



Briefing – Chapter 246 – 650 WAC

Newborn Screening for Pompe and MPS 1

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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)

Internal review of
CR-102 rule package
(May-June 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



Existing Rule Language: WAC 246-650-040 Reports to the board and the public

(2) The department shall compile an annual report for the public that includes:

(a) The compliance rate of each hospital in meeting the deadlines established under RCW 70.83.020 for newborn screenings;

(b) The performance rate of each individual hospital;

(c) The time taken by health care providers to notify parents and guardians after being notified by the department about infant screening tests that indicate a suspicion of abnormality that requires further diagnostic evaluation. Notification times will be summarized and reported in increments of days.

(3) The reports must be made available in a format that does not disclose the identifying information related to any infant, parent or guardian, or health care provider.

(4) The report must be posted in an accessible location on the department of health's web site.

(5) Subsections (2) through (4) of this section expire January 1, 2020.

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

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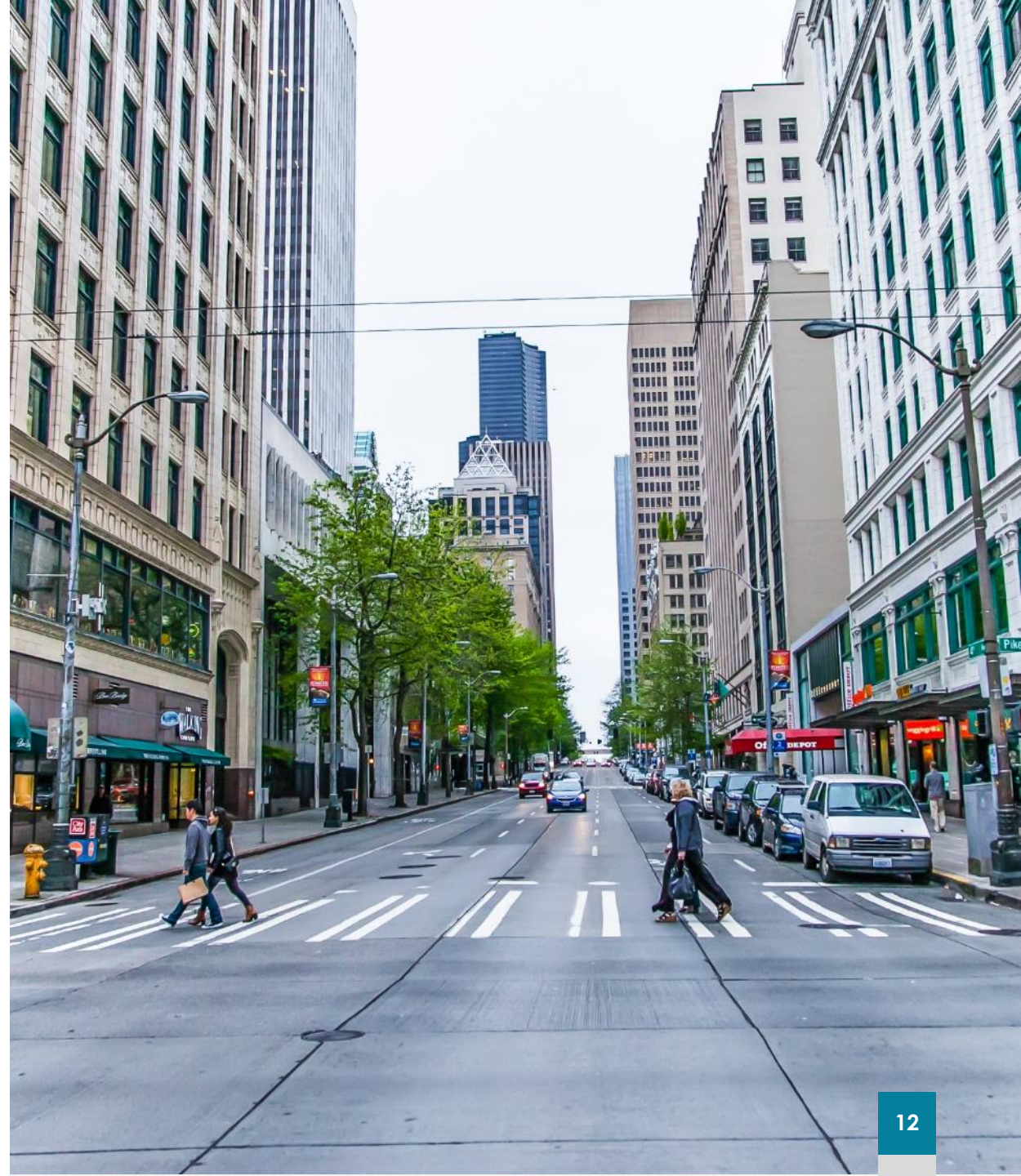
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Proposed Changes: WAC 246-650-050 and WAC 246-650-990

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)

Next Steps



File CR-102
(July 2019)

Rules Hearing
(August 2019)

File CR-103
(September 2019)

Rule goes into effect
(November 2019)

Screening begins
(November 2019)

Questions?

| Thank you