RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (October 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 27, 2023
TIME: 8:32 AM

WSR 23-04-050

Agency: Department of Health

Effective date of rule:
Emergency Rules
☒ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?
☐ Yes ☒ No If Yes, explain:

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 246-338-020 and 246-338-026. The amendment to WAC 246-338-026 mandates reporting of test results intended to detect SARS-CoV-2 or diagnose a possible case of coronavirus disease 2019 (COVID-19). These amendments align with federal changes published in 85 FR 54820 on September 2, 2020.

WAC 246-338-020 is also amended by adding a citation to the emergency amendments made to WAC 246-338-026. The amendments to WAC 246-338-020 bring department reporting, inspection, and fining processes in compliance with the new federal requirements. This ensures the current Clinical Laboratory Improvement Amendments (CLIA) exempt status is maintained and allows for the continued response to incidences of COVID-19 disease activity.

This is the eighth emergency rule for these amendments. It continues without change the emergency rule that was filed on September 30, 2022, under WSR 22-20-073, and the prior filings on June 3, 2022, under 22-13-016, February 4, 2022, under WSR 22-05-013, 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:
New: None
Repealed: None
Amended: WAC 246-338-020, 246-338-026
Suspended: None

Statutory authority for adoption: RCW 70.42.060

Other authority: None

EMERGENCY RULE
Under RCW 34.05.350 the agency for good cause finds:
☐ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
☒ 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 amends Washington rules to align with updated federal requirements published in 85 FR 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 must be satisfied to maintain CLIA exempt status. The Department of Health and Human Services (HHS) renewed the federal public health emergency on October 13, 2022.

The department continues to consider options for maintaining this requirement under a permanent rulemaking process, recognizing the temporary nature of the federal regulation. There are no updates currently. The department will make this

determination when it learns if the Centers for Medicare & Medicaid Services (CMS) intend to adopt permanent rules requiring laboratories to report Sars-CoV-2 data to HHS. If CMS adds permanent rules, the department will need to permanently adopt rules to align with CMS's CLIA program.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The 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
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	1	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	2	Repealed	0

Date: January 27, 2023	**Signature:**
Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH	
Title: Chief of Policy for Secretary of Health	

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. • 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 • As required to assess compliance with WAC 246-338-026(7)	• When indicated
(2) **PPMP**	• Restrict testing to tests classified as PPMP or 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; 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.	• Complaint • Technical assistance • 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. • 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 • As required to assess compliance with WAC 246-338-026(7)	• First 6 months of license • Every 2 years • When indicated • When indicated • When indicated
(b) **Accredited: Low Volume,**	• Perform tests classified as moderate or high complexity.	• Validation	• 2.5% of accredited sites annually

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
Category A-J	• 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; • Any disciplinary action and results of any disciplinary action taken by the accreditation organization against the medical test site.	• Complaint • On-site follow-up • Technical assistance • As required to assess compliance with WAC 246-338-026(7)	• When indicated • When indicated • When indicated

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.