STATE OF RHODE ISLAND RHODE ISLAND DEPARTMENT OF HEALTH CONCISE STATEMENT OF PROPOSED NON-TEHCNICAL AMENDMENTS (AMENDMENTS TO EXISTING REGULATIONS)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-1.7(b)(8), the following is

a concise statement of proposed non-technical amendments to Newborn Metabolic, Endocrine, and	
Hemoglobinopathy Screening Program and Newborn Hearing Loss Program (216-RICR-20-05-1).	

Amendment Coordinates

Rationale/Summary of Change

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),

Amendment Coordinates

Rationale/Summary of Change

• 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.

Amendment Coordinates	Rationale/Summary of Change		
§ 1.6 (D)			
• Removes duplicative language. Adds language for RIDOH to be reimbursed for newborn screenings when healthcare providers are compensated for the screening.			