

## WSR 22-21-125

## PROPOSED RULES

## DEPARTMENT OF HEALTH

[Filed October 18, 2022, 12:50 p.m.]

Original Notice.

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

Title of Rule and Other Identifying Information: WAC 246-338-990 Fees. The department of health (department) is proposing increases to initial and renewal licensing fees for medical test sites.

Hearing Location(s): On November 30, 2022, at 11:00 a.m. In order to help mitigate the transmission of coronavirus disease 2019 (COVID-19), the department will not provide a physical location. A virtual public hearing, without a physical meeting space, will be held instead.

We invite you to participate in our public rules hearing using your computer, tablet or smartphone.

Register in advance for this webinar <https://us02web.zoom.us/join/91111111111>.

After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: December 7, 2022.

Submit Written Comments to: Elizabeth Parent, P.O. Box 47852, Olympia, WA 98504, email <https://fortress.wa.gov/doh/policyreview>, by November 30, 2022.

Assistance for Persons with Disabilities: Contact Elizabeth Parent, phone 360-999-7769, TTY 711, email [Elizabeth.parent@doh.wa.gov](mailto:Elizabeth.parent@doh.wa.gov), by November 23, 2022.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: To address the rising costs of the medical test site program, negative cash flow, and build the recommended reserve, the department proposes raising medical test site licensing and renewal fees across all license categories effective April 1, 2023.

A medical test site is a laboratory that analyzes materials derived from the human body for the purposes of health care, treatment, or screening. The Centers for Medicare and Medicaid Services (CMS) regulates medical test sites through the clinical laboratory improvement amendments (CLIA) for all laboratories in the United States that test human samples for diagnosis and treatment. CMS issues exemptions from CLIA to states who apply and can demonstrate that they have regulations that are equivalent or more stringent and they follow CLIA guidelines (e.g., initial, and routine inspections at specific intervals).

Washington is an exempt state that retains regulatory authority at the state level, licensing and regulating more than 6,200 medical test sites to assure [ensure] they meet health and safety requirements. The exemption also includes the federal CLIA fee, so applicants pay only one fee to the department that includes both their state license and CLIA certification fee. Regulation of medical test sites includes issuing credentials, conducting initial and ongoing on-site inspections, following up on deficiencies, performing complaint investigations, monitoring test results for accuracy and reliability, and providing consultation and technical assistance.

The medical test site program assesses licensing fees on a two-year cycle and prorates fees for any new test sites licensed prior to the renewal period. The categorized and accredited license fee sched-

ules align with the federal CLIA fee categories and have a tiered schedule of rates set by the department based on the number of annual tests. The certificate of waiver and provider performed microscopic procedure license fees are set at a biennial rate of \$190 and \$250, respectively.

The certificate of waiver and the provider performed microscopic procedure fees will rise 36 percent and 16 percent, respectively, due to the additional oversight and administrative requirements required for these license types. The remaining license fees will rise 11 percent. The fee amounts proposed are what the department has determined are necessary to fund current and future program operations in accordance with RCW 43.70.250 (license fees for professions, occupations, and businesses), RCW 70.42.090 (regarding license fees for medical test sites), and the department's six-year fee recovery policy.

Reasons Supporting Proposal: RCW 70.42.090 and 43.70.250 require fees to fully fund the work of licensing and regulating health care facilities. Current revenue is not sufficient to maintain a positive fund balance throughout the biennium's two-year licensing cycle, resulting in a negative fund balance.

The department raised fees in November 2020 to bring revenue into compliance with routine cost increases. The program ended fiscal year (FY) 2021 with a fund balance of \$1,157,000 but will end FY 2022 with a balance of -\$186,000. The negative fund balance in FY 2022 is attributable to a 49 percent increase in the number of medical test site licensees and the added operational and support costs that come with it.

In addition, the medical test site program experienced an increase in CMS oversight requirements, policy and interested party activity, and a projected increase to the CMS exemption fee. Also, CMS determined that Washington lacked the needed skill set to provide oversight to labs providing cytology services, and the department will need to contract with an external agency to provide validation surveys of labs that provide cytology services.

The office of financial management also requires agencies to maintain a reasonable working capital reserve in state accounts to cover fluctuations in cash flow, which is typically two months of expenditures. The department forecasts the fund balance to fall below the recommended reserve level by \$450,000 in June 2027 and \$3,384,000 in June 2028.

The department projects that the costs required to support this growth will be \$1.3 million more than the previous projections made for the November 2020 fee increase. Due to these changes, the fund balance is projected to decrease to \$156,000 by June 2027 and -\$2,762,000 by June 2028.

In light of the program's financial forecast, the program requires a fee increase to bring revenue into alignment with the adjusted costs of regulating medical test sites.

Statutory Authority for Adoption: RCW 43.70.250, 70.42.090.

Statute Being Implemented: RCW 43.70.250, 70.42.090.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting: Ross Valore, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4531; Implementation and Enforcement: Elizabeth Parent, 111 Israel Road S.E., Tumwater, WA 98501, 360-999-7769.

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. RCW 34.05.328 (5) (b) (vi) exempts rules that set or adjust fees or rates pursuant to legislative standards.

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

Is exempt under RCW 19.85.025(3) as the rules set or adjust fees under the authority of RCW 19.02.075 or that set or adjust fees or rates pursuant to legislative standards, including fees set or adjusted under the authority of RCW 19.80.045.

Scope of exemption for rule proposal:

Is fully exempt.

October 18, 2022  
 Kristin Peterson, JD  
 Chief of Policy  
 for Umair A. Shah, MD, MPH  
 Secretary

**OTS-4093.1**

AMENDATORY SECTION (Amending WSR 20-20-030, filed 9/29/20, effective 11/1/20)

**WAC 246-338-990 Fees.** (1) The department will assess and collect biennial fees for medical test sites as follows:

(a) Charge fees, based on the requirements authorized under RCW 70.42.090 and this section;

(b) Assess additional fees when changes listed in WAC 246-338-026 occur that require a different type of license than what the medical test site currently holds;

(c) Charge prorated fees for the remainder of the two-year cycle when the owner or applicant applies for an initial license during a biennium as defined under WAC 246-338-022 (2) (c);

(d) Charge prorated fees for licenses issued for less than a two-year period under WAC 246-338-024(3); and

(e) Determine fees according to criteria described in Table 990-1.

**Table 990-1 License Categories and Fees**

Category of License	Number of Tests/Year	Biennial Fee
Certificate of Waiver	N/A	(\$190) \$260
PPMP	N/A	(\$250) \$300
Low Volume	1-2,000 tests	(\$560) \$620
Category A	2,001-10,000 tests, 1-3 specialties	(\$1,710) \$1,900

Table 990-1 License Categories and Fees

Category of License	Number of Tests/Year	Biennial Fee
Category B	2,001-10,000 tests, 4 or more specialties	<del>(\$2,210)</del> <u>\$2,450</u>
Category C	10,001-25,000 tests, 1-3 specialties	<del>(\$3,070)</del> <u>\$3,410</u>
Category D	10,001-25,000 tests, 4 or more specialties	<del>(\$3,520)</del> <u>\$3,910</u>
Category E	25,001-50,000 tests	<del>(\$4,230)</del> <u>\$4,700</u>
Category F	50,001-75,000 tests	<del>(\$5,230)</del> <u>\$5,810</u>
Category G	75,001-100,000 tests	<del>(\$6,240)</del> <u>\$6,930</u>
Category H	100,001-500,000 tests	<del>(\$7,290)</del> <u>\$8,090</u>
Category I	500,001-1,000,000 tests	<del>(\$12,960)</del> <u>\$14,390</u>
Category J	> 1,000,000 tests	<del>(\$15,550)</del> <u>\$17,260</u>
Accredited:		
Low Volume	1-2,000 tests	<del>(\$210)</del> <u>\$230</u>
Category A	2,001-10,000 tests, 1-3 specialties	<del>(\$260)</del> <u>\$290</u>
Category B	2,001-10,000 tests, 4 or more specialties	<del>(\$290)</del> <u>\$320</u>
Category C	10,001-25,000 tests, 1-3 specialties	<del>(\$660)</del> <u>\$730</u>
Category D	10,001-25,000 tests, 4 or more specialties	<del>(\$700)</del> <u>\$780</u>
Category E	25,001-50,000 tests	<del>(\$980)</del> <u>\$1,090</u>
Category F	50,001-75,000 tests	<del>(\$1,570)</del> <u>\$1,740</u>
Category G	75,001-100,000 tests	<del>(\$2,150)</del> <u>\$2,390</u>
Category H	100,001-500,000 tests	<del>(\$2,780)</del> <u>\$3,090</u>
Category I	500,001-1,000,000 tests	<del>(\$8,040)</del> <u>\$8,920</u>
Category J	> 1,000,000 tests	<del>(\$10,210)</del> <u>\$11,330</u>
Follow-up survey for deficiencies		Direct staff time
Complaint investigation		Direct staff time

(2) The following programs are excluded from fee charges when performing only waived hematocrit or hemoglobin testing for nutritional evaluation and food distribution purposes:

- (a) Women, infant and children programs (WIC); and
- (b) Washington state migrant council.

[Statutory Authority: RCW 43.70.250 and 70.42.090. WSR 20-20-030, § 246-338-990, filed 9/29/20, effective 11/1/20. Statutory Authority: RCW 70.42.090. WSR 06-15-132, § 246-338-990, filed 7/19/06, effective 8/19/06. Statutory Authority: RCW 70.42.090 and 2002 c 371. WSR 02-12-105, § 246-338-990, filed 6/5/02, effective 7/6/02. Statutory Authority: RCW 70.42.005, 70.42.060. WSR 01-02-069, § 246-338-990, filed 12/29/00, effective 1/29/01. Statutory Authority: RCW 70.42.090. WSR 99-24-061, § 246-338-990, filed 11/29/99, effective 12/30/99; WSR 96-12-011, § 246-338-990, filed 5/24/96, effective 6/24/96. Statutory Authority: Chapter 70.42 RCW. WSR 94-17-099, § 246-338-990, filed 8/17/94, effective 9/17/94; WSR 93-18-091 (Order 390), § 246-338-990, filed 9/1/93, effective 10/2/93; WSR 91-21-062 (Order 205), § 246-338-990, filed 10/16/91, effective 10/16/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-338-990, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.42 RCW. WSR 90-20-017 (Order 090), § 248-38-120, filed 9/21/90, effective 10/22/90.]