

**RHODE ISLAND GOVERNMENT REGISTER
PUBLIC NOTICE OF PROPOSED RULEMAKING**

DEPARTMENT OF HEALTH

Title of Rule: Newborn Genetic, Metabolic, Endocrine, and Hemoglobinopathy Screening Program and Newborn Hearing Loss Screening Program (216-RICR-20-05-1)

Rule Identifier: 216-RICR-20-05-1

Rulemaking Action: Proposed Amendment

Important Dates:

Date of Public Notice: 05/04/2020

End of Public Comment: 06/03/2020

Authority for this Rulemaking:

R.I. Gen. Laws §§ 23-13-13 and 23-13-14

Summary of Rulemaking Action:

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.

Additional Information and Comments:

All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until June 3, 2020 by contacting the appropriate party at the address listed below:

Paula Pullano
Department of Health
3 Capitol Hill
Room 410
Providence, RI 02908
Paula.Pullano@health.ri.gov

In accordance with R.I. Gen. Laws § 42-35-2.8, an oral hearing will be granted if requested by twenty-five (25) persons, by an agency or by an association having at least twenty-five (25) members. A request for an oral hearing must be made within thirty (30) days of this notice.

Regulatory Analysis Summary and Supporting Documentation:

RIDOH is proposing the requirement of screening all newborns for Spinal Muscular Atrophy (SMA).

SMA occurs 1 in every 11,000 newborns. Unscreened children with the most common type of SMA would die by two (2) years of age. With early detection, interventions can be implemented sooner to prolong the life of the child.

In 2019, there were approximately 10,671 births in Rhode Island. Therefore, RIDOH would expect one child with SMA to be born on average every year.

Based on these frequencies, over the next 10 years we would expect to have approximately ten (10) children born with SMA. As noted above, this condition can be fatal if not screened at birth.

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 this rule justify its costs.

For full regulatory analysis or supporting documentation see agency contact person above.