

**RULES AND REGULATIONS PERTAINING TO
THE NEWBORN METABOLIC, ENDOCRINE, AND
HEMOGLOBINOPATHY SCREENING PROGRAM AND
THE NEWBORN HEARING LOSS SCREENING PROGRAM**

[R23-13-MET/HRG]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

February 1988

As Amended:

October 1992

October 1992 (E)

July 1993

November 1993

January 1995

September 1995

January 2002 (re-filing in
accordance with the provisions of
§42-35-4.1 of the Rhode Island
General Laws, as amended)

December 2005

January 2006 (E)

April 2006

January 2007 (re-filing in
accordance with the provisions of
§42-35-4.1 of the Rhode Island
General Laws, as amended)

January 2008

January 2012 (re-filing in
accordance with the provisions of
§42-35-4.1 of the Rhode Island
General Laws, as amended)

September 2012

August 2014

INTRODUCTION

These amended *Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and Newborn Hearing Loss Screening Program* [R23-13-MET/HRG] are promulgated pursuant to the authority conferred under RIGL §§ 23-13-13, and 23-13-14, and are established for the purpose of updating a comprehensive metabolic, endocrine, and hemoglobinopathy screening program for newborns and a newborn hearing loss screening program and for adopting a fee structure for said programs.

Pursuant to the provisions of RIGL §42-35-3(a)(3) and §42-35.1-4, consideration was given to: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact on small business. Based on the available information, no known alternative approach, duplication or overlap was identified.

Upon promulgation of these amendments, these amended Regulations shall supersede all previous *Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and Newborn Hearing Loss Screening Program* promulgated by the Department of Health and filed with the Secretary of State.

TABLE OF CONTENTS

Section	Page
1.0 Definitions	1
2.0 Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program	2
3.0 Testing for Hearing Loss	3
4.0 Fees	3
5.0 Designation of Newborn Screening Program as a Covered Benefit	4
6.0 Severability	4

Section 1.0 *Definitions*

Wherever used in these rules and regulations the following terms shall be construed as follows:

- 1.1 "**Act**" means RIGL Chapter 23-13 entitled, "*Maternal and Child Health Services for Children with Special Health Care Needs.*"
- 1.2 "**Department**" means the Rhode Island Department of Health.
- 1.3 "**Director**" means the Director of the Rhode Island Department of Health.
- 1.4 "**Health care facilities**" means facilities licensed under the provision of RIGL 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.
- 1.5 "**Midwife**" means a person who has successfully completed an approved educational program in midwifery and is licensed to practice midwifery in Rhode Island pursuant to the *Rules and Regulations for Licensing of Midwives (R23-13-MID)* and RIGL §§ 23-13-9 and 23-1-1.
- 1.6 "**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.
- 1.7 "**Newborn testing for hearing loss**" means screening and evaluation through the Rhode Island Hearing Assessment Program (RIHAP), using procedures prescribed by the Director.
- 1.8 "**Physician**" means a person with a license to practice medicine in Rhode Island pursuant to the provisions of RIGL Chapter 5-37 entitled, "*Board of Medical Licensure and Discipline.*"
- 1.9 "**Newborn Screening Program**" means the Rhode Island metabolic, endocrine, hemoglobinopathy, and other clinics, and the Newborn Hearing Screening Program.
- 1.10 "**RIGL**" means Rhode Island General Laws, as amended.
- 1.11 "**These Regulations**" mean all parts of Rhode Island *Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and Newborn Hearing Loss Screening Program [R23-13-MET/HRG]*.

Section 2.0 *Newborn Metabolic, Endocrine and Hemoglobinopathy Screening Program*

2.1 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, if parents of a newborn child object thereto, on the grounds that such tests conflict with their religious tenets and practices pursuant to §23-13-14 of the Act, such tests shall not be performed.

Amino Acid Metabolism Disorders

- 2.1.1 Argininosuccinic Acidemia
- 2.1.2 Citrullinemia
- 2.1.3 Homocystinuria
- 2.1.4 Maple Syrup Urine Disease
- 2.1.5 Phenylketonuria
- 2.1.6 Tyrosinemia Type I

Organic Acid Metabolism Disorders

- 2.1.7 Beta-Ketothiolase Deficiency
- 2.1.8 Glutaric Acidemia Type I
- 2.1.9 Hydroxymethylglutaric aciduria, HMG-CoA lyase Deficiency, or 3-OH 3-CH₃ glutaric aciduria
- 2.1.10 Isovaleric Acidemia
- 2.1.11 3-Methylcrotonyl-CoA Carboxylase Deficiency
- 2.1.12 Methylmalonic Acidemia cbIA and cbIB forms
- 2.1.13 Methylmalonic Acidemia due to mutase deficiency
- 2.1.14 Multiple carboxylase Deficiency
- 2.1.15 Propionic Acidemia

Fatty Acid Oxidation Disorders

- 2.1.16 Carnitine Uptake Defect
- 2.1.17 Long-chain 3-OH acyl COA Dehydrogenase Deficiency (LCHAD)
- 2.1.18 Medium-chain 3-OH acyl COA Dehydrogenase Deficiency (MCHAD)
- 2.1.19 Very Long-chain 3-OH acyl COA Dehydrogenase Deficiency (VLCAD)
- 2.1.20 Trifunctional protein Deficiency

Hemoglobin Traits and Disorders

- 2.1.21 Sickle Cell Anemia
- 2.1.22 Hemoglobin S/Beta-Thalassemia
- 2.1.23 Hemoglobin S/C Disease
- 2.1.24 Others detectable through hemoglobin electrophoresis

Others

- 2.1.25 Biotinidase Deficiency
- 2.1.26 Congenital Adrenal Hyperplasia

- 2.1.27 Congenital Hypothyroidism
 - 2.1.28 Cystic Fibrosis
 - 2.1.29 Galactosemia
 - 2.1.30 Severe Combined Immunodeficiency (SCID) – [Effective 1 August 2014]
 - 2.1.31 Critical Congenital Heart Disease – [Effective 1 July 2015]
- 2.2 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.
- 2.3 Laboratories performing newborn screening tests shall be approved by the Director to perform the tests cited in §2.1 and as required by these Regulations.
- 2.3.1 All reports of newborn screening tests performed by a laboratory shall be submitted to the attending physician and the Department and shall include actual value and reference ranges used for each disorder.
 - 2.3.2 Each Newborn Screening Program or health care provider, as defined in §1.4 of these Regulations, 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.
- 2.4 Program services shall be subject to the fee schedule established in §4.0 of these Regulations.

Section 3.0 *Testing for Hearing Loss*

- 3.1 Pursuant to the provisions of RIGL §23-13-13, every newborn infant in Rhode Island shall be screened and evaluated in accordance with the “*Procedures for Evaluating Newborn Infants for Hearing Impairments*”. A copy of these Procedures may be viewed at www.health.ri.gov/programs/hearingassessment/. Provided, however, if parents of a newborn child object thereto, on the grounds that such tests conflict with their religious tenets and practices, such tests shall not be performed.

Section 4.0 *Fees*

4.1 [REMOVED]

- 4.2 The fee for the Newborn Screening Program shall be as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*. 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).

4.3 [REMOVED]

4.4 The coordination fee for testing for hearing loss in newborns shall be as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*. 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).

4.5 [REMOVED]

Section 5.0 *Designation of the Newborn Screening Program as a Covered Benefit*

5.1 The Newborn Screening Program shall be a covered benefit reimbursable by all health insurers, as defined in RIGL §27-38.2-2 (1) except for supplemental policies that only provide coverage for specific diseases, hospital indemnity, Medicare supplement, or other supplemental policies.

5.2 The Rhode Island Department of Human Services shall pay for the Newborn Screening Program when the patient is eligible for Medical Assistance under the provisions of RIGL Chapter 40-8, "*Medical Assistance*," or RIGL Chapter 42-12.3, "*Health Care for Children and Pregnant Women*,".

5.3 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 hospital or other health care facility where the birth occurred. Nothing in these Regulations shall preclude the hospital or health care facility from billing the patient directly.

5.4 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.

Section 6.0 *Severability*

6.1 If any provision of these Regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or applicability to these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.