

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

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INTRODUCTION

These ***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 23-13-13, 23-13-14 and 23-13-15 of the General Laws of Rhode Island, as amended, and are established for the purpose of establishing a comprehensive metabolic, endocrine, and hemoglobinopathy screening program for newborns and for adopting a fee structure for said Programs.

Pursuant to the provisions of Chapter 42-35-3 (c) of the General Laws, consideration was given to: (1) alternative approach to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact on small business as defined in Chapter 42-35 of the General Laws, which may result from the proposed regulations. No alternative approach, duplication or overlap was identified. The protection of the health and safety of newborns precludes the economic impact which may be incurred by these regulations.

These rules and regulations shall supersede all previous rules and regulations pertaining to these programs, 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:

- 1.1 **"Act"** means Chapter 23-13 of the General Laws of Rhode Island, as amended, 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 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 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 pursuant to the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended, entitled, "Board of Medical Licensure and Discipline."
- 1.9 **"The Programs"**, as used herein, means the Rhode Island Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program.

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. The following sections shall take effect on 1 July 2006: 2.1.1; 2.1.2; 2.1.6; 2.1.7; 2.1.8; 2.1.9; 2.1.10; 2.1.11; 2.1.12; 2.1.13; 2.1.14; 2.1.15; 2.1.16; 2.1.17; 2.1.19; 2.1.20; and 2.1.28.

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 Sick 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
- 2.2 The Department shall provide specimen 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 specimen 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 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.
- 2.4 Program services shall be subject to the fee schedule established in section 4.0 herein.

Section 3.0 Testing for Hearing Loss

- 3.1 Pursuant to the provisions of section 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. 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 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 one hundred and ten dollars (\$110.00) per initial specimen. This fee shall be adjusted annually to cover the cost of inflation using the Medicare Expenditure Index (MEI) for New England.
- 4.3 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 The coordination fee for testing for hearing loss in newborns shall be \$18.15 per test conducted. This fee shall be paid to the Department by the hospital or health care facility where the birth occurred. This fee shall be adjusted annually, beginning 1 July 2006, to cover the cost of inflation using the Medicare Expenditure Index (MEI) for New England.
- 4.5 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 as a Covered Benefit*

- 5.1 The Programs shall be a covered benefit reimbursable by all health insurers, as defined in section 27-38-6 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 when the patient is eligible for Medical Assistance under the provisions of Chapters 40-8, "Medical Assistance," and 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, including the coordination fee, shall be paid by the hospital or other health care facility where the birth occurred. Nothing herein 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 Programs, 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 the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.