



STATE OF WASHINGTON  
**DEPARTMENT OF HEALTH**

*PO Box 47890 • Olympia, Washington 98504-7890  
Tel: 360-236-4030 • TDD Relay Service: 800-833-6388*

October 5, 2020

To Whom It May Concern,

The Department of Health (department) is increasing the medical test sites licensing fees. This increase is needed to cover all of the costs of regulating these entities, as required by RCW 70.42.090. The department is responsible for licensing and regulating more than 4,100 medical test sites to assure they meet health and safety requirements. Providing regulatory oversight to medical test sites supports the department's mission to protect and improve the health of people in Washington.

To address the rising costs of the medical test site program, address the negative cash flow, and build the recommended reserve, the department is raising medical test site licensing and renewal fees by 25 percent across all license categories effective November 1, 2020. The fee amounts 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. Though the fee change would go into effect November 1, 2020, existing labs will not incur the new fees until renewal in June 2021. A copy of the adopted rules are attached.

The adopted rules are the same as the text of the proposed rule as it was published in the Washington State Register 20-14-106.

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

<b>Comment Received</b>	<b>Department of Health Response</b>
Of my various fees, including Washington State medical license, Federal Drug Enforcement Administration (DEA) license, Drug Addiction Treatment Act (DATA) 2000 waiver and the National Registry of Certified Medical Examiners, yours chews up more of the revenue generated in its category than any other fee. No one has ever come to my office to inspect us, and for what you assess, that's not surprising. We do a pretty limited and pretty simple suite of tests. I worked for some five years as a laboratory technician. As a primary care doc, I am	Answer:  We must meet federal requirements for laboratory licensing. If the facility in question is not a surveyed facility then it is a certificate of waiver lab, which means the cost of the license is largely just to register that the lab performs testing and granting the lab the ability to bill Medicare, Medicaid, and private insurance for testing.

<p>constantly evaluating my competence for each task that presents itself, so I know what to refer and what to accomplish myself, and these lab tests are pretty simple tasks.</p> <p>In this time of COVID-19, it seems the whole world is reviewing and adjusting its methods of operation.</p> <p>Does the legislature or DOH give you any latitude in how you operate? Is there some way to accomplish your goal with less work? How about an on-line test, timed such that we must demonstrate our competence without looking for an answer online, for example?</p> <p>Please look at what you are trying to accomplish and see if you can figure out how to achieve that task in the most cost-effective way.</p>	<p>Since the law requires the program to be self-supporting, the department needs to charge fees to cover the cost of this registration.</p>
<p>I expect that much of the efforts and costs associated with regulating test sites has limited evidence to justify the costs, based on measurable health benefits.</p> <p>The risk aversion strategies currently implemented to regulate labs are excessive in comparison to the cost effectiveness of other investments. And the costs seem to ever go up. The costs are immense for our regulatory responses. Already the labs have licensed professionals. If they are to considered professionals and licensed let them be responsible for poor outcomes/results rather than simply dotting the i's or crossing the ts.</p>	<p>Answer:</p> <p>There are no license requirements for Lab professionals and nothing under the professional license for medical doctors (MD) directors or even medical assistants (MA) that would specifically regulate proficiency testing, records, personnel, quality control, or quality assurance in a laboratory. This increase is needed to cover all of the costs of regulating these entities, as required by <a href="#">RCW 70.42.090</a>.</p>
<p>My question is whether the Medical Test Site program has any objective evidence that the program activities have led to improvements in safety and quality? If there are parts of the program that can't show any objective evidence of those key things, then rather than increase the cost of the program we should cut those parts of the program to reduce expense and maintain or reduce the current fee structure. I believe that an external independent audit would be the only way to get this information and would like to see results of that type of audit before any fee increases are allowed</p>	<p>Answer:</p> <p>The medical test site program is independently audited by the Centers for Medicare and Medicaid Services (CMS) annually in January of each year and at our federal exemption audit when it comes due. The next exemption audit is due in 2023. These reviews verify that the program is at least equivalent to federal Clinical Laboratory Improvement Amendments (CLIA). The results of the latest federal exemption can be found here <a href="https://www.federalregister.gov/document/2019/09/30/2019-21062/medicare-medicare-and-clia-programs-clinical-laboratory-improvement-amendments-of-1988-exemption-of">https://www.federalregister.gov/document/2019/09/30/2019-21062/medicare-medicare-and-clia-programs-clinical-laboratory-improvement-amendments-of-1988-exemption-of</a></p>

--	--

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 [Stephanie.vaughn@doh.wa.gov](mailto:Stephanie.vaughn@doh.wa.gov).

Cordially,

/S/Honora Estes, MS, MLS(ASCP)<sup>CM</sup>  
Program Manager