

# **Washington State Board of Health**

## **PROCESS TO EVALUATE CONDITIONS FOR INCLUSION IN THE REQUIRED NEWBORN SCREENING PANEL**

The Washington State Board of Health (Board) has the duty under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for heritable conditions. Chapter 246-650-020 WAC lists conditions for which all newborns must be screened. Members of the public, staff at Department of Health (Department), and/or Board members can request that the Board review a particular condition for possible inclusion in the newborn screening (NBS) panel. ~~In order to~~ determine which conditions to include in the ~~newborn screening~~NBS panel, the Board convenes an newborn screening technical advisory committee (TAC) to evaluate candidate conditions using guiding principles and an established set of criteria.

~~The following is document is a description of~~describes the Qualifying Assumption, Guiding Principles, and Criteria ~~which~~ the Board has approved ~~in order to~~ evaluate conditions for possible inclusion in the newborn screening panel. The ~~Washington State Board of Health~~Board and Department ~~of Health~~ apply the qualifying assumption. The Board appointed Newborn Screening Advisory Committee TAC applies the following three guiding principles and evaluates the five criteria ~~in order to~~ make recommendations to the Board on which condition(s) to include in the state's required NBS panel.

## QUALIFYING ASSUMPTION

Before ~~an the Board convenes a TAC~~advisory committee is convened to review a candidate condition against the ~~Board's~~ five newborn screening ~~requirements~~criteria, ~~a staff should complete a~~ preliminary review ~~should be done to~~ determine whether ~~there is sufficient scientific evidence~~sufficient scientific evidence is available to apply the criteria for inclusion. ~~If the candidate condition is on the Health Resources and Services Administration (HRSA) Recommended Uniform Screening Panel (RUSP), the Board and Department will~~ assume consider if ~~meets the qualifying assumption met~~ and convene a TAC.

*A note on the RUSP: The RUSP is a list of -conditions that the Secretary of the Department of Health and Human Services (HHS) recommends states screen for as part of their newborn screening programs. Once a new condition has been recommended by the HHS Secretary, the Board and Department will review it for possible inclusion in the Washington NBS panel within two years of the recommendation.*

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## THREE GUIDING PRINCIPLES

**Three guiding principles govern all aspects of the evaluation of a candidate condition for possible inclusion in the NBS panel.**

- Decision to add a screening test should be driven by evidence. For example, test reliability and available treatment have been scientifically evaluated, and those treatments can improve health outcomes for affected children.
- All children who screen positive should have reasonable access to diagnostic and treatment services.
- Benefits of screening for the disease/condition should outweigh harm to families, children and society.

## CRITERIA

**1. Available Screening Technology:** Sensitive, specific and timely tests are available that can be adapted to mass screening.

**2. Diagnostic Testing and Treatment Available:** Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.

**3. Prevention Potential and Medical Rationale:** The newborn identification of the condition allows early diagnosis and intervention.

Important considerations:

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The benefits of detecting and treating early onset forms of the condition (within one year of life) balance the impact of detecting late onset forms of the condition.
- Newborn screening is not appropriate for conditions that only present in adulthood.

**4. Public Health Rationale:** Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.

**5. Cost-benefit/Cost-effectiveness:** The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in economic analyses include:

- The prevalence of the condition among newborns.
- The positive and negative predictive values of the screening and diagnostic tests.
- Variability of clinical presentation by those who have the condition.
- The impact of ambiguous results. For example the emotional and economic impact on the family and medical system.
- Adverse effects or unintended consequences of screening.