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Exempt Action Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-71
Regulation title(s)	Regulations Governing Virginia Newborn Screening Services
Action title	Amend regulations to add Pompe disease and mucopolysaccharidosis type I (MPS I) to the Virginia Newborn Screening System's core panel of heritable disorders and genetic diseases
Final agency action date	8/1/18
Date this document prepared	7/4/18

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA) or an agency's basic statute, the agency is not required, however, is encouraged to provide information to the public on the Regulatory Town Hall using this form. Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Legislation enacted during the 2018 legislative session required the Virginia Department of Health to amend regulations governing newborn screening to include certain diseases: HB1174 and SB449 were approved by the Governor on March 30, 2018.

The legislation requires that the regulations governing newborn screening be amended regulations to include Pompe disease and mucopolysaccharidosis type I (MPS I). This regulatory action seeks to conform the regulations to changes in Virginia statutory law.

The amendment to add Pompe disease and mucopolysaccharidosis type I (MPS I) to the Virginia Newborn Screening System’s core panel of heritable disorders and genetic diseases is consistent with the Health Resources and Services Administration’s Advisory Committee on Heritable Disorders in Newborns and Children Recommended Uniform Screening Panel (RUSP). Pompe disease and MPS I were recommended to be added to the RUSP in 2015 and 2016, respectively.

Statement of final agency action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The State Health Commissioner approved these amendments to the Regulations Governing Virginia Newborn Screening Services, on behalf of the State Board of Health while the Board was not in session, on August 1, 2018.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The amended regulations will not strengthen or erode the rights of parents in the education, nurturing or supervision of their children. Parents have the right to refuse newborn screening for religious reasons. Parents also have the right to seek additional newborn screening testing outside of the state program if desired.

The amended regulations will not encourage or discourage economic self-sufficiency, self-pride or the assumption of responsibility for oneself, one’s spouse, one’s children and/or elderly parents.

The amended regulations will not strengthen or erode marital commitment.

The amended regulations will not increase or decrease disposable family income.