



Brenda Fitzgerald, MD, Commissioner | Nathan Deal, Governor

2 Peachtree Street NW, 15th Floor
Atlanta, Georgia 30303-3142
dph.ga.gov

7 April 2016

NOTICE OF PROPOSED RULEMAKING
“Newborn Screening Specimen Cards and Laboratory Analysis”
Revision to Regulation 511-5-5-.04

The Department of Public Health proposes the attached amendment to DPH Regulation 511-5-5-.04, pursuant to its authority under O.C.G.A. Sections 31-2A-6 and 31-12-6(f).

This amendment is solely intended to increase the fee charged for newborn screening analysis, to reflect the Department’s increased costs in providing this service. No other substantive change is intended.

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

Sidney R. Barrett, Jr.
General Counsel
Georgia Department of Public Health
2 Peachtree Street, NW, 15th Floor
Atlanta GA 30303

Comment may also be presented in person at a public meeting scheduled for 1:30 p.m., 14 May 2016, in room 15-460 at 2 Peachtree Street, NW, Atlanta, Georgia 30303.



Sidney R. Barrett, Jr.
General Counsel



We Protect Lives.

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 \$63.00 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.