WSR 24-05-019
PROPOSED RULES
DEPARTMENT OF HEALTH
[Filed February 9, 2024, 10:12 a.m.]

Original Notice.

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

Title of Rule and Other Identifying Information: Medical test site (MTS) licensure for naturopath and nurse midwife professions. To align with federal rules, the department of health (department) is proposing removing the professions of naturopath licensed under chapter 18.36A RCW and midwife licensed under chapter 18.50 RCW from the list of licensed professionals that may perform a provider-performed microscopic procedure (PPMP) in WAC 246-338-020. The department is proposing to clarify that both the laboratory director and testing personnel of PPMP must be a licensed professional. The department is also proposing a technical citation adjustment to a definition in WAC 246-338-010.

Hearing Location(s): On April 4, 2024, at 2:00 p.m., at the Department of Health, Town Center 2, 111 Israel Road S.E., Rooms 166 and 167, Tumwater, WA 98501; or virtually via Zoom. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_1aNy5RneSbCY6UIdm3AyVA. After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: April 11, 2024.

Submit Written Comments to: Jessica Holloway, P.O. Box 47843, Olympia, WA 98504-7843, email https://fortress.wa.gov/doh/policyreview/, by April 4, 2024.

Assistance for Persons with Disabilities: Contact Jessica Holloway, phone 360-236-2927, email Jessica.Holloway@doh.wa.gov, by March 21, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The department is proposing to amend WAC 246-338-010 and 246-338-020 to align with the federal rules related to qualifications of laboratory directors under 42 C.F.R. 493.1357 and testing personnel under 42 C.F.R. 493.1363 for laboratories performing PPMPs. The federal rules stipulate that both the laboratory director and testing personnel of laboratories performing PPMPs must: (1) Be a physician as defined in 42 C.F.R. 493.2; (2) be a mid-level practitioner as defined in 42 C.F.R. 493.2; or (3) be a dentist as defined in 42 C.F.R. 493.2.

Currently, WAC 246-338-020 allows for naturopaths to be testing personnel, but naturopaths do not meet the federal definition of physician, mid-level practitioner, or dentist described in 42 C.F.R. 493.2; therefore, naturopaths cannot qualify as a laboratory director or testing personnel under a PPMP MTS license.

Additionally, WAC 246-338-020 currently lists midwife as a qualification for testing personnel under a PPMP license. The department has determined that a midwife licensed under chapter 18.50 RCW does not meet the qualification described in 42 C.F.R. 493.2. Instead, a nurse midwife serving as a mid-level practitioner and holding a master's degree in nursing and licensure as an advanced registered nurse practitioner (ARNP) under chapter 18.79 RCW will qualify for the PPMP MTS license. ARNP is already listed as an approved licensed professional in WAC 246-338-020 and the following ARNP designations listed in WAC 246-840-302 will remain qualified for the PPMP MTS license: Nurse

practitioner, certified nurse-midwife (CNM), certified registered nurse anesthetist (CRNA), and clinical nurse specialist (CNS).

The department is proposing an amendment to WAC 246-338-020 to remove naturopath and midwife as a qualification for laboratory director and testing personnel under a PPMP license and to clarify that only physicians, ARNPs, physician assistants, or dentists may serve as the laboratory director of the PPMP MTS license.

The department is also proposing an amendment to WAC 246-338-010 to update a cross-reference to remove the reference to naturopaths and midwives.

Reasons Supporting Proposal: Clinical Laboratory Improvement Amendments (CLIA) provide federal standards that are applicable to all United States facilities or sites that test human specimens for health assessment to diagnose, prevent, or treat disease. Washington is CLIA-exempt, meaning that all laboratories in the state must obtain an MTS license instead of a federal CLIA license to perform medical tests. Washington receives approval from CLIA to enforce federal rules for laboratories. The MTS program must comply with federal requirements described in 42 C.F.R. Part 493 to maintain the exemption from CLIA. Updating the qualifications for laboratory directors and testing personnel for PPMP MTS licenses will align chapter 246-338 WAC with the federal requirements.

Statutory Authority for Adoption: RCW 70.42.220.

Statute Being Implemented: Chapter 70.42 RCW.

Rule is necessary because of federal law, 42 C.F.R. §§ 493.2, 493.1357, 493.1363.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Jessica Holloway, 111 Israel Road S.E., Tumwater, WA 98504, 360-236-2927.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. Exempt due to RCW 34.05.328 (5)(b)(iii) due to adoption of federal requirements and RCW 34.05.328 (5)(b)(iv), rules that only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Citation of the specific federal statute or regulation and description of the consequences to the state if the rule is not adopted: 42 C.F.R. 493.2 provides definitions of physicians, dentists, and mid-level practitioners. 42 C.F.R. 493.1357 describes the qualifications of laboratory directors of facilities performing PPMPs. 42 C.F.R. 493.1363 describes the qualifications of testing personnel of facilities performing PPMPs. CMS-3326-F final rule making states that a nurse midwife requires at least a master's degree in nursing. If the rules are not adopted, Washington state could lose its exemption from CLIA.

Is exempt under RCW 19.85.025(3) as the rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

Explanation of exemptions: The proposed rules adopt federal requirements and correct or clarify language of the rule without changing the effect.

Scope of exemption for rule proposal:

Is fully exempt.

February 9, 2024
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary

OTS-5121.3

AMENDATORY SECTION (Amending WSR 16-18-073, filed 9/2/16, effective 10/3/16)

WAC 246-338-010 Definitions. For the purposes of this chapter, the following words and phrases have these meanings unless the context clearly indicates otherwise.

(1) "Accreditation organization" means a public or private organization or agency approved by CMS as having standards which are consistent with federal law and regulation, and judged by the department to be equivalent to this chapter.

(2) "Authorized person" means any individual allowed by Washington state law or rule to order tests or receive test results.

(3) "Biannual verification" means a system for verifying the accuracy of test results, at least twice a calendar year, for those tests for which proficiency testing is not required by the department.

(4) "Calibration" means a process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.

(5) "Calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results.

(6) "Calibrator" means a material, solution, or lyophilized preparation designed to be used in calibration. The values or concentrations of the analytes of interest in the calibration material are known within limits ascertained during its preparation or before use.

(7) "Case" means any slide or group of slides, from one patient specimen source, submitted to a medical test site, at one time, for the purpose of cytological or histological examination.

(8) "CDC" means the federal Centers for Disease Control and Prevention.

(9) "CMS" means the federal Centers for Medicare and Medicaid Services.

(10) "CLIA" means Section 353 of the Public Health Service Act, Clinical Laboratory Improvement Amendments of 1988, and regulations implementing the federal amendments, 42 C.F.R. Part 493-Laboratory Requirements in effect on September 22, 2003.

(11) "Control" means a material, solution, lyophilized preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the analytes of interest in the control material are known within limits ascertained during its preparation or before routine use.

(12) "Control slide" means a preparation of a material known to produce a specific reaction which is fixed on a glass slide and is used in the process of quality control.

(13) "Days" means calendar days.

(14) "Deemed status" means recognition that the requirements of an accreditation organization have been judged to be equal to, or more stringent than, the requirements of this chapter and the CLIA requirements, and the accreditation organization has agreed to comply with all requirements of this chapter and CLIA.

(15) "Deficiency" means a finding from an inspection or complaint investigation that is not in compliance with this chapter and requires corrective action.

(16) "Department" means the department of health.

(17) "Direct staff time" means all state employees' work time; travel time; telephone contacts and staff or management conferences; and expenses involved with a complaint investigation or an on-site follow-up visit.

(18) "Director," defined as the designated test site supervisor in RCW 70.42.010, means the individual responsible for the technical functions of the medical test site. This person must meet the qualifications for Laboratory Director, listed in 42 C.F.R. Part 493 Subpart M - Personnel for Nonwaived Testing.

(19) "Disciplinary action" means license or certificate of waiver denial, suspension, condition, revocation, civil fine, or any combination of the preceding actions, taken by the department against a medical test site.

(20) "Facility" means one or more locations within one campus or complex where tests are performed under one owner.

(21) "Forensic" means investigative testing in which the results are never used for clinical diagnosis, or referral to a health care provider for treatment of an individual.

(22) "HHS" means the federal Department of Health and Human Services.

(23) "High complexity" means a test system, assay, or examination that is categorized under CLIA as a high complexity test.

(24) "May" means permissive or discretionary.

(25) "Medical test site" or "test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A medical test site does not mean:

(a) A facility or site, including a residence, where a test approved for home use by the Federal Food and Drug Administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction; or

(b) A facility or site performing tests solely for forensic purposes.

(26) "Moderate complexity" means a test system, assay, or examination that is categorized under CLIA as a moderate complexity test.

(27) "Must" means compliance is mandatory.

(28) "Nonwaived" means all tests categorized under CLIA as:

(a) Moderate complexity tests, including provider-performed microscopic procedures; or

(b) High complexity tests.

(29) "Owner" means the person, corporation, or entity legally responsible for the business requiring licensure or a certificate of waiver as a medical test site under chapter 70.42 RCW.

(30) "Patient's personal representative" means a person legally authorized to make health care decisions on an individual's behalf.

(31) "Performance specification" means a value or range of values for a test that describe its accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference range.

(32) "Person" means any individual, public organization, private organization, agent, agency, corporation, firm, association, partnership, or business.

(33) "Physician" means an individual with a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine, or equivalent degree who is a licensed professional under chapter 18.71 RCW Physicians; chapter 18.57 RCW Osteopathy—Osteopathic medicine and surgery; or chapter 18.22 RCW Podiatric medicine and surgery.

(34) "Provider-performed microscopic procedures" means only those moderate complexity tests listed under WAC 246-338-020 (2)(b)(i) through (x), when the tests are performed in conjunction with a patient's visit by a licensed professional meeting qualifications specified in WAC 246-338-020 (2)(a)(i) through ((~~(vi)~~)) (iv).

(35) "Provisional license" means an interim approval issued by the department to the owner of a medical test site.

(36) "Records" means books, files, reports, or other documentation necessary to show compliance with the quality control and quality assurance requirements under this chapter.

(37) "Reference material" means a material or substance, calibrator, control, or standard where one or more properties are sufficiently well established for use in calibrating a process or for use in quality control.

(38) "Specialty" means a group of similar subspecialties or tests. The specialties for a medical test site are as follows:

(a) Chemistry;

(b) Cytogenetics;

(c) Diagnostic immunology;

(d) Immunohematology;

(e) Hematology;

(f) Histocompatibility;

(g) Microbiology;

(h) Pathology; and

(i) Radiobioassay.

(39) "Standard" means a reference material of fixed and known chemical composition capable of being prepared in essentially pure form, or any certified reference material generally accepted or officially recognized as the unique standard for the assay regardless of level or purity of the analyte content.

(40) "Subspecialty" means a group of similar tests. The subspecialties of a specialty for a medical test site are as follows, for:

(a) Chemistry, the subspecialties are routine chemistry, urinalysis, endocrinology, and toxicology;

(b) Diagnostic immunology, the subspecialties are syphilis serology and general immunology;

(c) Immunohematology, the subspecialties are ABO grouping and Rh typing, antibody detection, antibody identification, and compatibility testing;

(d) Hematology, the subspecialties are routine hematology and coagulation;

(e) Microbiology, the subspecialties are bacteriology, mycology, parasitology, virology, and mycobacteriology; and

(f) Pathology, the subspecialties are histopathology (including dermatopathology), diagnostic cytology, and oral pathology.

(41) "Supervision" means authoritative procedural guidance by an individual qualified under 42 C.F.R. Part 493 Subpart M - Personnel for Non-waived Testing, assuming the responsibility for the accomplishment of a function or activity by technical personnel.

(42) "Technical personnel" means individuals employed to perform any test or part of a test.

(43) "Test" means any examination or procedure conducted on a sample taken from the human body.

(44) "Validation inspection" means an on-site inspection by the department of an accredited medical test site to determine that the accreditation organization's regulations are equivalent to this chapter and are enforced.

(45) "Waived test" means a test system that is:

(a) Cleared by the Food and Drug Administration for home use; or

(b) A simple laboratory examination or procedure that has an insignificant risk of an erroneous result.

In order for a test system to be waived, it must be approved for waiver under CLIA.

(46) "Will" means compliance is mandatory.

AMENDATORY SECTION (Amending WSR 02-12-105, filed 6/5/02, effective 7/6/02)

WAC 246-338-020 Licensure—Types of medical test site licenses. After July 1, 1990, any person advertising, operating, managing, owning, conducting, opening, or maintaining a medical test site must first obtain a license from the department. License types are described in Table 020-1.

(1) Certificate of waiver.

Applicable if the medical test site performs only the tests classified as waived.

(2) Provider performed microscopic procedures (PPMP).

Applicable if the medical test site restricts its testing performance to one or more of the following moderate complexity tests performed by one of the licensed professionals listed, in conjunction with a patient's visit. In addition, the medical test site can perform tests classified as waived with this type of license.

(a) ((~~PPMP may be performed only by one of~~)) The following licensed professionals may serve as the laboratory director and testing personnel for microscopic procedures under a PPMP medical test site license:

(i) 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;

(ii) Advanced registered nurse practitioner, licensed under chapter 18.79 RCW, Nursing care;

(iii) ((~~Midwife licensed under chapter 18.50 RCW, Midwifery;~~ ~~(iv)~~)) Physician assistant licensed under chapter 18.71A RCW, Physician assistants; or

((~~(v) Naturopath licensed under chapter 18.36A RCW, Naturopathy; or~~ ~~(vi)~~)) (iv) Dentist licensed under chapter 18.32 RCW, Dentistry.

(b) Microscopic procedures authorized under a PPMP license are:

(i) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements;

(ii) All potassium hydroxide (KOH) preparations;

(iii) Pinworm examinations;

(iv) Fern tests;

(v) Postcoital direct, qualitative examinations of vaginal or cervical mucous;

(vi) Urine sediment examinations;

(vii) Nasal smears for granulocytes;

(viii) Fecal leukocyte examinations;

(ix) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility); and

(x) Any other tests subsequently categorized under CLIA as provider-performed microscopy procedures.

(3) Moderate/high complexity.

(a) Low volume, Category A-J, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived or qualified as PPMP under subsection (2) of this section. Under this type of license, the medical test site may also perform tests classified as waived.

(b) Accredited: Low volume, Category A-J, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived, and is accredited and inspected by an accreditation organization approved by the department under WAC 246-338-040. Under this type of license, the medical test site may also perform tests classified as waived.

020-1 Table of Requirements for Each License Type

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
(1) **Certificate of Waiver**	• Restrict testing to tests classified as waived. • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections. • Follow manufacturers' instructions for performing the test.	• Complaint • Technical assistance	• When indicated
(2) **PPMP**	• Restrict testing to tests classified as PPMP or waived.	• Complaint	• When indicated

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
	• Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing the test.	• Technical assistance	
(3) **Moderate/High Complexity**			
(a) **Low Volume, Category A-J**	• Perform tests classified as moderate or high complexity. • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing test.	• Initial • Routine • Complaint • On-site follow-up • Technical assistance	• First 6 months of license • Every 2 years • When indicated • When indicated • When indicated
(b) **Accredited: Low Volume, Category A-J**	• Perform tests classified as moderate or high complexity. • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/ Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing the test. • Submit to the department upon request, or authorize the accreditation organization to submit: • Proof of accreditation; • On-site inspection results; • Statement of deficiencies; • Plan of correction for the deficiencies cited;	• Validation • Complaint • On-site follow-up • Technical assistance	• 2.5% of accredited sites annually • When indicated • When indicated • When indicated

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
	• Any disciplinary action and results of any disciplinary action taken by the accreditation organization against the medical test site.		