



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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May 23, 2024

To Whom It May Concern,

The Department of Health (department) has adopted amendments to WAC 246-338-010 and 246-338-020 to align with federal rules related to qualifications of laboratory directors and testing personnel for medical test sites (MTS) performing provider performed microscopic procedures (PPMP). The amended rule aligns with federal law by requiring that both the laboratory director and testing personnel of laboratories performing microscopic procedures be restricted to the following licensed professionals:

- (1) Physician licensed under chapter 18.71 RCW, Physicians; chapter 18.57 RCW, Osteopathy—Osteopathic medicine and surgery; or chapter 18.22 RCW, Podiatric medicine and surgery;
- (2) Advanced registered nurse practitioner, licensed under chapter 18.79 RCW, Nursing care;
- (3) Physician assistant licensed under chapter 18.71A RCW, Physician assistants; or
- (4) Dentist licensed under chapter 18.32 RCW, Dentistry.

Previously, WAC 246-338-020 allowed naturopaths licensed under chapter 18.36A RCW, Naturopathy, and midwives, licensed under chapter 18.50 RCW, Midwifery, to be laboratory directors and testing personnel under the PPMP MTS facility license. Naturopaths and midwives do not meet the definition of physician, advanced registered nurse practitioner, physician assistant or dentist, therefore, naturopaths and midwives no longer qualify as a laboratory director or testing personnel under a PPMP MTS facility license.

A technical citation adjustment to a definition in WAC 246-338-010 is also included in the amendments.

The adopted amendments will become effective on June 13, 2024. A copy of the adopted rules is attached. The adopted rule language is identical to the text of the proposed rule as it was published in the Washington State Register 24-05-019.

The following table is a summary of all comments received and the department's response:

WAC Section	Comment Received	Department of Health Response
246-338-020 Licensure – Types of medical test site licenses.	The department received one written comment supporting the proposed rule change and alignment with federal rules. One verbal and two written comments	The department must proceed with rulemaking in order to align with federal rules. If WAC 246-338-020 is not in compliance with the federal rules, it could jeopardize

	<p>in opposition to the proposed rule were received. Some professionals in the naturopath physician community oppose the rule because they have been able to serve as laboratory directors and testing personnel of the PPMP MTS license for over 30 years in Washington, and the reversal implies a limitation to their scope of practice. They believe that removal of naturopathic physicians and midwives from the rule will be a detriment to the health and wellness of Washington residents, especially in rural and underserved areas of the state. They state that the proposed rule could also delay care because naturopathic physicians and midwives will no longer be able to quickly perform microscopic procedures in their office to assist patient treatment decisions, which also could incur additional costs to the patient by need of referral of certain tests to a referral laboratory.</p>	<p>the state’s ability to maintain exemption from Clinical Laboratory Improvement Amendments (CLIA). Information and alternative licensure options were provided to both the naturopath and midwife groups in various meetings and GovDelivery notifications. Guidance on how to contact CLIA with their concerns about the federal rule was also provided to both groups.</p>
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All current license holders who do not meet the amended requirements will not be able to renew their license on June 30, 2025. Alternate MTS license options are available for those that meet the licensure requirements described in WAC 246-338-020.

Any person may petition the adoption or amendment of these rules in accordance with RCW 34.05.330.

For more information regarding these rules, you may contact me by email at jessica.holloway@doh.wa.gov or by phone at 360-236-2927.

Cordially,



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