

RULES AND REGULATIONS  
PERTAINING TO THE FEE STRUCTURE FOR THE NEWBORN METABOLIC  
AND SICKLE CELL DISEASE CONTROL PROGRAM  
AND THE NEWBORN HEARING IMPAIRMENT  
SCREENING PROGRAM

(R23-13-MET/HRG)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

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in accordance with the  
provisions of section  
42-35-4.1 of the Rhode  
Island General Laws, as  
amended)**

## INTRODUCTION

These Rules and Regulations Pertaining to the Fee Structure for the Newborn Metabolic and Sickle Cell Disease Control Program and Newborn Hearing Impairment 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 clarifying the responsibilities of the Department of Health in assuring a comprehensive metabolic and sickle cell disease control program for newborns and for adopting a fee structure for the Newborn Metabolic and Sickle Cell Disease Control Program and the Newborn Hearing Impairment Screening Program.

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 pertaining to the responsibilities of the Department of Health and the fee structure for the Newborn Metabolic and Sickle Cell Disease Control Program and the Newborn Hearing Impairment Screening Program 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" refers to Chapter 23-13 of the General Laws of Rhode Island, as amended, entitled, "Maternal and Child Health/Crippled Children's Services".
- 1.2 "Director" refers to the Director of the Rhode Island Department of Health.
- 1.3 "Division of Laboratories" refers to the Division of Laboratories of the Rhode Island Department of Health.
- 1.4 "Health Care Facilities" refers to facilities licensed under the provision of Chapter 23-17 of the General Laws of Rhode Island, as amended, and the regulations thereunder. Health Care Facilities include hospitals, birth centers and other health care facilities subject to licensure.
- 1.5 "Newborn Disease" refers to such inborn errors of metabolism which have their origin in mutational events that alter the genetic constitution of an individual and/or disrupts normal functions through some other disease mechanism and such other conditions including sickle cell disease.
- 1.6 "Midwife" means a person who has successfully completed an Approved Educational Program in Midwifery and is licensed to practice midwifery in Rhode Island pursuant to the Rules and Regulations for Licensing of Midwives (R23-13-MID).
- 1.7 "Physician" means a person with a license to practice allopathic or osteopathic 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."
- 1.8 "Newborn Testing for Hearing Impairment" shall mean screening and evaluation through the Rhode Island Hearing Assessment Program (RIHAP), using the Evoked Otoacoustic Emissions (EOAE) method.

## **Section 2.0 Newborn Metabolic and Sickle Cell Disease Control 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, except, 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 and 23-13-15 of the Act.

- 2.1.1. Biotinidase Deficiency
- 2.1.2. Congenital Adrenal Hyperplasia
- 2.1.3. Congenital Hypothyroidism
- 2.1.4. Galactosemia
- 2.1.5. Homocystinuria
- 2.1.6. Maple Syrup Urine Disease
- 2.1.7. Phenylketonuria
- 2.1.8. Sickie Cell Disease

2.2 The Division of Laboratories 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 Division of Laboratories.

2.3 Newborn disease screening tests performed on a newborn elsewhere than by the Division of Laboratories must be performed by a laboratory approved by the Director and include the tests cited in section 2.1.

2.3.1 All reports of newborn disease screening tests performed on a newborn by a laboratory other than the Division of Laboratories shall be submitted to the attending physician and the Division of Laboratories.

2.4 Newborn Disease Control Program services for newborns shall be subject to the fee schedule established in accordance with the provisions of section 4.0 herein.

### **Section 3.0 Testing for Hearing Impairments**

3.1 Pursuant to the provisions of section 23-13-13 of the general laws, every newborn infant in Rhode Island shall be screened and evaluated according to the procedures prescribed by the Director, except however if parents of a newborn child object thereto, on the grounds that such tests conflict with their religious tenets and practices.

### **Section 4.0 Criteria For the Determination of Fees**

4.1 The fee for the Newborn Metabolic and Sickie Cell Disease Control Program conducted by the Division of Laboratories 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 which may be incurred in the Newborn Disease Control Program. The fee for the Newborn Disease Control Program which includes, but is not limited to, screening, diagnostic and treatment services shall be adjusted as needed.

- 4.2 Effective twenty days after the filing of these regulations, the fee for the Newborn Disease Control Program for newborns shall be fifty-nine dollars (\$59.00) per initial specimen.
- 4.3 The fee for testing for hearing impairments 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. All fees established shall be approved by the Director.
- 4.4 Effective twenty days after the filing of these regulations, the Coordination fee for testing for hearing impairments in newborns shall be \$18.15 per test conducted. This fee shall be paid to the Department of Health by the hospital or health care facility where the birth occurred.
- 4.5 All fees generated by the Newborn Metabolic and Sickle Cell Disease Control Program and the Newborn Hearing Impairment Screening Program shall be deposited into the General Fund of the state of Rhode Island.

**Section 5.0 Designation of Newborn Metabolic and Sickle Cell Disease Control Program and the Newborn Hearing Impairment Screening Program as a Covered Benefit**

- 5.1 The Newborn Metabolic and Sickle Cell Disease Control Program and Newborn Hearing Impairment Screening Program shall be a covered benefit reimbursable by all health insurers, as defined in section 27-38-6 of the General Laws, except for supplemental policies which 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 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.
- 5.5 Billing information shall be provided to the Rhode Island Department of Health by hospitals or other health care facilities or providers and shall be complete and in sufficient detail to meet requirements of third party payors.

## **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.