

Significant Analysis
for Rule Concerning Newborn Screening
WAC 246-650

Briefly describe the proposed rule.

Amend Chapter 246-650 Washington Administrative Code (WAC) to add sixteen conditions to the required newborn screening panel.

Is a Significant Analysis required for this rule?

Yes. Adding these conditions to the screening panel in Section -020 significantly amends policy.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

RCW 70.83.010. Declaration of policy and purpose.

It is hereby declared to be the policy of the state of Washington to make every effort to detect as early as feasible and to prevent where possible phenylketonuria and other preventable heritable disorders leading to developmental disabilities or physical defects.

RCW 70.83.020. Screening tests of newborn infants.

It shall be the duty of the department of health to require screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders leading to mental retardation or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

These are severe, debilitating, life threatening disorders that frequently cause permanent disability or death before they are detected. However, with early detection through newborn screening most or all of these consequences can be prevented through early treatment. The Board of Health and Department of Health have held meetings with medical experts knowledgeable about these disorders and have convened a Newborn Screening Advisory Committee comprised of a broad range of interested parties: payers, professional organizations, parents, and medical specialists. These groups have concluded, and the Board of Health has concurred, that the evidence supports adding the conditions to the screening panel.

Adopting these amendments will allow screening to be conducted on the same small sample of dried blood that is currently collected from each newborn and submitted to the

DOH for screening to detect the other ten disorders that are in the current rule. Absent rule making, universal screening will not occur and children born with these disorders will suffer unnecessary harm such as developmental disabilities or physical defects because they will not receive the benefits available through early detection and treatment. State law RCW 70.83.020 gives the State Board of Health authority to require screening tests of all newborn infants. It is necessary to adopt the sixteen new disorders in the regulation so that the requirement of screening is enforceable.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

DOH has prepared a cost-benefit analysis for the addition of each of these conditions (see attached). The probable benefits of early detection of these disorders through newborn screening are found to be significantly greater than the probably costs.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

The proposed rule does not place additional requirements outside of the DOH (which is required to add testing for the 16 disorders to the screening panel). Screening will be conducted from the same small blood specimen that is already required to be sent to DOH for screening to detect the disorders on the current panel (no additional blood will be required).

Alternatives are: 1) continue the current status of detecting children with these disorders after symptoms appear and permanent damage or death has occurred. This places significant burden on the children and their families. 2) encourage birthing providers to seek screening on their own. This would add significantly to the costs; decrease the reliability of the testing; decrease the likelihood that affected infants would be linked to appropriate clinical care in time to realize the benefits of early detection; and thus increase the number of infants with these disorders who would suffer permanent harm or death because they would not receive the benefits available through early detection and treatment.

As described above, the possible alternatives do not achieve the state's objective to "...detect as early as feasible and to prevent where possible phenylketonuria and other preventable heritable disorders leading to developmental disabilities or physical defects."

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.