Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration proposed amendments to the Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and Newborn Hearing Loss Screening Program [R23-13-MET/HRG] pursuant to the authority conferred under §§23-13-13, and 23-13-14 and Chapter 42-35 of the Rhode Island General Laws, as amended. The purpose of the proposed amendments is to update a comprehensive metabolic, endocrine, and hemoglobinopathy screening program for newborns and a newborn hearing loss screening program.

Concurrent with the adoption of these amendments, the Director of the Rhode Island Department of Health is also proposing to amend Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health [R23-1-17-Fee] to update the baseline fee, which is adjusted annually to cover the cost of inflation using the Medicare Economic Index (MEI), to cover the cost of the Newborn Screening Program.

Notice is hereby given in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws, as amended, that the Director will hold a public hearing on the above mentioned matters, in the AUDITORIUM of the Rhode Island Department of Health (on the lower level of the Cannon Building), Three Capitol Hill, Providence, Rhode Island on MONDAY, 30 JUNE 2014 AT 1:00 PM at which time and place all persons interested therein will be heard. The seating capacity of the room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

In the development of the rules and regulations, consideration was given to the following: (1) alternative approaches; (2) overlap or duplication with other statutory and regulatory provisions and (3) financial impact on small business. No alternative approach, duplication, or overlap was identified based upon available information.

For the sake of accuracy, it is requested that statements to be made relative to any aspect of the regulations, including alternative approaches or overlap, be submitted in writing at the time of the hearing or in electronic format prior to the hearing date to: Christelle Farrow, Sr. Public Health Promotion Specialist: Christelle.Farrow@health.ri.gov or 401-222-5950.

Copies of the regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, on the Secretary of State’s website: http://www.sos.ri.gov/ProposedRules/, by calling 401-222-7767 or by e-mail to Bill.Dundulis@health.ri.gov.

The Department of Health is accessible to the handicapped. If communication assistance (readers/ interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-7767 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

Signed this 8th day of May 2014
Original signed by Michael Fine, MD
Michael Fine, M.D., Director of Health
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
June 2014 (Proposed)

COMPILER’S NOTES:
Proposed Additions: Double-Underlined
Proposed Deletions: Strikeouts
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 sections RIGL §§23-13-13, and 23-13-14 and 23-13-15 of the General Laws of Rhode Island, as amended, and are established for the purpose of establishing 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 Chapter 42-35-3(c) RIGL §42-35-3(a)(3) and §42-35.1-4, of the General Laws of Rhode Island, as amended, consideration was given to: (1) alternative approaches to the regulations; and (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 rules and Regulations shall supersede all previous Rules and Regulations Pertaining to these programs, 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.
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Section 1.0 Definitions

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


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 of the General Laws of Rhode Island, as amended, 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 sections RIGL §§23-13-9 and 23-1-1 of the Rhode Island General Laws, as amended.

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 this state Rhode Island pursuant to the provisions of RIGL Chapter 5-37 of the General Laws of Rhode Island, as amended, entitled, "Board of Medical Licensure and Discipline."

1.9 “The Newborn Screening Programs”, as used herein means the Rhode Island Newborn metabolic, endocrine, and hemoglobinopathy, and other clinics, Screening Program and the Newborn Hearing Loss 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 section §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
2.1.10Isovaleric Acidemia
2.1.113-Methylcrotonyl-CoA Carboxylase Deficiency
2.1.12Methylmalonic Acidemia cbIA and cbIB forms
2.1.13Methylmalonic Acidemia due to mutase deficiency
2.1.14Multiple carboxylase Deficiency
2.1.15Propionic Acidemia

**Fatty Acid Oxidation Disorders**

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

**Hemoglobin Traits and Disorders**

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

**Others**

2.1.25Biotinidase Deficiency
2.1.26Congenital 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 collection testing kits 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 collection testing kits shall contain instructions for the collection and submission of specimens to the laboratory contracted by the Department.

2.3 Laboratories performing newborn disease screening tests shall be approved by the Director to perform the tests cited in section §2.1 and as required by these Regulations herein.

2.3.1 All reports of newborn disease 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 section §4.0 of these Regulations herein.

Section 3.0 Testing for Hearing Loss

3.1 Pursuant to the provisions of section RIGL §23-13-13 of the Rhode Island General Laws, as amended, every newborn infant in Rhode Island shall be screened and evaluated according to the procedures prescribed by the Director these Regulations. 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 Criteria for the Determination of Fees

4.1 [REMOVED] The fee for the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program conducted by the Department shall be reasonable and shall be determined on the basis of projected costs for conducting such programs. The costs shall include administrative, personnel, equipment and such other related costs that may be
incurred in the Newborn Screening Program. The fee for the Newborn Screening Program that includes, but is not limited to, screening, diagnostic, and treatment services, shall be adjusted as needed and shall be payable to the General Treasurer, State of Rhode Island.

4.2 Effective 1 July 2006, 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] The fee for testing for hearing loss shall be reasonable and shall be determined on the basis of projected costs for conducting such a program. The costs shall include administrative, personnel, equipment and other related costs as well as the coordination fee payable to the General Treasurer, State of Rhode Island.

4.4 Effective 1 February 2008, 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] All fees generated by the Programs shall be deposited into the General Fund of the State of Rhode Island.

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

5.1 The Programs Newborn Screening Program shall be a covered benefit reimbursable by all health insurers, as defined in section RIGL §27-38.2-2 (1) of the Rhode Island General Laws, as amended, 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 Programs Newborn Screening Program when the patient is eligible for Medical Assistance under the provisions of RIGL Chapters 40-8, "Medical Assistance," or RIGL Chapter 42-12.3, "Health Care for Children and Pregnant Women," of the General Laws of Rhode Island, as amended.

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 Programs Newborn Screening Program, including the coordination fee, shall be paid by the hospital or other health care facility where the birth occurred. Nothing herein in these Regulations shall preclude the hospital or health care facility from billing the patient directly. Said fees shall be deposited into the General Fund of the State of Rhode Island.
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. Said fee shall be made payable by check or money order to the General Treasurer, State of Rhode Island.

Section 6.0 **Severability**

6.1 If any provision of these rules and 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 rules and Regulations which can be given effect, and to this end the provisions of these rules and Regulations are declared to be severable.