WASHINGTON STATE DEPARTMENT OF HEALTH

Small Business Economic Impact Statement

WAC 246-650-010 & 246-650-020

A Rule Concerning Newborn Screening – Adding Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase (GAMT) Deficiency, and Arginase 1 Deficiency (ARG1-D) to the list of screening tests performed by the Department of Health

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Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

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For more information or additional copies of this report:

Washington State Board of Health

Molly Dinardo

PO Box 47990

Olympia, WA 98504-7990

(360) 236-4110

molly.dinardo@sboh.wa.gov

SECTION 1

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The Washington State Board of Health (board) in collaboration with the Department of Health (department) is proposing amendments to the newborn screening requirements in WAC 246-650-010 and WAC 246-650-020. The proposed rule expands the Washington State newborn screening (NBS) panel of required tests by adding three new conditions: Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase (GAMT) Deficiency, and Arginase 1 Deficiency (ARG1-D). To implement screening for these conditions, the board must amend WAC 246-650-010 and WAC 246-650-020. Early detection of OTCD, GAMT deficiency, and ARG1-D is critical for saving lives and improving long-term health outcomes for affected infants and their families.

The NBS program, operated by the Washington State Department of Health (department) , tests all babies for rare but treatable health conditions using a dried blood sample. Washington State law (RCW 70.83.050) requires that the board create rules for newborn screening. These rules are found in chapter 246-650 WAC. Specifically, WAC 246-650-010 and WAC 246-650-020 define and list the conditions that the department must screen all babies for after birth.

Anyone may petition the board to review a condition for possible inclusion in the NBS panel, including members of the public, department staff, and board members. To evaluate candidate conditions, the board convenes a Technical Advisory Committee (TAC), which reviews evidence against guiding principles and established criteria. The TAC provides findings and recommendations for board consideration.

In 2021, the board formed a Technical Advisory Committee (TAC) to review OTCD following a petition from a family whose child had passed away from the condition. In 2023, the board formed another TAC to review GAMT Deficiency and ARG1-D after two parent advocates submitted petitions. After reviewing evidence, hearing from families, and consulting experts, both TACs recommended adding the conditions to the screening panel. The board considered these recommendations at its meetings in October 2021 and October 2023 and voted to proceed with rulemaking to amend chapter 246-650 WAC.

Through this rulemaking, the board proposes amendments to chapter 246-650 WAC to support the addition of three new conditions to Washington's newborn screening panel: OTCD, GAMT deficiency, and ARG1-D. These amendments include adding formal

definitions for each of the three conditions and incorporating them into the list of newborn screening tests performed by the Department of Health.

In addition, the Board is proposing minor housekeeping changes. These include updating the definition of amino acid disorders and reclassifying relevant conditions under a new definition, "urea cycle disorders" as OTCD, ARG1-D and citrullinemia type I (CIT) are specific types or urea cycle disorders. The rulemaking also removes outdated language related to prior screening requirements that sunset in 2020 and are no longer applicable.

Adding OTCD, GAMT deficiency, and ARG1-D to the newborn screening (NBS) panel requires an increase in the NBS fee. This fee is not adopted in rule, and falls under the department's fee authority established in RCW 43.70.250(2), which requires legislative approval to increase spending authority for department programs, permit fees, etc.

The department charges a one-time screening fee that covers all required newborn screens in Washington State, including repeat or follow-up screens when medically necessary. This fee, collected for each tested infant in Washington, covers the costs of laboratory screening, follow-up services, and coordination with specialty care.

The department bills the screening fee to the facility that collects the infant's initial specimen. This is typically the birth hospital but may also include a clinic, birth center, or laboratory. Facilities can usually recover the cost through insurance reimbursement or patient billing. Medical facilities may charge their own administrative fees for collecting or processing specimens, which are separate from the department's screening fee.

For specimens collected in an at home setting, the department bills the client's insurance directly when the specimen is accompanied by the insurance information. If the patient is uninsured, they must pay the screening fee out of pocket via check or money order.

To implement screening for these additional conditions, the department secured increased spending authority from the Legislature during the 2025 legislative session. Beginning January 1, 2026, the screening fee will increase by $4.02 to cover the cost of testing for OTCD, GAMT deficiency, and ARG1-D. This increase is expected to be covered by public or private insurance, or by families directly.

The proposed rule does not impose any new compliance requirements on small businesses. It applies only to the Department of Health's administration of the NBS Program and updates the list of conditions for which newborns are screened.

Healthcare providers, birthing centers, midwives, and hospitals already participate in the program, and have for decades, by collecting blood samples and sending them to the state laboratory—practices that will remain unchanged. The same blood sample is used to test for these new conditions. There are no new reporting, procedural, or equipment requirements for these entities. Because the proposed rule does not alter existing

procedures for facilities, no additional professional services are anticipated to be needed by small businesses to comply.

SECTION 2

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
524114	Direct Health and Medical Insurance Carriers[1]	61	$111,059.38
621399	Offices of All Other Miscellaneous Health Practitioners[2]	5,023	$927.25

[1] This U.S. industry comprises establishments primarily engaged in initially underwriting (i.e., assuming the risk and assigning premiums) health and medical insurance policies. Group hospitalization plans and HMO establishments that provide health and medical insurance policies without providing health care services are included in this industry.

[2] This U.S. industry comprises establishments of independent health practitioners. We are using this code to account for midwives with their own practices, that collect the newborn screening blood spot sample, and send to the PHL.

SECTION 3

Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

The following SBEIS Table 2 identifies rule sections or portions of rule sections that have been determined exempt based on the exemptions.

SBEIS Table 2. Exempted Sections

WAC Section and Title	Description of Proposed Changes	Rationale for Exemption Determination
WAC 246-650-010 – Definitions	Adding definitions for OTCD, GAMT deficiency, and ARG1-D; amending the definition of amino acid disorders; and adding a definition for urea cycle disorders.	Exempt from SBEIS under RCW 34.05.310 (4)(d) because the proposed changes clarify the meaning of terms used in the rules by adding new definitions for OTCD, GAMT, and ARG1-D. Defining these conditions is not setting screening standards. Tests for screening (required newborn screening tests) are listed under WAC 246-650-020.

WAC 246-650-010 Definitions.

Description: Defines terms that apply throughout the rule chapter. The proposed rule adds definitions for OTCD, GAMT, and ARG1-D. These proposed changes are exempt from the SBEIS under RCW 34.05.310(4)(d) because they clarify the meaning of terms used in the rules. Defining these conditions is not setting screening standards. Tests for screening (required newborn screening tests) are listed under WAC 246-650-020. The impacts of adding the new conditions are analyzed below.

WAC 246-650-020 Performance of Screening Tests.

Description: This section of the rule establishes the list of heritable conditions that all babies in Washington must be screened for within 48 hours after birth. It also sets the responsibilities of hospitals and birth care providers in conducting newborn screening, including parental notification, specimen collection, and timely submission. In addition, the rule details the department's newborn screening program duties upon receipt of specimens, including the specific heritable conditions to be tested.

The board is proposing to amend WAC 246-650-020(2)(b) to add three new candidate conditions, OTCD, GAMT, and ARG1-D to the list of conditions on the Washington State mandatory newborn screening panel.

Additionally, the board is proposing to repeal subsection (3) as the requirement for the attending health care provider to notify the department of the date on which the test results were disclosed to the parent or guardian expired January 1, 2020.

Cost(s): Total cost of the rule: $4.02 fee increase per baby * 83,000 estimated births annually in Washington = **$333,660.** These costs will be covered by either private insurance, Medicaid, or patients will pay out of pocket.

Summary of all Cost(s):

Approximately 50% of births in Washington are covered by Medicaid; the remaining 50% are assumed to be covered by private insurance. Based on this, the cost impact is estimated as follows:

- Medicaid: $166,830
- Private Insurance: $166,830

To estimate potential cost impacts for providers serving uninsured populations (i.e., not covered by Medicaid or private insurance), we assume an 8% uninsured rate, based on 2024 U.S. Census[3] and CDC data.[4] Accordingly, the estimated cost impact on health providers collecting newborn screening specimens for uninsured patients is: $333,660 * 0.08 = $26,692

SBEIS Table 3. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-650-020 – Performance of Screening Tests, Addition of OTCD	The cost of screening would be approximately $594,241.00 per year, or $8.03 per baby. Total expenses, including the costs of screening, courier service, and false positive diagnostic testing, would be $633,179.55.
WAC 246-650-020 – Performance of Screening Tests, Addition of GAMT Deficiency	The cost of screening would be approximately $82,008.19 per year, or $0.99 per baby. Total expenses, including the costs

[3] U.S. Census Bureau Health Insurance Coverage by State: 2023 and 2024. Health Insurance Coverage by State: 2023 and 2024

[4] Centers for Disease Control and Prevention (CDC). National Center for Health Statistics. FastStats Health Insurance Coverage. FastStats - Health Insurance Coverage

	of screening and those associated with false positives, would be $84,186.94 per year.
WAC 246-650-020 – Performance of Screening Tests, Addition of ARG1-D	The cost of screening would be approximately $82,008.19 per year, or $0.99 per baby. This includes startup lab costs, laboratory staffing, and supplies. Total expenses, including the costs of screening and those associated with false positives, would be $87,263.32 per year.

SECTION 4

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

No, the costs of the proposed rule (annual average per establishment of $2,735) are less than the minor cost threshold ($111,059.38) for direct health and medical insurance carriers.

No, the costs of the proposed rule (annual average per establishment up to $126.50) are less than the minor cost threshold ($927.25) for Offices of All other Miscellaneous Health Practitioners.

Summary of how the costs were calculated

Health insurance carriers

The total cost of the rule is $4.02 per baby * 83,000 estimated births in Washington State (annual) = $333,660

The following assumptions and calculations were used to estimate the potential average annual costs per businesses in this sector to comply with the proposed rule:

- Medicaid covers about fifty percent of the births in Washington state. The other half are assumed to be covered by private insurance.[5] Total annual costs ($333,660) / 2 (half of births) = $166,830 annually.
- Average cost of establishment was calculated for each of the estimated 61 businesses, $166,830 / 61 businesses = $2,735

Offices of miscellaneous health providers – including midwives and other health practitioners offices

This U.S. industry comprises establishments of independent health practitioners. The department and board selected this NAICS code to account for midwives with their own practices, that collect the newborn screening blood spot sample, and send to the public health lab. This NAICS code includes not only midwives' offices but also other health practitioner offices that do not collect newborn blood spot specimens (e.g., dental hygienists' offices and herbalists' offices). According to the Midwives Association of

[5] Uninsured births were not assumed in the calculated estimate, which likely leads to an overestimate.

Washington State approximately 211 licensed midwives are practicing in Washington State.[6]

The total cost of the rule: $4.02 fee increase per baby * 83,000 estimated births = $333,660.

The following assumptions and calculations were used to estimate the potential average annual costs per business in this sector to comply with the proposed rule:

- Medicaid covers about fifty percent of the births in Washington state. The other half are assumed to be covered by private insurance. Total annual costs ($333,660) / 2 (half of births) = $166,830 annually.
- Assume that 8% of births annually are uninsured.[7] Total costs $333,660 * (0.08) = $26,692
- Average cost of establishment was calculated for each of the estimated 5,023 businesses and the estimated 211 licensed midwife businesses operating in Washington State.
    - $26,692 / 5,023 businesses = $5.32
    - $26,692 / 211 businesses = $126.50

[6] Midwives Association of Washington State. 2025 Licensed Midwifery in Washington State FAQ. 2025 LM Licensed Midwifery in Washington State Fact Sheet

[7] U.S. Census Bureau Health Insurance Coverage by State: 2023 and 2024. Health Insurance Coverage by State: 2023 and 2024 & Centers for Disease Control and Prevention (CDC). National Center for Health Statistics. FastStats Health Insurance Coverage. FastStats - Health Insurance Coverage

SECTION 5

(ONLY ANSWER IF SECTION 4 IS YES. IF SECTION 4 IS NO, THE SBEIS IS CONSIDERED COMPLETE)

Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

SECTION 6

(ONLY ANSWER IF SECTION 5 IS YES. IF SECTION 5 IS NO, THE SBEIS IS CONSIDERED COMPLETE)

If the proposed rule has a disproportionate impact on small businesses, the following steps have been identified and taken to reduce the costs of the rule on small businesses.

1. **Reducing, modifying, or eliminating substantive regulatory requirements;**
2. **Simplifying, reducing, or eliminating recordkeeping and reporting requirements;**
3. **Reducing the frequency of inspections;**
4. **Delaying compliance timetables;**
5. **Reducing or modifying fine schedules for noncompliance; or**
6. **Any other mitigation techniques including those suggested by small businesses or small business advocates.**

If costs cannot be reduced an explanation has been provided below about why the costs cannot be reduced.

SECTION 7

(ONLY ANSWER IF SECTION 5 IS YES. IF SECTION 5 IS NO, THE SBEIS IS CONSIDERED COMPLETE)

Description of how small businesses were involved in the development of the proposed rule.

SECTION 8

(ONLY ANSWER IF SECTION 5 IS YES. IF SECTION 5 IS NO, THE SBEIS IS CONSIDERED COMPLETE)

The estimated number of jobs that will be created or lost in result of the compliance with the pro–posed rule.