216-RICR-20-05-1

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 20 – COMMUNITY HEALTH

SUBCHAPTER 05 – MATERNAL AND CHILD HEALTH

PART 1 – Newborn Genetic, Metabolic, Endocrine, and Hemoglobinopathy Screening Program and Newborn Hearing Loss Screening Program

1.1 Authority

These rules and regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws §§ 23-13-13 and 23-13-14, and are established for the purpose of updating a comprehensive genetic, metabolic, endocrine, and hemoglobinopathy screening program for newborns and a newborn hearing loss screening program and for adopting a fee structure for said programs.

1.2 Definitions

A. Wherever used in this Part the following terms shall be construed as follows:

1. "Act" means R.I. Gen. Laws Chapter 23-13 entitled, "Maternal and Child Health Services for Children with Special Health Care Needs."

2. “Department” means the Rhode Island Department of Health.

3. "Director" means the Director of the Rhode Island Department of Health.

4. "Health care facilities" means facilities licensed under the provision of R.I. Gen. Laws Chapter 23-17 and the regulations promulgated thereunder. Health care facilities include, but are not limited to, hospitals, birth centers, and other health care facilities subject to licensure.

5. "Health care provider" means any person licensed by the State of Rhode Island to provide health care services, including, but not limited to, a physician, health care facility, nurse, pharmacist, and any officer, employee or agent of that provider acting in the course and scope of his or her employment or agency related to or supportive of health services.

6. "Midwife" means a person who has successfully completed an approved educational program in midwifery and is licensed to practice midwifery in Rhode Island pursuant the Rules and Regulations for Licensing of

Midwives (Part 40-05-23 of this Title) and R.I. Gen. Laws §§ 23-13-9 and 23-1-1.

7.~~6.~~ "Newborn disease" means conditions that have their origin in mutational events that alter the genetic constitution of an individual and/or disrupts normal functions through some other disease mechanism.

8.~~7.~~ "Newborn testing for hearing loss" means screening and evaluation through the Rhode Island Early Hearing Detection and Intervention Program (RI-EHDI) ~~Hearing Assessment Program (RIHAP)~~, using procedures prescribed by the Director.

9~~8~~. "Physician" means a person with a license to practice medicine in Rhode Island pursuant to the provisions of R.I. Gen. Laws §Chapter ~~Chapter~~ 5-37 entitled, "Board of Medical Licensure and Discipline."

10~~9~~. "Newborn Screening Program" means the Rhode Island Department of Health, Office of Newborn Screening and Follow-up program of screening all newborns for genetic, metabolic, endocrine, hemoglobin, hearing, and developmental conditions. ~~Rhode Island genetic, metabolic, endocrine, hemoglobinopathy, and other clinics, and the Newborn Hearing Screening Program.~~

1.3 Newborn Genetic, Metabolic, Endocrine, and Hemoglobinopathy Screening Program

A. The physician and/or midwife attending a newborn child shall cause said child to be subject to screening tests for the conditions listed below. ~~Provided, however~~Notwithstanding the foregoing, if parents of a newborn child object ~~thereto~~to the screening tests~~,~~ on the grounds that such tests conflict with their religious tenets and practices~~, pursuant to R.I. Gen. Laws § 23-13-14,~~ such tests shall not be performed, in accordance with R.I. Gen. Laws § 23-13-14.

1. Amino Acid Metabolism Disorders
    a. Argininosuccinic Acidemia
    b. Citrullinemia
    c. Homocystinuria
    d. Maple Syrup Urine Disease
    e. Phenylketonuria

f. Tyrosinemia Type I

2. Organic Acid Metabolism Disorders

   a. Beta-Ketothiolase Deficiency

   b. Glutaric Acidemia Type I

   c. Hydroxymethylglutaric aciduria, HMG-CoA lyase Deficiency, or 3-OH 3-CH3 glutaric aciduria

   d. Isovaleric Acidemia

   e. 3-Methylcrotonyl-CoA Carboxylase Deficiency

   f. Methylmalonic Acidemia cblA and cblB forms

   g. Methylmalonic Acidemia due to mutase deficiency

   h. Multiple Carboxylase Deficiency

   i. Propionic Acidemia

3. Fatty Acid Oxidation Disorders

   a. Carnitine Uptake Defect

   b. Long-chain 3-OH acyl COA Dehydrogenase Deficiency (LCHAD)

   c. Medium-chain 3-OH acyl COA Dehydrogenase Deficiency (MCHAD)

   d. Very Long-chain 3-OH acyl COA Dehydrogenase Deficiency (VLCAD)

   e. Trifunctional protein Deficiency

4. Hemoglobin Traits and Disorders

   a. Sickle Cell Anemia

   b. Hemoglobin S/Beta-Thalassemia

   c. Hemoglobin S/C Disease

   d. Others detectable through hemoglobin electrophoresis

5. Genetic Disorders

a. Spinal Muscular Atrophy (SMA)

6. Others

a. Biotinidase Deficiency

b. Congenital Adrenal Hyperplasia

c. Congenital Hypothyroidism

d. Cystic Fibrosis

e. Galactosemia

f. Severe Combined Immunodeficiency (SCID)

g. Critical Congenital Heart Disease

h. Pompe

i. Adrenoleukodystrophy (X-ALD)

j. Mucopolysaccharidosis (MPS-1)

~~B. The Department shall provide filter specimen slips to health care facilities where births are known to occur and to physicians and midwives attending newborns in locations other than health care facilities. The filter specimen slips shall contain instructions for the collection and submission of specimens to the laboratory contracted by the Department.~~

B~~C~~. The hospital or health care facility, or, in the event the birth occurred in a location other than a health care facility, the physician and/or midwife attending a newborn child shall cause a filter specimen for the newborn, on a slip supplied by the Department, to be submitted to the laboratory designated by the Department.

C. Any ~~Laboratories~~ laboratory ~~performing~~ designated by the Department to analyze newborn screening tests shall be approved by the Director to perform the tests cited in § 1.3(A) of this Part and as required in this Part.

1. All reports of newborn screening tests ~~performed by a laboratory~~ shall be communicated by the designated laboratory to the Department's designee for follow-up. All such reports shall ~~submitted to the newborn's primary care provider attending physician and the Department and shall~~ include actual value and reference ranges used for each disorder.

2. Any reports of inconclusive results shall be communicated by the Department's designee for follow-up to the newborn's primary care physician for repeat testing.

3. Any reports of positive results shall be communicated by the Department's designee for follow-up to the newborn's primary care physician and any applicable pediatric specialty diagnostic clinic for diagnosis confirmation.

4. Confirmation of diagnosis shall be communicated to the Newborn Screening Program by the confirming health care provider, e.g., specialty diagnostic clinic, within ninety (90) days of confirmation of the diagnosis. Such confirmation shall include:

~~2. Each birthing hospitalpediatric specialty diagnostic clinic or health care provider shall report the following data and information to the Department's Newborn Screening Program within ninety (90) days of the confirmed newborn screening diagnosis:~~

a. Each confirmed newborn screening diagnosis;

b. Diagnostic test type;

c. Treatment type; and

d. Any additional information the Director may require for surveillance, or for other program or grant purposes.

~~Each Newborn Screening Program or health care provider, as defined in § 1.2 of this Part, shall be responsible to report to the Department's Newborn Screening Program, or agency designated by the Director, each confirmed newborn screening diagnosis, diagnostic test type, treatment type, and such information that the Director may require from time to time for surveillance, or as a grant or Newborn Screening Program may require. Each Newborn Screening Program or health care provider shall submit such data and information on confirmed cases to the Department's Newborn Screening Program within ninety (90) days of when the newborn screening diagnosis was confirmed.~~

~~D. Program services~~ The cost of screening a newborn for genetic, metabolic, endocrine and hemoglobinopathy diseases and disorders ~~shall be subject to the fee schedule established in § 1.5 of this Part.~~

1.4 Testing for Hearing Loss

A. Pursuant to the provisions of R.I. Gen. Laws § 23-13-13, the physician and/or midwife attending a newborn child shall cause said child to be every newborn infant in Rhode Island shall be screened and evaluatedsubject to newborn testing for hearing loss, in accordance with procedures approved by the Department. the "Procedures for Evaluating Newborn Infants for Hearing Impairments,". A copy of these Procedures which are incorporated herein by reference and may be viewed at https://health.ri.gov/publications/procedures/EvaluatingNewbornInfantsForHearingImpairments.pdf. www.health.ri.gov/programs/hearingassessment/. Notwithstanding the foregoing, Provided, however, if parents of a newborn child object theretoto the newborn testing for hearing loss, on the grounds that such teststesting conflicts with their religious tenets and practices, such tests testing shall not be performed, in accordance with R.I. Gen. Laws § 23-13-13.

1.5 Fees

The fee for the Newborn Screening Programnewborn screening (per newborn) and the coordination fee for testing for hearing loss in newborns (per newborn) shall be as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health, Part 10-05-2 of this Title). This fee shall be paid to the Department by the hospital or health care facility where the birth occurred in the absence of a third-party payor. This These fees shall be adjusted annually to cover the cost of inflation using the Medicare Economic Index (MEI).

B. The coordination fee for testing for hearing loss in newborns shall be as set forth in the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (216-RICR-10-05-2) Part 10-05-2 of this Title). This fee shall be paid to the Department by the hospital or health care facility where the birth occurred in the absence of a third-party payor. This fee shall be adjusted annually to cover the cost of inflation using the Medicare Economic Index (MEI).

1.6 Designation of the Newborn Screening Program as a Covered Benefit

A. The Newborn Screening Programnewborn screenings and testing for hearing loss shall be a covered benefit reimbursable by all health insurers, as defined in R.I. Gen. Laws § 27-38.2-2(1)4), providing health insurance coverage in Rhode Island except for supplemental policies which only provide coverage for specific diseases, hospital indemnity, Medicare supplement or other supplemental

policies. ~~provided however, that the Newborn Screening Program shall not be a covered benefit under except for supplemental policies that only provide coverage for specific diseases, hospital indemnity, Medicare supplement, or other supplemental policies~~

B. ~~The Rhode Island Executive Office of Health and Human Service Department of Human Services shall pay for the Newborn Screening Programnewborn screenings and testing for hearing loss w~~When the patient is eligible for Medical Assistance under the provisions of R.I. Gen. Laws Chapter 40-8, "Medical Assistance," or R.I. Gen. Laws Chapter 42-12.3, "Health Care for Children and Pregnant Women.~~.~~" the cost of the newborn screenings and testing for hearing loss shall be paid in accordance with ~~by the State agency identified in~~ R.I. Gen. Laws § 23-13-14(b).

C. In the absence of a third-party payor, or in the absence of insurance information sufficient for billing and collection, the cost~~s~~ for the ~~Newborn Screening Program,~~newborn screenings and testing for hearing loss ~~including the coordination fee,~~ shall be paid by the hospital or other health care facility where the birth occurred, or, in the event the birth occurred in a location other than a health care facility, by the physician or midwife attending the newborn. ~~Nothing in this Part shall preclude the hospital or health care facility from billing the patient directly.~~

D. Any health care provider compensated for the newborn screenings and testing for hearing loss shall reimburse the Department for such newborn screenings and testing for hearing loss in accordance with Part 10-05-2 of this Title. ~~Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (216 RICR 10-05-2).~~

~~D. In the absence of a third-party payor, or in the absence of insurance information sufficient for billing and collection, the costs for the Newborn Screening Program, including the coordination fee, shall be paid by the health care facilities, and physicians and midwives who attend newborns in locations other than health care facilities.~~