Rules Hearing– Chapter 246 – 650 WAC

Newborn Screening for Pompe and MPS 1
August 14, 2019

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Mucopolysaccharidosis I (MPS I)

- Progressive, multi-system disorder characterized by skeletal disease and cognitive decline that results in heart and lung failure.
- Autosomal recessive, affects males and females equally.
- Spectrum disorder from severe infantile onset to less-severe childhood onset.
- Clinical Prevalence
  - 1: 50,000 severe form
  - 1: 123,000 less-severe

Pompe Disease

- Progressive, neuromuscular disorder characterized by muscle weakness, cardiac & respiratory failure
- Autosomal recessive, affects males and females equally
- Spectrum disorder from severe infantile onset to slowly progressing adult onset
- Prevalence
  - 1:88,000 infantile form
  - 1:39,000 later-onset form

Rulemaking Progress

Filed CR-101
(October 2017)

Request to the Legislature for the authority to increase the newborn screening fee
(January-June 2018)

Rulemaking delayed
(June 2018-March 2019)

Stakeholder comments on preliminary draft
(May 2019)

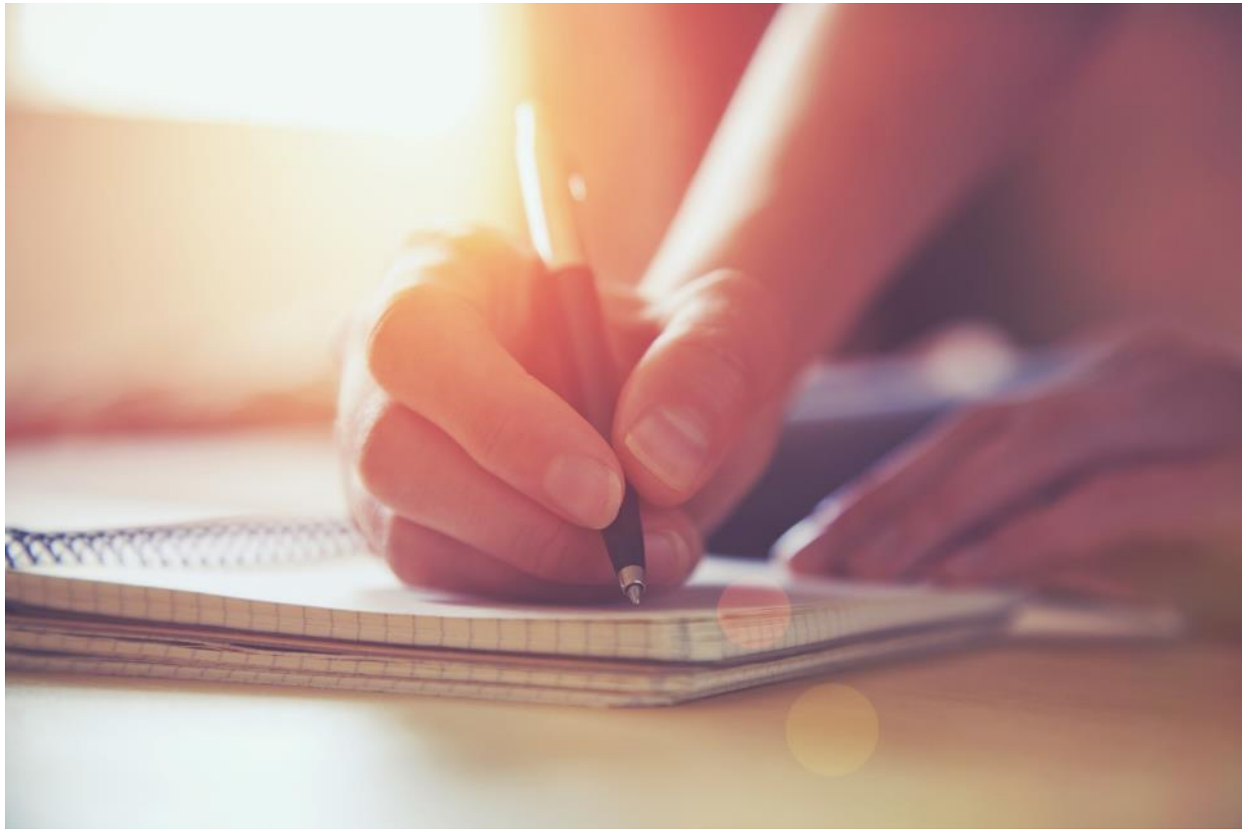
Filed CR-102
(July 2019)

Proposed Changes: WAC 246-650-010 - Definitions

Adding definitions for:

- Critical congenital heart disease
- Mucopolysaccharidosis I (MPS-I)
- Pompe disease

Revising existing definitions for clarity and consistency



Proposed Changes: WAC 246-650-020 – Performance of Screening Tests

Refining rule language for consistency throughout the rule (i.e. use of “parents” vs. “responsible parties” vs. “guardians”, etc.)

Alphabetized the list of screening tests that are required to be performed

Proposed Changes: WAC 246-650-035 – Screening for critical congenital heart disease

Creating a new section to integrate requirements for critical congenital heart disease screening according to RCW 70.83.090

- Substitute House Bill 1285 - 2015

Proposed Changes: WAC 246-650-040 – Reports to the board and the public

Editorial changes

Removing language about reporting requirements that will expire January 1, 2020

The Department will voluntarily maintaining the majority of reporting requirements

Proposed Changes: WAC 246-650-050 and WAC 246-650-990

Editorial changes only

Proposed Changes: WAC 246-650-991 – Screening Charge

Aligning the rule language more closely with RCW 70.83.023 (Specialty clinics—Defined disorders—Fee for infant screening and sickle cell disease)

Summary of Written Comments

Comment in Opposition	Staff Recommendation
Anyone should be able to opt out of any state medical procedure or test. We should be able to achieve any proper public health objective through voluntary persuasion and peaceful means. If we use force (all law is ultimately backed up by the threat of police force) then we will tend to drive the extreme fringe further in to the shadows of extremism and make problems such as the anti-vax movement worse. We should want to live in a peaceful society, and not one that to quickly resorts to force in health situations. We each own our own bodies. People should have their bodily integrity respected.	**Recommendation: Adopt as proposed.** • Chapter 70.83 RCW directs the State Board of Health to adopt rules necessary for newborn screening. • The Department of Health partners with birth facilities and midwives to provide a strong newborn screening system to prevent death and disability for babies. • State law around newborn screening allows for parents or guardians to opt out of newborn screening if it conflicts with their religious beliefs.

Next Steps

Rules Hearing
(August 2019)

File CR-103
(September 2019)

Rule goes into effect
(October 2019)

Screening begins
(October 2019)

Questions?

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Thank you

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