



2020 Supplemental Budget Decision Package

Agency: 303 - Department of Health
Decision Package Code-Title: A8 - Maintain Med Test Site Inspections
Budget Session: 2020 Supp
Budget Level: Maintenance Level
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Agency Recommendation Summary

The number of inspections and complaint investigations in the Medical Test Sites program is increasing. Current spending authority is insufficient to support the program's current resource needs. The Washington State Department of Health requests additional, ongoing spending authority for the program to maintain inspection of licensed laboratories and protect patient safety.

Fiscal Summary

Dollars in Thousands

Operating Expenditures	FY 2020	FY 2021	FY 2022	FY 2023
Fund 202 - 1	\$263	\$267	\$271	\$271
Total Expenditures	\$263	\$267	\$271	\$271
Biennial Totals		\$530		\$542
Staffing	FY 2020	FY 2021	FY 2022	FY 2023
FTEs	1.0	1.0	1.0	1.0
Average Annual		1.0		1.0
Object of Expenditure	FY 2020	FY 2021	FY 2022	FY 2023
Obj. A	\$111	\$113	\$113	\$113
Obj. B	\$43	\$42	\$42	\$42
Obj. E	\$82	\$84	\$88	\$88
Obj. G	\$16	\$17	\$17	\$17
Obj. J	\$1	\$1	\$1	\$1
Obj. T	\$10	\$10	\$10	\$10
Revenue	FY 2020	FY 2021	FY 2022	FY 2023

Revenue	FY 2020	FY 2021	FY 2022	FY 2023
202 - 0420	\$0	\$530	\$47	\$495
Total	\$0	\$530	\$47	\$495
Biennial Totals		\$530		\$542

Package Description

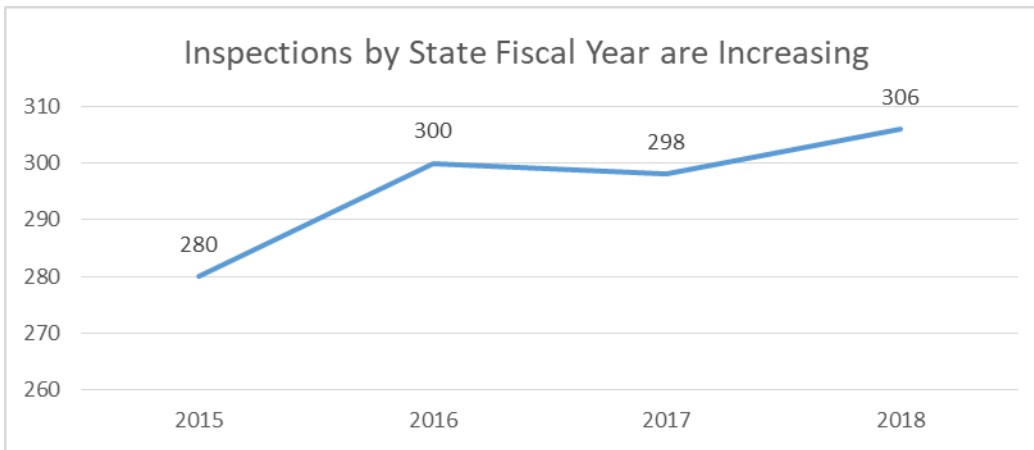
The Department of Health (DOH) regulates more than 4,000 medical test sites in Washington to ensure licensed laboratories provide safe laboratory services. Medical test sites (MTS) must meet quality standards which promote accurate and reliable analysis, thus improving health care through uniform test site licensure and regulation. This includes quality control, quality assurance, and proficiency testing. Medical test sites must also meet the requirements of federal regulations regarding licensing and medical testing. DOH performs approximately 555 routine inspections and (on average) 50 revisits each biennium for laboratories renewing their licenses. Additional on-site visits are required to investigate complaints and to assure the laboratories are following plans of correction following enforcement actions. The program also provides education, technical assistance, and consultation to assist laboratories in meeting compliance with standards or regulations.

During the 2013-2015 biennium, the Legislature redirected \$2.35 million from the Medical Test Site Licensure Account to pay for laboratory services that were historically funded through the general fund. As a result, the program was unable to fill a vacancy in a position which performs inspections and investigations since October 2016. Due to this resource constraint, the workload is currently being redistributed to other staff, including the program manager. This limited other critical program activities such as:

- Supervisor availability to staff experiencing inspection or investigation challenges in the field;
- Updates on rule sets in accordance with five-year rule review requirement;
- Delayed response to provider requests for information and technical assistance; and
- Inability to continue provider outreach activities aimed at improving facility compliance critical to ensuring patient safe access to care.

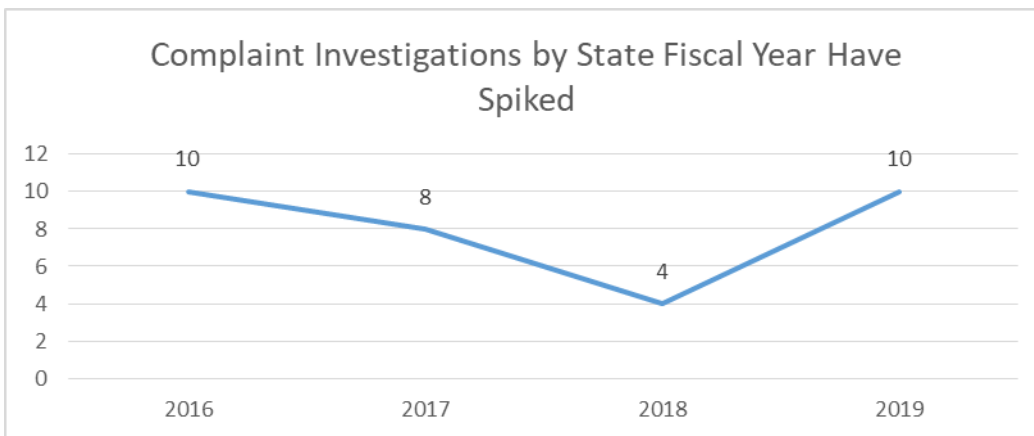
Problem Statement:

The number of inspections and complaint investigations performed by the Medical Test Sites program is increasing. Based on this trend, the department requests an increase in spending authority from the Medical Test Site Licensure Account to support its licensing and other program related activities.



Source: ILRSdatabase

The additional number of inspections being required from the staff competes with other activities, such as maintaining the federal Clinical Laboratory Improvement Amendments (CLIA) database, proficiency testing, and complaint investigations.



Data Source: ILRS database

**2019 Investigation only reflects the number up to June 24, 2019, not the whole fiscal year.*

Along with increased investigations, the complexity of those investigations are increasing, resulting in more serious systemic findings that may require a directed plan of correction (DPOC) and potential enforcement actions. As costs increase for licensees, laboratories are cutting costs by decreasing number of staff, and in some instances, even utilizing under-trained staff. This business practice creates the need for the program to spend extra time and effort consulting and educating the laboratories in order for them to meet compliance with rules and regulations.

In 2016, there were 89 laboratories with serious or repeat deficiencies; 74 in 2017, and 163 in 2018. Repeat deficiency inspections usually require on-site follow-up revisits that may also lead to the issuance of a DPOC. This in turn also increases the overall number of inspections required to be completed annually. When a DPOC becomes necessary, inspection duration usually takes twice as long and also involves the manager's time and oversight prior to issuance. This level of enforcement and compliance activity is consistent with the Centers for Medicare and Medicaid Services' (CMS) expectations and is reportable on an ongoing basis.

An increase to spending authority allows the department to fill the advisory laboratorian position currently vacant which is critical to performing timely and quality inspections, investigations, and other related activities while at the same time right-sizing the program's biennial budget within its required operational expenses.

Assumptions and Calculations

Expansion or alteration of a current program or service:

This proposal does not expand or alter the current MTS program.

Detailed assumptions and calculations:

The proposal will fund 1.0 FTE Advisory Laboratorian and support additional administrative activities due to changes in business practices, increases in the federal exemption fee and staff reallocations.

The federal exemption fee refers to an annual payment that the state makes to CMS out of licensing revenue in order to maintain program activities at the federal level. This fee is required in order for the Washington laboratories to maintain CMS certification and eligibility for federal reimbursement. The federal exemption fee has steadily increased at an average annual rate of 1.3 percent over the last three years.

Workforce Assumptions:

See attached financial calculator (FNCAL)

Strategic and Performance Outcomes

Strategic framework:

This request supports Results Washington Goal 4: Healthy and Safe Communities by ensuring access to quality healthcare.

This request also supports the following Agency Strategic Plan goals:

Goal 1: Public Safety - Protect everyone in Washington from communicable diseases and other health threats. Resolve health care provider and facility complaints and allegations of misconduct or unsafe care.

Performance outcomes:

Filling the vacant Advisory Laboratorian position through the requested appropriation will enable the department to continue to ensure that inspections and investigations are done within the established frequency and timeline while continuing to ensure high quality inspections, timely consultations, and robust technical assistance.

Other Collateral Connections

Intergovernmental:

This request does not have intergovernmental impacts.

Stakeholder response:

Medical test sites seeking initial licensure, re-licensure, and technical assistance would benefit by receiving timely responses to technical assistance needs.

Legal or administrative mandates:

This request is not driven by a legal or administrative mandate against the state.

Changes from current law:

This request does not require any changes to statutes or rules.

State workforce impacts:

This request does not impact existing collective bargaining.

State facilities impacts:

This request does not impact facilities and workplace needs.

Puget Sound recovery:

This request is not related to Puget Sound recovery efforts.

Reference Documents

- ML-A8 Maintain Med Test Site Inspections-FNCAL.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