

CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health (RIDOH)

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-20-05-1

RULE TITLE: Newborn Genetic, Metabolic, Endocrine, and Hemoglobinopathy Screening Program and Newborn Hearing Loss Screening Program

REASON FOR RULEMAKING:

This amendment to the regulations requires screening for spinal muscular atrophy (SMA); removes superfluous language; clarifies responsibility of specimen collecting, analyzing of the specimen and reporting instructions for inconclusive and confirmed diagnosis; clarifies how services are paid for with insurance, without insurance and when an individual is eligible for medical assistance.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS: No Comments were received

CHANGES TO THE TEXT OF THE RULE:

Part 1 Adds “Genetic” after “Newborn” and before “Metabolic” in the title, which currently reads Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program.

§ 1.1 (A) Adds “genetic” after “comprehensive” and before “metabolic”.

§ 1.2 (A)(5) Adds the definition of the word “Health Care Provider”.

§ 1.2 (A)(8), formerly § 1.2 (A)(7) Revises definition to correctly reference Rhode Island’s Hearing Detection and Intervention Program.

§ 1.2 (A)(10), formerly § 1.2 (A)(9) Revises definition to correctly describe RIDOH’s Newborn Screening Program.

§ 1.3 Adds “Genetic” after “Newborn” and before “Metabolic” in the section title.

§ 1.3 (A) Revises language for clarity and correctly cites R.I. Gen. Laws § 23-13-14.

§ 1.3 (A)(5) Adds a new disorder type “Genetic Disorders.”

§ 1.3 (A)(5)(a) Adds a new disorder “Spinal Muscular Atrophy (SMA) as a condition for which newborn children must be screened.

§ 1.3 (B) Removes duplicative language; creates language to give responsibility of collecting a filter specimen for a newborn to the health care facility, hospital, or in the event the birth occurs in a location other than a health care facility to the physician and/or midwife attending the birth.

§ 1.3 (C) Revises language for clarity on laboratory responsibilities for analyzing newborn screening tests.

§ 1.3 (C)(1) Adds language to clarify who receives the newborn screening reports.

§ 1.3 (C)(2) Adds language to instruct what happens when newborn screening results are inconclusive.

§ 1.3 (C)(3) Adds language to instruct what happens when newborn screening results are positive.

§§ 1.3 (C)(4), 1.3 (C)(4)(a), 1.3 (C)(4)(b), 1.3 (C)(4)(c), and 1.3 (B)(C)(d) Adds language to give reporting instructions for when a diagnosis is confirmed and revises language for clarity on what information must be reported to RIDOH.

§ 1.3 (D) Removes duplicative language.

§ 1.4 (A) Revises language to align with Rhode Island statute and correctly references procedures for testing hearing loss in newborns.

§ 1.5 (A) Revises language to correctly site the fee for testing all newborns for genetic, metabolic, endocrine, and hemoglobinopathy diseases and disorders and hearing.

§ 1.5 (B) Removes duplicative language.

§ 1.6 (A) Revises language for clarity on newborn screening health insurance coverage and aligns to match Rhode Island statute.

§ 1.6 (B) Revises language to determine what services are paid for when a patient is eligible for medical assistance; revises payment responsibility with what is in statute; and revises to correctly reference R.I. Gen. Laws §§ 40-8 and 42-12.3.

§ 1.6 (C) Adds language on who pays for the newborn screening, whether born in a health care facility or in a location other than the health care facility, if there is an absence of a third-party payor.

§ 1.6 (D) Removes duplicative language. Adds language for RIDOH to be reimbursed for newborn screenings when healthcare providers are compensated for the screening.

REGULATORY ANALYSIS:

In the development of this rule, consideration was given to:

1) alternative approaches; 2) overlap or duplication with other statutory and regulatory provisions; and 3) significant economic impact on small business.

No alternative approach, duplication, or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.