**WSR 22-13-016**
**EMERGENCY RULES**
**DEPARTMENT OF HEALTH**

[Filed June 3, 2022, 8:49 a.m., effective June 3, 2022, 8:49 a.m.]

Effective Date of Rule: Immediately upon filing.

Purpose: WAC 246-338-020 and 246-338-026, medical test site licensure and notification requirements. The department of health (department) is adopting an emergency rule to amend WAC 246-338-026 mandating reporting of test results intended to detect SARS-CoV-2 or diagnose a possible case of the coronavirus disease 2019 (COVID-19) in alignment with the federal changes published in 85 F.R. 54820 on September 2, 2020. WAC 246-338-020 is amended to add language referencing the new subsection in WAC 246-338-026. These changes will allow the new reporting, inspection, and fining processes in compliance with the new federal requirements which will ensure the current clinical laboratory improvement amendments (CLIA) exempt status is not threatened and will respond to the current public health emergency created by the COVID-19 pandemic. This is the sixth emergency rule for these amendments. It continues without change the emergency rule that was filed on February 4, 2022, under WSR 22-05-013; and the prior filings on October 8, 2021, under WSR 21-21-013; June 11, 2021, under WSR 21-13-045; February 12, 2021, under WSR 21-05-048; and October 15, 2020, under WSR 20-21-062.

Citation of Rules Affected by this Order: Amending WAC 246-338-020 and 246-338-026.

Statutory Authority for Adoption: RCW 70.42.060.

Under RCW 34.05.350 the agency for good cause finds that state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this Finding: This emergency rule updates Washington rules to align with updated federal requirements published in 85 F.R. 54820, which include new reporting and inspection requirements and fines for nonreporting. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest and federal compliance requirements, which could threaten the current CLIA exempt status. The department continues to consider options for continuing this requirement under a permanent rule-making process, recognizing the temporary nature of the federal regulation. The department will make this determination when it learns if Centers for Medicare and Medicaid Services (CMS) intends to add permanent regulations to the C.F.R. requiring laboratories to report SARS-CoV-2 data to the United States Department of Health and Human Services. If CMS adds a permanent rule after the public health emergency ends, the department will need to add a permanent rule to align with CMS's CLIA program.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 1, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 1, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 2, Repealed 0.

Date Adopted: May 31, 2022.

Kristin Peterson, JD
Deputy Secretary
Policy and Planning
for Umair A. Shah, MD, MPH
Secretary

**OTS-2664.2**

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:

(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;

(v) Naturopath licensed under chapter 18.36A RCW, Naturopathy; or

(vi) 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.<br>• 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.<br>• Follow manufacturers' instructions for performing the test. | • Complaint<br>• Technical assistance<br>• As required to assess compliance with WAC 246-338-026(7) | • When indicated |
| (2) **PPMP** | • Restrict testing to tests classified as PPMP or waived.<br>• 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.<br>• Follow manufacturers' instructions for performing the test. | • Complaint<br>• Technical assistance<br>• As required to assess compliance with WAC 246-338-026(7) | • When indicated |
| (3) **Moderate/High Complexity** | | | |
| (a) **Low Volume, Category A-J** | • Perform tests classified as moderate or high complexity. | • Initial | • First 6 months of license |

| 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.<br>• Follow manufacturers' instructions for performing test. | • Routine<br>• Complaint<br>• On-site follow-up<br>• Technical assistance<br>• As required to assess compliance with WAC 246-338-026(7) | • Every 2 years<br>• When indicated<br>• When indicated<br>• When indicated |
| (b) **Accredited: Low Volume, Category A-J** | • Perform tests classified as moderate or high complexity.<br>• 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.<br>• Follow manufacturers' instructions for performing the test.<br>• Submit to the department upon request, or authorize the accreditation organization to submit:<br>• Proof of accreditation;<br>• On-site inspection results;<br>• Statement of deficiencies;<br>• Plan of correction for the deficiencies cited;<br>• Any disciplinary action and results of any disciplinary action taken by the accreditation organization against the medical test site. | • Validation<br>• Complaint<br>• On-site follow-up<br>• Technical assistance<br>• As required to assess compliance with WAC 246-338-026(7) | • 2.5% of accredited sites annually<br>• When indicated<br>• When indicated<br>• When indicated |

[Statutory Authority: RCW 70.42.090 and 2002 c 371. WSR 02-12-105, § 246-338-020, filed 6/5/02, effective 7/6/02. Statutory Authority: RCW 70.42.005, 70.42.060. WSR 01-02-069, § 246-338-020, filed 12/29/00, effective 1/29/01. Statutory Authority: RCW 70.42.005, 70.42.060 and chapter 70.42 RCW. WSR 00-06-079, § 246-338-020, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 70.42.005. WSR 97-14-113, § 246-338-020, filed 7/2/97, effective 8/2/97. Statutory Authority: Chapter 70.42 RCW. WSR 94-17-099, § 246-338-020, filed 8/17/94, effective 9/17/94; WSR 93-18-091 (Order 390), § 246-338-020, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-020, filed

10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-020, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-020, filed 9/21/90, effective 10/22/90.]

AMENDATORY SECTION (Amending WSR 00-06-079, filed 3/1/00, effective 4/1/00)

**WAC 246-338-026 Notification requirements.** (1) The owner must notify the department in writing at least thirty days prior to the date of opening or closing the medical test site.

(2) The owner must notify the department in writing within thirty days of any changes in:

(a) Name of site;

(b) Director;

(c) Location of site;

(d) Tests, specialties, and subspecialties; and

(e) Test methodologies.

(3) Proposed change of ownership. Transfer or reassignment of a license is prohibited without the department's approval, and must be initiated by the current owner sending a written notice to the department thirty days prior to transfer.

(a) The current owner of a medical test site must notify the department, in writing at least thirty days prior to the change and provide the following information:

(i) Name, address, and federal tax ID number of the medical test site;

(ii) Full name, address, and location of the current owner and prospective new owner; and

(iii) The date of the proposed change of ownership.

(b) The prospective new owner must submit the following information at least thirty days prior to the change of ownership:

(i) New name and federal tax ID number of the medical test site;

(ii) Changes in technical personnel and supervisors;

(iii) Any changes in tests, specialties, and subspecialties; and

(iv) Other information as requested by the department.

(4) The medical test site must authorize an approved accreditation organization to notify the department of the test site's compliance with the standards of the accreditation organization.

(5) The owner of an accredited license must notify the department in writing within thirty days of the medical test site having its accreditation denied or terminated by the accreditation organization or voluntarily dropping its accreditation status.

(6) The owner must notify the department in writing within thirty days of any convictions of fraud and abuse, false billing, or kickbacks under state or federal law.

(7) During the public health emergency, as defined in 42 C.F.R. 400.200, each medical test site that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report SARS-CoV-2 test results to HHS in such form and manner, and at such timing and frequency, as the department may prescribe. For the purposes of this subsection, "SARS-CoV-2 test" means any test that is intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19.

[Statutory Authority: RCW 70.42.005, 70.42.060 and chapter 70.42 RCW. WSR 00-06-079, § 246-338-026, filed 3/1/00, effective 4/1/00.]