



Department of Health  
2023-25 Regular Budget Session  
Policy Level - HL - Medical Test Site Fees

### Agency Recommendation Summary

The Department of Health requests an increase in spending authority to address a 49% rise in the number of licensees since 2019 and an expansion in the inspection work required by the Center for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA).

### Fiscal Summary

Fiscal Summary <i>Dollars in Thousands</i>	Fiscal Years		Biennial	Fiscal Years		Biennial
	2024	2025	2023-25	2026	2027	2025-27
<b>Staffing</b>						
FTEs	3.0	3.1	3.05	3.1	3.1	3.1
<b>Operating Expenditures</b>						
Fund 202 - 1	\$925	\$940	\$1,865	\$959	\$977	\$1,936
Total Expenditures	\$925	\$940	\$1,865	\$959	\$977	\$1,936
<b>Revenue</b>						
202 - 0420	\$925	\$940	\$1,865	\$959	\$977	\$1,936
Total Revenue	\$925	\$940	\$1,865	\$959	\$977	\$1,936

### Decision Package Description

The department licenses and regulates more than 6,200 medical test sites to assure they meet health and safety requirements under chapter 70.42 RCW. A medical test site (MTS) is a laboratory that analyzes materials derived from the human body for the purposes of health care, treatment, or screening ([RCW 70.42.010](#)). Regulation of medical test sites includes issuing credentials, conducting initial and ongoing on-site inspections (also referred to as surveys) and following up on deficiencies, performing complaint investigations, monitoring test results for accuracy and reliability, providing consultation and technical assistance, and maintaining a state licensure database.

The federal Centers for Medicare and Medicaid Services (CMS) also 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 with regulations that are equivalent or more stringent and that comply with CLIA guidelines (e.g., initial and routine inspections at specific intervals). Washington is a CLIA-exempt state, which means that medical tests sites only have to pay one fee to the department that includes both their state license and CLIA certification.

Over the course of the COVID-19 public health emergency, the Medical Test Site (MTS) regulatory program has experienced significant growth in the number of licensed facilities and associated activities. To conduct COVID-19 testing, fire stations, school districts, and other entities needed to apply for a type of MTS license called a “certificate of waiver.” In addition, the department recently learned that adult family homes are doing COVID-19 and other testing that requires a “certificate of waiver” license. The department is working with the Department of Social and Health Services (which regulates adult family homes) to get these facilities appropriately licensed.

Since 2019, the number of licensees has grown 49% from 4,187 to 6,219. The anticipated addition of 3,700 licenses for adult family homes will bring the total licensees to 9,919, an increase of 137% since 2019. Because we have found that schools and adult family homes often conduct other tests that require a certificate of waiver, such as glucose monitoring, we expect the need for these additional MTS licensees to continue even after the need for COVID testing subsides, with an expected growth rate that mirrors the growth rate of adult family homes.

Although the growth in MTS licensees will generate additional revenue, it will not be enough to cover the cost of regulatory oversight. This is largely because the department must meet new state and CMS CLIA requirements to maintain the state’s CLIA-exempt status. These new requirements include:

- Conducting an onsite inspection during the first six months of licensure and every two years for sites with a “Categorized” license.

- Conducting an onsite inspection of 2.5% of sites annually for sites with an “Accredited” license.
- Conducting the new requirement of inspecting a 5% sample of “Certificate of Waiver” and “Provider Performed Microscopic Procedures” licensed facilities. The changes will result in approximately 150 new inspections each year.
- Posting of inspection and investigation documents for access by the public utilizing the department’s external website. This component is required to comply with SHB 2426 approved by the legislature in 2020.

These changes will increase the cost of regulating the program, driving the need for additional spending authority. The department also anticipates paying CMS a higher annual fee for CLIA exemption since this requirement is directly proportional to the number of licensees, which is projected to rise from \$530,000 to \$880,000 per year in FY 2023. The added costs will be spread across the profession’s projected 9,919 licensees, necessitating a fee increase. The proposed fee amount is currently being finalized but is expected to range from \$40-\$90 for Certificate of Waiver and Provider Performed Microscopic Procedure licensees. The proposed fee change for Accredited and Categorized licenses ranges widely from \$20- \$3,600 dependent on license type, category, and fee strategy. We will be working on finalizing a fee strategy over the next few months and will refine it as we begin rulemaking in 2023.

The department requests an increase in MTS spending authority to cover the costs associated with a rise in the number of licensees and an expansion in the inspection work required by CMS (\$825,000 in FY 24 and \$853,000 in FY 25). The expansion of inspection work associated with new CMS requirements will require a fee increase planned in spring 2023. To maintain regulatory oversight and to ensure alignment with CMS requirements for CLIA exemption, the program must hire the following positions:

- One Health Service Consultant 4: Previously, we were able to use a grant for the pandemic relief funds to hire this position about a year ago to focus on stakeholder engagement, rulemaking, and policy activities. However, that grant funding is due to expire in FY 2023 while the ongoing work remains. Additionally, the program work and management of compliance activity had been covered by a single FTE. This is no longer possible due to the growth in facilities and additional oversight requirements, and the increase in policy activity previously described.
- One Health Service Consultant 1: This position would support the day-to-day administrative and data entry requirements for the increase in licensee applications and new oversight inspections, as well as renewals.
- One Advisory Laboratorian: Recent increases in the number of licensed facilities along with new oversight activities will require the FTE to perform the additional required inspections and investigations.
- 0.14 FTE Forms Record Analyst to support posting of inspection and investigation documents.

This request also includes \$100,000 per fiscal year to contract with a third-party expert to perform periodic inspection of cytology testing (mainly used to screen for cancer) in laboratories that test gynecologic preparations. Currently, the program does not have staff with the specific expertise in this field, which is also required to maintain state’s CMS CLIA exemption status.

If approved, the increased spending authority would allow the department to hire the needed staff for the program to continue to provide quality regulatory oversight while simultaneously meeting the new CMS inspection requirements vital to maintaining the state’s CLIA exemption status. Ultimately, this benefits all Washingtonians receiving health care.

An alternative to increasing MTS spending authority would be to request GF-S to cover the cost of the work or pull back on oversight activities. However, both of those options would not align with our federal and state mandate.

If we are unsuccessful in funding the necessary new staff to conduct these increased oversight activities, the department will be unable to fulfill all requirements necessary to maintain Washington’s status as a CLIA-exempt state, such as timelines for on-site inspections and processing of applications and ongoing data management. If the state were to lose the CLIA exemption, Washington’s 6,200 medical test sites would have to pay the CLIA fee in addition to the state licensing fee and would receive both state and federal inspections. There would also be a substantial regulatory burden with the transition because all medical test sites would have to reapply for licensure.



## Assumptions and Calculations

### **Expansion, Reduction, Elimination or Alteration of a current program or service:**

N/A

### **Detailed Assumptions and Calculations:**

- 1.0 FTE Health Services Consultant 1 to provide licensing support for the Medical Test Sites Program,
- 1.0 FTE Advisory Laboratorian to provide investigation and inspection activities,
- 0.9 FTE Health Services Consultant 4 in FY24 and 1.0 FTE in FY25 and ongoing to provide policy support to the program,
- 0.4 FTE Health Services Consultant 1 and 0.7 FTE Fiscal Analyst 2 for administrative support,
- 0.1 FTE Forms Record Analyst to support posting of inspection and investigation documents.
- Increases in CLIA exemption payments to CMS (calculated by estimating the increase in Washington State licenses and a 2% growth rate based on prior bills), and
- \$100,000 contract to provide cytology inspections to comply with CMS requirements

### **Workforce Assumptions:**

Workforce Assumptions FY24 Projections Only				
Job Classification	Salary	Benefits	Startup Costs	FTE Related Costs
HEALTH SERVICES CONSULTANT 4	\$76,000.00	\$29,000.00	\$4,000.00	\$7,000.00
ADVISORY LABORATORIAN	\$83,000.00	\$32,000.00	\$4,000.00	\$8,000.00
HEALTH SERVICES CONSULTANT 1	\$56,000.00	\$26,000.00	\$4,000.00	\$8,000.00
FORMS & RECORDS ANALYST 2	\$5,000.00	\$2,000.00	\$0.00	\$1,000.00
	<b>\$220,000.00</b>	<b>\$89,000.00</b>	<b>\$12,000.00</b>	<b>\$24,000.00</b>

## Strategic and Performance Outcomes

### **Strategic Framework:**

#### Results Washington

This proposal supports the Results Washington goal area of healthy and safe communities by assuring that the testing services provided in medical test sites are high-quality and effective.

#### Department of Health Transformational Plan

This proposal supports the department's Transformational Plan I. Health and Wellness that all Washingtonians have the opportunity to attain their full potential of physical, mental, and social health and well-being. It does this by supporting our ability to engage and partner with the medical test site community to ensure compliance with applicable standards and provide equitable access to safe, high-quality care.

### **Performance Outcomes:**

The addition of the dedicated HSC4 program manager will allow for the following:

- The resumption and timely response to request for technical assistance which have been put on hold due to staffing constraints.
- Timely response to data sought by the state public health laboratory to understand testing capability across the state.
- Timely rule revision in response to changes to federal CLIA standards and our requirement to maintain substantially equivalent licensing laws.

The addition of the HSC 1 support position is expected to yield the following:

- The ability to process new licensing applications in a timely manner. As of July 07, 2022, there is backlog of 331 pending applications that existing staff are working through. This backlog is expected to grow as the program begins to license the medical test sites associated with the adult family homes.
- Timely response to renewal application and change of information. There is a backlog of workorders associated with these two categories of work that will again grow as the number licenses has and is expected to grow in the future.

The addition of the Advance Laboratorian is expected to yield the following:

- The new oversight requirement for Medical Test Site Waived (MTSW) and Provider Performed Microscopic Procedures (PPMP) is anticipated to take approximately eight (8) hours per inspection, at the 5% sample rate, which roughly equates to one (1) FTE. The position would ensure that we could perform this work without taking away from the existing regulatory work.

The other regulatory work includes the ability to conducting onsite inspection during the first six months of licensure, at 150 per year, and every two years for sites with a “Categorized” license. Work that is being delayed due to staffing constraints. As well as posting of inspection and investigation documents for access by the public utilizing the department’s external website.

## Equity Impacts

### **Community outreach and engagement:**

This proposal supports our ability to engage and partner with the medical test sites to ensure compliance with applicable standards and provide equitable access to safe, high-quality care. We are working with key partners to get feedback on the proposal and will work with those partners and the public throughout the rulemaking process.

### **Disproportional Impact Considerations:**

None anticipated

### **Target Populations or Communities:**

This proposal supports the department’s cornerstone values of equity and engagement. Assuring that medical test sites in Washington provide safe, high quality health care promotes the health of all Washingtonians. This is especially important for historically marginalized communities that experience higher risk of poor health outcomes and barriers to accessing care.

## Other Collateral Connections

### ***Puget Sound Recovery:***

N/A

### ***State Workforce Impacts:***

Adult family homes may exercise their collective bargaining rights with DSHS if fees are increased.

### ***Intergovernmental:***

Several state agencies have MTS licenses and will be affected by the fee increase including the Department of Corrections, Department of Social and Health Services, and Washington State University. Washington State Community Colleges also hold MTS licenses. Local government impacts include school districts and fire departments that hold MTS licenses.

When DSHS informed adult family homes of the requirement for MTS licensure to perform COVID-19 and other tests, they exercised their collective bargaining rights with DSHS which was centered on the cost of the license. We assume that they may do the same in the event of a fee increase.

### ***Stakeholder Response:***

Because the department raised the MTS fees two years ago, licensees may be concerned about another fee increase. We have started to engage with stakeholders regarding the decision package and will continue to do so through the fee rulemaking processes, including providing a fee study and cost drivers, some that are specific to the COVID-19 emergency, that necessitate the fee increases.

Stakeholding will take place after we have finalized the DP but before legislative session and also during our fee setting part of the rulemaking process which takes place after leg session.

### ***State Facilities Impacts:***

N/A

### ***Changes from Current Law:***

The department will be revising the fee section of the MTS rule to effect the fee increases.

### ***Legal or Administrative Mandates:***

N/A

## Reference Documents

[2021-23 MTS DP Backup.xlsx](#)

[NEW - MTS fees - FinancialCalculator\\_2023-25\\_ver24.1 \(2\).xlsm](#)

## IT Addendum

***Does this Decision Package include funding for any IT-related costs, including hardware, software, (including cloud-based services), contracts or IT staff?***

No

### Objects of Expenditure

Objects of Expenditure <i>Dollars in Thousands</i>	Fiscal Years		Biennial	Fiscal Years		Biennial
	2024	2025	2023-25	2026	2027	2025-27
Obj. A	\$278	\$283	<b>\$561</b>	\$283	\$283	<b>\$566</b>
Obj. B	\$117	\$118	<b>\$235</b>	\$118	\$118	<b>\$236</b>
Obj. C	\$463	\$480	<b>\$943</b>	\$499	\$517	<b>\$1,016</b>
Obj. E	\$18	\$21	<b>\$39</b>	\$21	\$21	<b>\$42</b>
Obj. G	\$14	\$14	<b>\$28</b>	\$14	\$14	<b>\$28</b>
Obj. J	\$12	\$0	<b>\$12</b>	\$0	\$0	<b>\$0</b>
Obj. T	\$23	\$24	<b>\$47</b>	\$24	\$24	<b>\$48</b>

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