
Atlanta, Georgia 30303-3142

dph.ga.gov

October 20, 2021

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, "Testing for Inherited Disorders in the Newborn," pursuant to its authority under Georgia Code Sections 31-2A-6 and 31-12-6.

The purpose of the proposed rulemaking is to update the newborn baby screening requirements to require testing for Krabbe disease as a three-year pilot program.

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:

Melanie Simon
General Counsel
Georgia Department of Public Health
2 Peachtree Street, N.W., 15th Floor
Atlanta, Georgia 20202
melanie.simon@dph.ga.gov

Written comments must be submitted on or before November 5, 2021. Due to the COVID-19 pandemic, there will not be a physical in-person meeting; however, oral comments may be presented via phone at a public meeting scheduled for 10:00 a.m. on November 3, 2021. To join the public meeting:

- To join by computer:
  - https://gdph.webex.com/gdph/j.php?MTID=me99f29337b59e1dd0be5a9334e818143
  - Meeting number: 2340 887 6082
  - Password: 8QgJPjtg@25 (8745784 from phones)

- To join by phone:
  - +1-408-418-9388 United States Toll
  - Access code: 2340 887 6082
  - Password: 8745784

The Commissioner of Public Health will consider the proposed rules for adoption on or about November 8, 2021, to become effective on or about December 9, 2021.

Melanie Simon

Melanie Simon
General Counsel
Georgia Department of Public Health

RULES OF
DEPARTMENT OF PUBLIC HEALTH

CHAPTER 511-5
HEALTH PROMOTION

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

TABLE OF CONTENTS

RULES OF THE
DEPARTMENT OF PUBLIC HEALTH

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

Rule 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; 31-22-1 et seq.

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 3-year pilot program beginning September 21, 2021;

~~(o)~~ (p) long-chain acyl-CoA dehydrogenase deficiency;

~~(p)~~ (q) maple syrup urine disease;

~~(q)~~ (r) medium-chain acyl Co-A dehydrogenase deficiency;

~~(r)~~ (s) methylmalonic acidemia;

~~(s)~~ (t) mucopolysaccharidosis type 1;

~~(t)~~ (u) multiple carboxylase deficiency;

~~(u)~~ (v) phenylketonuria;

~~(v)~~ (w) pompe disease;

~~(w)~~ (x) propionic acidemia;

~~(x)~~ (y) severe combined immunodeficiency (SCID);

~~(y)~~ (z) sickle cell hemoglobinopathies;

~~(z)~~ (aa) spinal muscular atrophy;

~~(aa)~~ (bb) trifunctional protein deficiency;

~~(bb)~~ (cc) tyrosinemia;

~~(cc)~~ (dd) very long-chain acyl-CoA dehydrogenase deficiency;

~~(dd)~~ (ee) x-linked adrenoleukodystrophy;

~~(ee)~~ (ff) 3-methylcrotonyl-CoA carboxylase deficiency; and

~~(ff)~~ (gg) 3-OH 3-CH3 glutaric aciduria.

(2) Unless otherwise noted in subparagraph (1) above, testing for conditions (1)(c) through (1)~~(ff)~~ (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 -7.

Rule 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)~~ (gg), 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)~~

(gg), 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; 31-22-1 et seq.

Rule 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; 31-22-1 et seq.