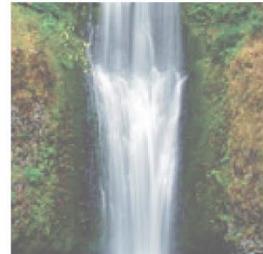




Secretary of State Oregon Audits Division



Oregon Liquor Control Commission
Oregon Health Authority

Oregon's Framework for Regulating Marijuana Should Be Strengthened to Better Mitigate Diversion Risk and Improve Laboratory Testing

January 2019
2019-04

Secretary of State Dennis Richardson
Audits Division Director Kip Memmott

This page intentionally left blank



Secretary of State Audit Highlights

January 2019

Oregon Liquor Control Commission, Oregon Health Authority Oregon's Framework for Regulating Marijuana Should Be Strengthened to Better Mitigate Diversion Risk and Improve Laboratory Testing

Report Highlights

Gaps in Oregon's developing marijuana regulatory framework increase the risk of legal marijuana diverting to the black market, especially in the medical marijuana program. To improve marijuana laboratory testing and protect public health, the state should consider requiring testing for heavy metals and microbiological contaminants, enhance test oversight, and ensure labs meet accreditation standards.

Background

Voters approved Measure 91 in 2014, legalizing the production and sale of recreational marijuana in Oregon. However, marijuana remains illegal federally, and federal officials have expressed serious concerns about marijuana from Oregon crossing into other states. The Oregon Liquor Control Commission (OLCC) regulates the recreational marijuana market, while the Oregon Health Authority (OHA) oversees medical marijuana and marijuana lab testing rules. As of November 2018, retail sales had generated \$207 million in tax revenue.

Purpose

This audit's purpose was to determine whether Oregon has adequate controls to deter the diversion of legal marijuana to the black market and to oversee marijuana laboratory testing to ensure test results are accurate.

Key Findings

1. OLCC is still establishing a regulatory framework for recreational marijuana and has put many controls in place, such as requiring seed-to-sale product tracking and surveillance cameras. However, with no cap on the number of licenses and more applications than expected, staffing and inspections have not kept pace. As a result, only 3% of retailers and 32% of growers have had a compliance inspection.
2. Structural weaknesses in the medical marijuana program greatly increase the risk of diversion. In contrast to OLCC, OHA lacks the authority to put important controls in place, such as requiring medical growers to have surveillance cameras. The agency has only four permanent staff to inspect roughly 14,000 grow sites and has struggled with decreasing revenues, turnover, and performance management.
3. All recreational marijuana in Oregon must be tested for pesticides and solvents, but most medical marijuana is not required to be tested. Also, OHA does not require heavy metal and microbiological testing, in contrast to some other states. These contaminants could pose a risk to consumers.
4. Without a mechanism for verifying test results, Oregon's marijuana testing program cannot ensure that test results are reliable and products are safe. Limited authority, inadequate staffing, and inefficient processes reduce OHA's ability to ensure Oregon marijuana labs consistently operate under accreditation standards and industry pressures may affect lab practices and the accuracy of results.

Recommendations

OLCC and OHA agreed with all 23 of our recommendations; for three of them, OHA indicated it would be unable to take action without further statutory authority. The agencies' responses are included at the end of the report.

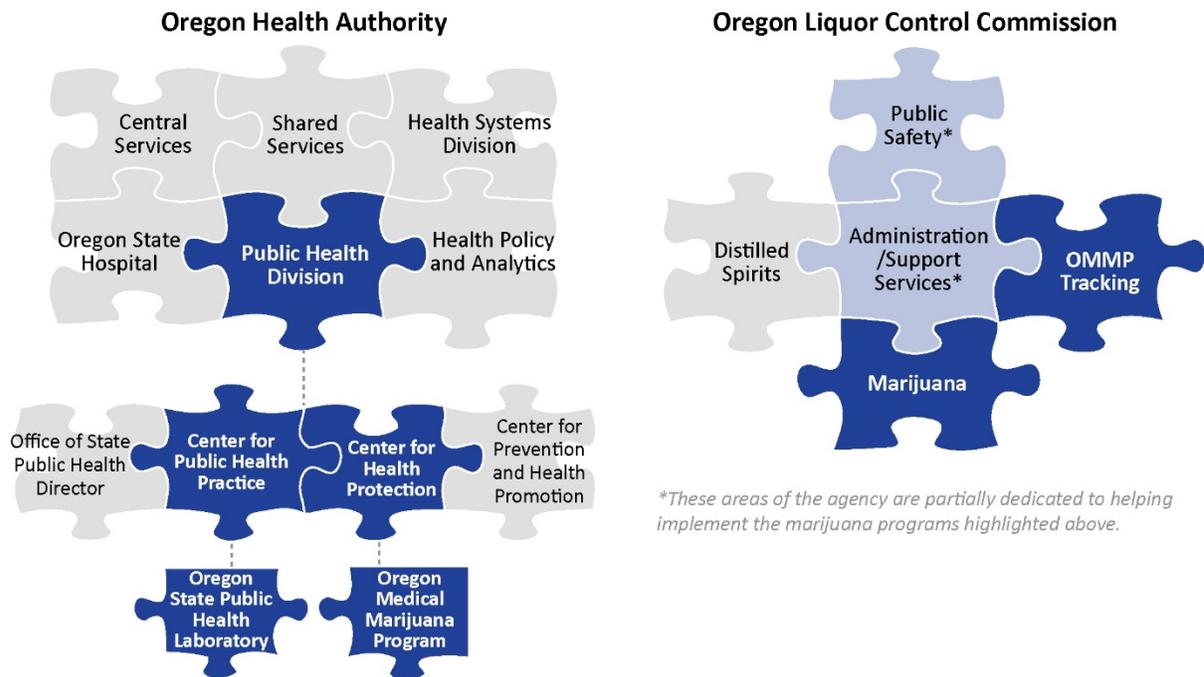
Introduction

While marijuana is still federally illegal, Oregon voted to legalize medical marijuana in 1998 and recreational marijuana sixteen years later. Marijuana use was first legalized only for patients with a qualifying medical condition. The measure established a patient registry now administered by the Oregon Health Authority (OHA), an agency committed to protecting public health. Though the state’s involvement in the medical market expanded in subsequent years, regulatory controls remained limited. Voter legalization of recreational marijuana in 2014 created an entirely new regulated market in Oregon and has led to numerous changes to state laws and rules, expanding state oversight in the years since the measure’s passage.

The Oregon Liquor Control Commission (OLCC) is charged with regulating recreational marijuana in Oregon, including licensing recreational marijuana growers, processors, and retail shops. The state’s medical marijuana system falls under the oversight of the Oregon Medical Marijuana Program (OMMP), housed within OHA. OMMP registers medical marijuana patients, caregivers, and growers. OHA also writes the rules for marijuana testing (which includes testing for potency, pesticides, and other contaminants), and oversees the accreditation of marijuana testing laboratories.

Federal law enforcement officials have expressed concerns about legal marijuana from Oregon being diverted to the black market in other states, in violation of both federal and state law. News reports since legalization have also raised questions about potential contaminants in recreational and medical marijuana.

This audit focused on whether the state has adequate controls in place to prevent the diversion of legal marijuana to the black market and to oversee marijuana laboratory testing to ensure the accuracy of test results.



included “preventing the diversion of marijuana from states where it is legal under state law in some form to other states.”

In 2018, United States Attorney General Jeff Sessions rescinded the Cole Memo, reaffirming the federal government’s prosecutorial discretion. This action removed federal guidance for an acceptable state regulatory structure, resulting in uncertainty for the future of federal enforcement.

Diversion as defined by the Cole Memo

A key federal enforcement priority identified by the memo included: “Preventing the diversion of marijuana from states where it is legal under state law in some form to other states.”

Oregon’s history of marijuana legalization has affected the state’s evolving regulatory framework

Oregon has long been on the leading edge of marijuana legalization among states. In 1973, Oregon became the first state to decriminalize minor marijuana possession, lowering penalties to those comparable to a traffic ticket. Oregon’s law followed a federal commission’s recommendation that Congress legalize small amounts of marijuana, a proposal rejected by the Nixon administration.³ In 1998, voters approved a ballot measure that legalized marijuana for medical purposes. Despite additional legislative changes that focused on developing Oregon’s medical marijuana program, state controls for preventing leakage from the medical market into the black market remained relatively limited. Voters approved the legalization of recreational marijuana in 2014.

Early medical marijuana legislation only legalized patient use and access

In 1998, Oregon joined a handful of states in legalizing medical marijuana when voters approved Measure 67. The measure allowed patients with qualifying medical conditions to obtain a medical marijuana card that allows them to grow, possess, and use limited amounts of marijuana. The new law created a registry for patients and their designated primary caregivers who could assist them in accessing medical marijuana.

Subsequently, OMMP, which administers the patient registry, was created within the Public Health Division of OHA. In 2005, the Oregon Legislature mandated a state registry for marijuana grow sites, permitting patients to obtain marijuana from an assigned grower. Beyond the registry, the law did not implement regulatory controls for preventing medical marijuana leakage into the black market.

To curb black market activity, lawmakers legalized medical dispensaries and introduced controls under OHA

Following legalization of medical marijuana, the number of medical cardholders grew steadily while patient and grower limits were expanded. Since 2006, registered patients can legally possess up to 24 ounces, or 1.5 pounds, of marijuana, and registered grow sites can produce multiple pounds, an increase above amounts initially allowed. At the same time, the medical grow sites remained unregulated; OMMP would not have authority to conduct grow site inspections until 2016.

Media reports alleged high levels of diversion out of state from the medical market from 2010 to 2012. One news report claimed that law enforcement agencies identified over a dozen operations illegally exporting hundreds of pounds of medical marijuana to at least seven states. By 2013, illegal dispensaries existed across the state, according to a legislative summary for

³ President Nixon appointed the 1972 National Commission on Marihuana and Drug Abuse, which recommended amending federal law to decriminalize marijuana possession, use, and low-level retail.



A registered indoor medical grow.

House Bill 3460. Concerns also arose among patients about their ability to access safe and reliably sourced marijuana.

In 2013, the state Legislature passed House Bill 3460 legalizing medical marijuana dispensaries and establishing a new registry program. This added a new regulatory component to OHA's role in medical marijuana, which had previously focused more on health. The law introduced regulatory controls to the medical market: dispensary registrants were required to install security systems, participate in product testing, and submit to inspections. The law also gave the agency authority to inspect dispensaries. A compliance unit tasked with conducting those inspections was later formed in 2015.

Recreational marijuana legalization required more robust regulatory oversight

In 2014, Oregon voters approved Measure 91 to legalize the production, sale, and use of recreational marijuana. In a 2017 letter to the United States Attorney General, Governor Kate Brown affirmed that Oregon's regulatory framework for the state-sanctioned marketplace met the Cole Memo's standards for preventing diversion and promoting public safety and health.

The Governor highlighted several controls the state had implemented for tracking marijuana, such as security systems for facilities, grow limits, and a "robust testing regime." These controls, as well as the state agencies responsible for their implementation, are authorized in state law. The law defines Oregon's entire regulatory structure, including provisions for preventing out-of-state diversion and requiring testing.⁴

OLCC was tasked with overseeing and implementing preventative controls for the recreational marijuana market, while OMMP retained responsibility for the medical side. Since then, numerous legislative changes have increased both OLCC and OMMP's oversight authority, but have also posed a challenge for these regulatory agencies.

OLCC and OHA, charged with marijuana regulation, face challenges from rapid legislative changes in an emergent and dynamic market

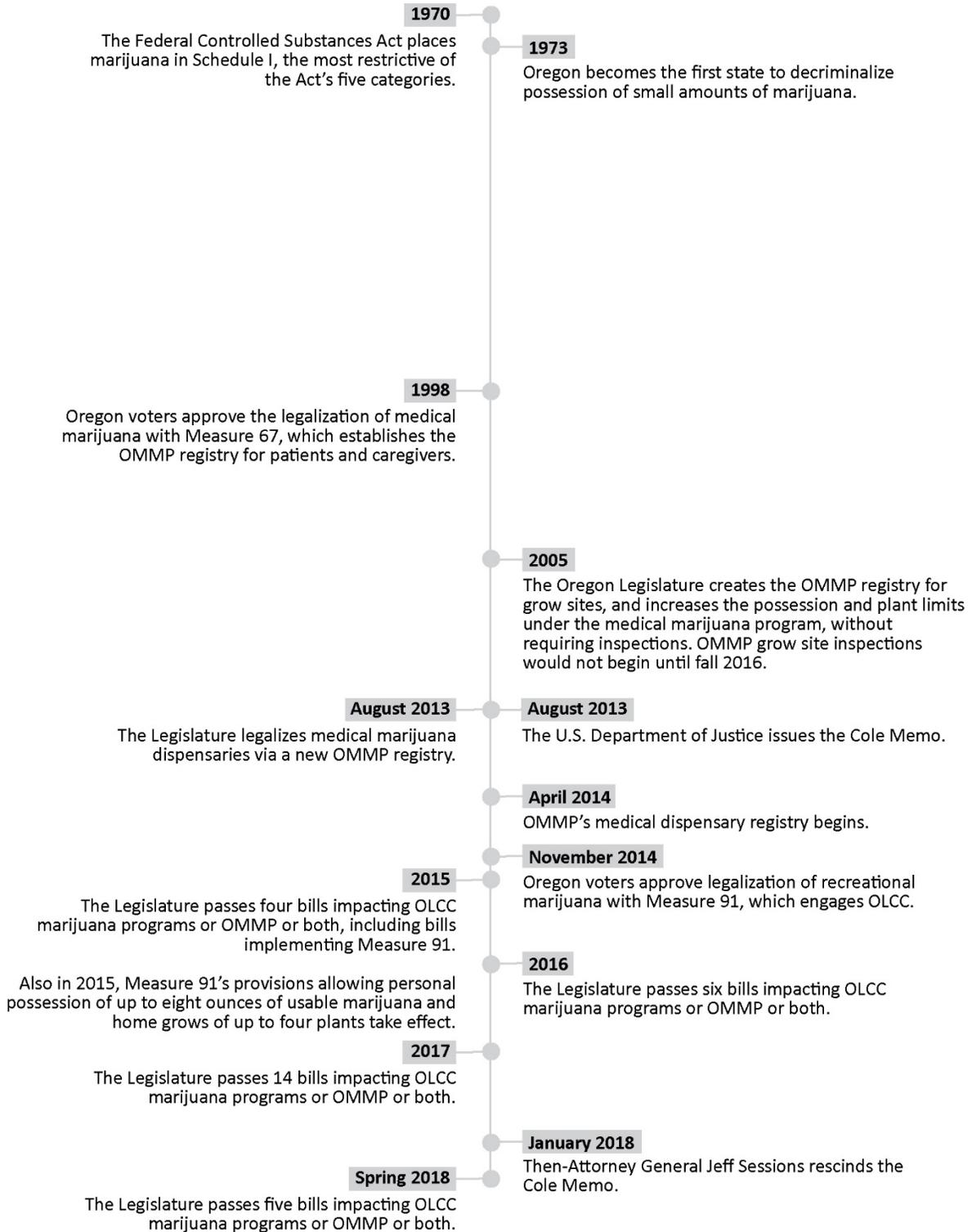
OLCC is responsible for regulating recreational marijuana

OLCC's authority includes licensing, investigating, and rulemaking for the production, processing, and sale of recreational marijuana. The agency also oversees the distribution and sales of all distilled spirits in Oregon.

Governed by a seven-member Board of Commissioners, the agency consists of three major operational programs: the Distilled Spirits Program, the Recreational Marijuana Program, and the Public Safety Program. OLCC employs 304 staff with roughly 59 assigned exclusively to marijuana licensing, enforcement, and program administration as of 2018. However, many other OLCC employees not exclusively assigned to recreational marijuana also help manage and support the program.

⁴ Oregon Revised Statutes Chapter 475B.

Figure 2: Marijuana regulatory milestones for Oregon, 1970 – 2018



The Recreational Marijuana Program is exclusively authorized to allow recreational marijuana sales to consumers through retail stores. The program also tracks the growing, transporting, processing, and selling of recreational marijuana products. The Public Safety Program is responsible for licensing and regulating both liquor and recreational marijuana in Oregon. Senate Bill 1057, passed in 2017, resulted in the Medical Marijuana Tracking Program,

OLCC Licensing Fees

For the 2017-19 biennium, the agency expects to collect about \$19 million in licensing fees.

responsible for administering tracking and inspections of medical marijuana dispensaries, processors and certain growers as discussed further below.

As of October 2018, OLCC had a total of 2,038 active licenses, made up of retailers, producers (growers), processors,

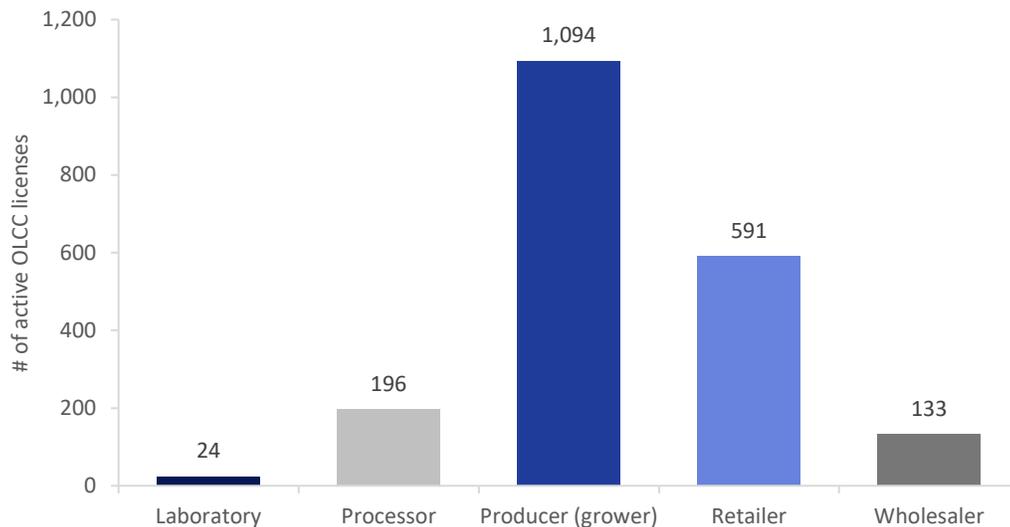
wholesalers, and testing laboratories. Growers make up the largest group, at 1,094 active licenses.

Figure 3: Definitions for OLCC marijuana license types

License type	Definition
Producer	Also known as a grower; may grow marijuana outdoors, indoors, or both.
Processor	A business that transforms the raw marijuana into another product (topicals, edibles, concentrates, or extracts).
Wholesaler	A business that buys in bulk and sells to licensees rather than to consumers.
Retailer	A business that sells directly to consumers.
Laboratory	A lab that tests marijuana based on rules established by OHA and is accredited by the Oregon Environmental Laboratory Accreditation program (ORELAP). All labs licensed in Oregon are private sector businesses.

OLCC collects approximately \$1.4 billion in revenue per biennium, with 95% resulting from distribution of distilled spirits. After accounting for agency expenditures, inventory purchases, and liquor agent compensation, about \$327 million of alcohol revenue is remitted to the state General Fund, while approximately \$229 million is allocated to cities and counties.

Figure 4: The bulk of OLCC's active licenses are for growers, otherwise known as producers



Note: Numbers current as of October 2018.
Source: OLCC.

OLCC's recreational marijuana program is solely funded by fees and fines paid by marijuana licensees. For the 2017-19 biennium, the agency expects to collect about \$19 million in licensing fees. The agency also receives up to \$1.25 million in marijuana tax revenue per quarter to cover

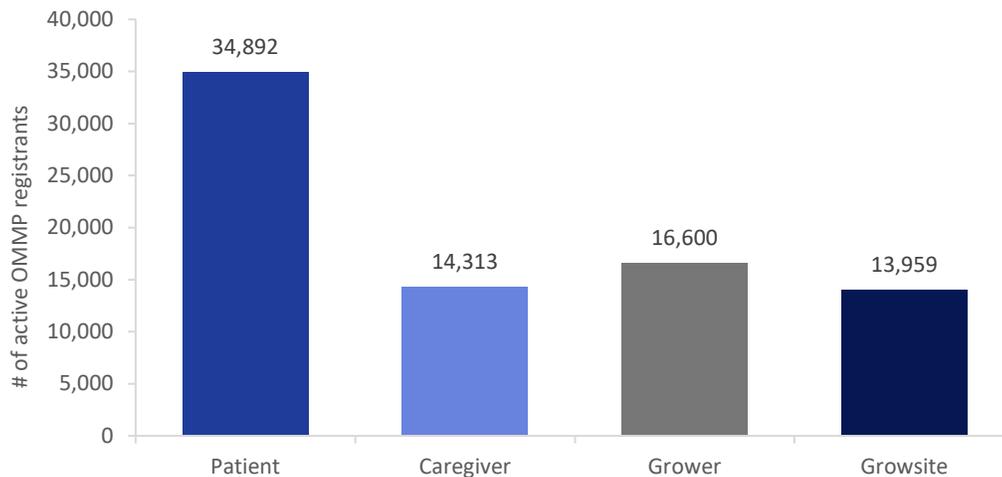
tracking and inspection costs for some medical growers. Apart from licensing fees, no agency revenue is dedicated to marijuana licensing or compliance efforts.

OHA oversees Oregon’s medical marijuana program and testing

OMMP registers and regulates medical marijuana patients, caregivers, dispensaries, processors, growers, and grow sites. OMMP’s Compliance unit works to ensure compliance with statutory and administrative requirements for program participants by conducting site visits and investigating complaints. As of December 2018, the compliance program included four permanent Compliance Specialist positions and four limited duration staff positions. The program also administers the Oregon Medical Marijuana Online System, a database for reporting and tracking the production and transfer of medical marijuana products, as well as a database for recording registrants.

As of October 2018, OMMP had a total of 65,805 registrants and 13,959 registered grow sites.

Figure 5: Patients still make up the largest group of OMMP active registered cardholders



Note: Numbers current as of October 2018.
Source: OHA.

OMMP is housed within OHA’s Public Health Division, Center for Health Protection, which has a biennial budget of \$5.5 million, a very small percentage of the \$17 billion OHA budget. OMMP is funded through a combination of General Fund dollars (\$250,000 per biennium for administering the Oregon Cannabis Commission) and card registration fees. Declining enrollment directly impacts funding. Fiscal Year 2018 actual and projected net revenues were about \$12.4 million, but costs are projected to exceed revenues in Fiscal Year 2019. The program is expected to operate at a \$4.6 million deficit in Fiscal Year 2019, of which roughly \$3.6 million is due to legislation directing OMMP funds to support other public health programs.

In addition to managing OMMP, OHA also promulgates marijuana testing rules, setting requirements for testing, labeling, and dosage of all recreational and medical marijuana products. Another OHA program, Oregon’s Environmental Lab Accreditation Program (ORELAP), accredits qualified marijuana laboratories for testing marijuana. ORELAP’s main work consists of accrediting over 150 environmental laboratories in Oregon, other states, and several countries, with drinking water safety considered a main priority. ORELAP receives funding from the EPA to perform accreditations of drinking water labs. Marijuana labs pay a fee to undergo a biannual assessment as part of the accreditation process. No additional federal or state funding has been made available to assess and audit marijuana labs. The program includes just five staff,

OMMP deficit

OMMP is expected to operate at a \$4.6 million deficit in Fiscal Year 2019.

which devote part of their time to marijuana accreditation. While ORELAP accredits labs, OLCC is responsible for licensing labs for marijuana testing. Labs must be accredited for specific marijuana tests in order to obtain an OLCC license.

OHA and OLCC also work with the Oregon Department of Agriculture on issues related to the use of pesticides. Both agencies can make referrals to the Oregon Department of Agriculture when test results reveal the potential use of illegal pesticides by medical and recreational growers.

The Department of Revenue manages marijuana sales tax collections and distributions

The recreational marijuana system in Oregon is expected to generate over \$540 million in sales in 2018. Recreational marijuana sales are subject to a 17% tax, administered and collected by the Oregon Department of Revenue. Cities and counties can also vote to place an additional local sales tax of up to 3% on recreational marijuana. From January 2016 to November 2018, the Department of Revenue collected approximately \$207 million in state tax revenue from retail sales. By law, all state marijuana tax revenue is distributed using the following formula:

- 40% to the State School Fund;
- 20% to the Mental Health, Alcoholism, and Drug Services Account;
- 20% to cities and counties;
- 15% to Oregon State Police; and
- 5% to OHA, for drug treatment and prevention.

When the recreational marijuana program first started, OLCC loaned \$1.5 million in funding from its liquor program to help cover startup costs until enough license fees were received to fund the program. That loan was paid back from state marijuana tax revenues, meaning the first of those tax revenues collected went for that purpose. This requirement contributed to a delay in the distribution of funds to schools and the other groups required under the law until 2017.

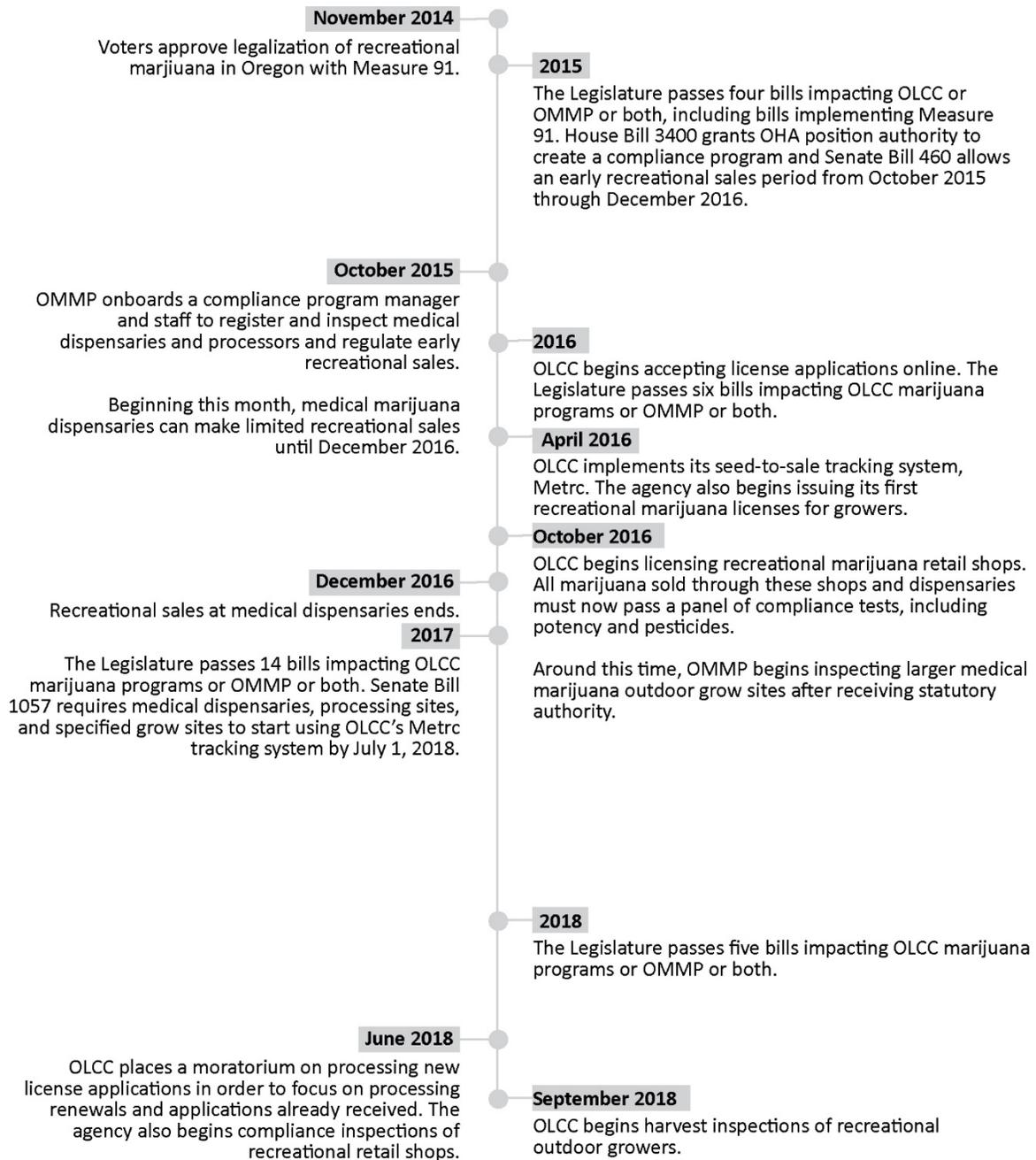
The Department of Revenue requires licensed retail shops to file marijuana tax returns every quarter. Retailers are also required to make monthly deposits of the taxes they have collected. According to the Department of Revenue, about 60% of deposits are made in cash.

Other than the small amount of ongoing tax revenue that goes to OLCC to cover the cost of including some medical growers in its Metrc tracking system, no marijuana tax revenue is dedicated to recreational marijuana compliance or licensing.

Since recreational marijuana was legalized, OLCC and OMMP have faced frequent legislative changes and a rapidly expanding recreational retail market

Between 2015 and 2018, the Legislature passed numerous bills expanding the oversight authority and responsibilities of OLCC and OMMP, and modifying the requirements for market participants that both agencies regulate. For both agencies, implementation of many of these bills required extensive rulemaking, creation of policies and procedures, substantial technology changes, and a variety of related tasks. Changes in the law also imposed tight deadlines, providing little time for implementation.

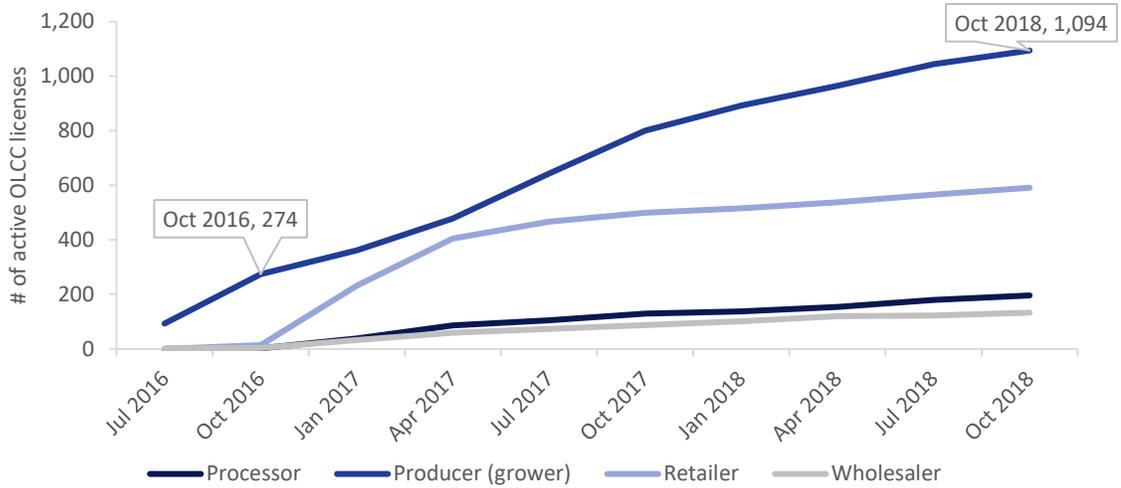
Figure 6: Recent legislative changes and agency implementation milestones, 2014 – 2018



Following recreational marijuana legalization in 2014, the Legislature allowed medical dispensaries to sell limited amounts of marijuana and marijuana products to recreational customers until OLCC had developed its recreational licensing system. Per OMMP, this early retail sales period, which lasted from October 2015 through December 2016, incentivized profit-seeking businesses to register, increasing medical dispensary and processor registrations until OLCC began issuing recreational licenses. In an assessment released in May 2018, OMMP reported that their compliance program was not sufficiently staffed to review the influx of dispensary and processor applications, and address compliance issues.

Since OLCC began issuing recreational licenses in 2016, the number of all types of active OLCC licensees has trended upward, with growers increasing most significantly as shown in Figure 7. In October 2018, there were a total of 1,094 active OLCC grower licensees, up almost 400% from 274 in October 2016.

Figure 7: Since OLCC began issuing licenses in 2016, the number of active processor, producer, retailer and wholesaler licenses has trended upward



Source: OLCC.

OLCC implemented “seed to sale” tracking for both markets

Statute requires that all recreational marijuana legally produced in Oregon be tracked. OLCC uses Metrc, a proprietary “seed to sale” system that captures data showing the entire “chain of custody” of a marijuana plant from when it was still a seed through the final retail sale to consumers. This virtual tracking, combined with identification tags on the marijuana itself, camera coverage of licensed facilities, and OLCC inspections to verify inventory levels, is intended to help prevent diversion by accounting for marijuana at all stages of production.

Starting in July 2018, tracking in Metrc was extended to all medical dispensaries and processors, as well as all medical grow sites growing for three or more patients. OLCC’s Medical Marijuana Tracking Program now has authority to administer the tracking and to perform compliance inspections of these medical grow sites, though OHA retains the authority to address violations. OLCC and Governor Brown have characterized this medical marijuana tracking in Metrc as an important step for preventing diversion from the medical market.

Oregon’s persistent black market heightens the importance of preventive controls

According to law enforcement and news reports, black market marijuana prices in states without a legal recreational market are several times higher than prices in Oregon’s legal market, creating compelling profit incentives for the diversion of both illegally grown marijuana and marijuana from Oregon’s legal recreational and medical systems. Oregon’s total marijuana production is unknown and difficult to determine, largely due to black market production and the state’s still emergent tracking of the legal market. The legality of homegrown marijuana further complicates production estimates. However, the industry has flourished, with the volume produced estimated to significantly exceed local consumption.

The Oregon-Idaho High Intensity Drug Trafficking Area (HIDTA) program⁵ released a report⁶ in August 2018 providing rough estimates of marijuana production and consumption in Oregon,

⁵ The Oregon-Idaho High Intensity Drug Trafficking Area (HIDTA) program, established by the White House Office of National Drug Control Policy (ONDCP), consists of 14 counties and the Warm Springs Indian Reservation. The program is committed to facilitating collaborative drug control efforts among law enforcement agencies and community-based organizations and reducing the impact of illegal trafficking and use of drugs throughout Oregon and Idaho.

⁶ “An Initial Assessment of Cannabis Production, Distribution, and Consumption in Oregon 2018 – An Insight Report.” Oregon-Idaho HIDTA, August 16, 2018. Accessed at <http://oridhidta.org/cannabis-production-distribution-consumption-assessment/>

based on an analysis of data from OLCC, law enforcement, and other indicators. The study estimated that Oregon can produce between 440,000 and 911,500 kilograms of marijuana annually — up to roughly two million pounds. Consumers in the state are estimated to use between 84,000 and 169,000 kilograms a year. However, these consumption estimates are based on surveys of marijuana users, so actual use among Oregon residents could be considerably higher or lower.

Marijuana production estimate

Oregon-Idaho HIDTA estimates that Oregon can produce between 440,000 and 911,500 kilograms of marijuana annually.

Additionally, a decline in marijuana prices in Oregon has made profitability challenging for some growers and retailers. Per OLCC,⁷ the substantive number of licensed retailers have driven down prices, as evidenced by a significant decline in average price per gram for usable marijuana (marijuana flower) — from \$9.73 in October 2016 to \$4.62 in June 2018. Low prices make it challenging for some licensed growers to earn a profit on the marijuana they have grown, which could cause some growers to try to recoup their profits by selling their marijuana in other states where marijuana is still illegal and prices are higher.

OLCC has already had experience with diversion to the black market. In September 2018, the agency revoked a recreational grower's license in response to 13 compliance violations, which included misrepresenting marijuana information in the state's tracking system. Two of the licensee's plants reported as destroyed were found at a residence where a butane explosion had occurred earlier in the year, linking the grower to black market activity. OLCC suspended the license of a processor, as well, after its investigation of potential license violations and the arrest of a managing member of the business in November 2017 for attempting to deliver marijuana in Nebraska.

HIDTA reports that between July 2015 and January 2018, approximately \$48 million worth of marijuana believed by law enforcement to have possibly originated in Oregon was apprehended in 37 states. In August 2018, six individuals not licensed by OLCC were charged for their parts in two large interstate conspiracies to traffic marijuana grown in Portland to three other states.

Another black market problem relates to the unlawful and unregulated marijuana extraction performed at unlicensed processing facilities, which endangers public safety. Butane, an inexpensive and flammable solvent, can be used to extract THC from marijuana plants to make hash oil.⁸ In improperly ventilated areas, the solvent easily ignites. The Oregon State Police's Drug Enforcement Section has witnessed a dramatic increase in the number of clandestine butane hash oil labs. From July 2015 through January 2018, law enforcement discovered 64 unlicensed marijuana extraction labs, and during the same period, the Legacy Oregon Burn Center treated 71 victims of burns from butane hash oil. According to news reports, one 2017 explosion destroyed two homes in Portland and caused two deaths.

Marijuana testing is critical for protecting public health and consumer interests

Marijuana and its products can become contaminated and must be tested to protect public health. Current state testing requirements are intended to ensure products for sale are reasonably safe and have accurate potency levels. However, as state regulations for marijuana

⁷ OLCC 2019-2021 Agency Request Budget, accessed at https://www.oregon.gov/olcc/docs/Budget/Legislative_Budget_19_21/2_Agency_Summary.pdf

⁸ Butane hash oil is a concentrated form of marijuana involving a process that uses butane to extract THC and other cannabinoids from marijuana leaves and flowers. For more information, see "What is butane hash oil or BHO? Definition of popular marijuana terms." Oregonian, May 12, 2014. Accessed at https://www.oregonlive.com/marijuana/index.ssf/2014/05/butane_hash_oil_glossary_of_te.html

testing have developed in Oregon, independent investigations by Portland newspaper *The Oregonian* found persistent contamination in marketed marijuana products.

Marijuana cultivation and processing methods make it susceptible to contamination

Marijuana grows operate on a wide spectrum of sophistication. Some grows are tightly controlled in technologically advanced indoor facilities; plants are grown in climate controlled chambers where every aspect of the plant's cultivation is monitored. Other grows are comparatively "low-tech," often set outdoors and dependent on seasonal cycles.

After harvest, marijuana is dried and divided into batches. Batches are then divided up and may be sold as flower or processed into edibles and other derived products before being sold in retail shops all over the state. Processing often involves the use of solvents to extract or concentrate the active ingredients from marijuana.

Marijuana cultivation, both indoor and outdoor, is associated with a variety of pests, bacteria, and fungi. Growers have used a wide variety of pesticides to ward off insect infestation. Pesticide misuse poses serious health risks to consumers. Exposure may cause a host of symptoms, such as difficulty breathing, abdominal pain, vomiting, dizziness, and muscle cramps; some pesticides are potentially carcinogenic.

Marijuana and its products can also be contaminated with microbiological contaminants,⁹ such as mold or salmonella, potentially hazardous growth enhancers, and even heavy metals such as chromium and lead. While marijuana in any form is prone to contamination, extracts and concentrates may present a greater risk as any contaminants will become concentrated during processing.



Climate controlled grow chambers used by a large indoor facility.

To protect consumers against exposure to pesticides, solvents, and other contaminants, marijuana and marijuana products are tested to ensure they are reasonably safe for consumption.

Batches are tested for THC and CBD potency and screened for specific contaminants. This testing may happen at different points along the seed-to-sale route; raw flower may be tested shortly after being dried, and processed batches are tested after the extract or concentrate has been made. All marijuana products must be tested prior to being transferred to retail facilities.

Inaccurate testing prefaces OHA's expanding responsibilities

An investigation in 2015 by *The Oregonian* claimed to identify a number of potentially harmful pesticides in marijuana products that had cleared mandated testing and were being sold at medical dispensaries.¹⁰ The newspaper reported that independent labs they commissioned to perform blind testing found 14 pesticides on 10 marijuana extracts. Most of the pesticides were considered potential carcinogens and either exceeded the state's permitted levels or were excluded from pesticide regulation. A separate investigation by *The Oregonian* earlier that year also claimed to discover discrepancies between the THC levels advertised on the labels of

⁹ Microbiological contamination is the introduction of microbes, such as bacteria, fungi, viruses, and other toxins to products.

¹⁰ "A tainted high." *Oregonian*, June 11, 2015, accessed at <https://www.oregonlive.com/marijuana-legalization/pesticides/#>

edibles and levels found in lab re-testing.¹¹ While testing allows for a margin of error, some of the labeled potency results were substantially higher or lower than advertised.

The discovery came only a couple of years after the legalization of medical dispensaries, when the Legislature first introduced requirements for marijuana testing, specifically for mold, mildew, and pesticides in products sold in medical marijuana dispensaries. At this time, only a few legitimate marijuana testing companies existed in Oregon. Apart from the limited state testing requirements for the marijuana products sold at medical dispensaries, lab procedures and practices for marijuana testing remained largely unregulated. In addition, the news media reported that a “cottage industry” of marijuana testing had emerged across the state and nation.

In the wake of recreational marijuana legalization, the Legislature expanded OHA’s role to set testing requirements for all medical and recreational marijuana sold in Oregon. OHA convened a workgroup in 2015 to make recommendations for specific marijuana testing and tolerance levels. Because marijuana is federally illegal, there are no pesticides that have been explicitly approved for use by the U.S. Environmental Protection Agency (EPA), which means that recommendations are needed at the state level. Many of the pesticides used in Oregon are known to be unsafe for human consumption above a certain threshold.

The workgroup created a list of high-risk pesticides and solvents known to be used during marijuana cultivation and processing. Action levels¹² for these chemicals were set for marijuana testing labs based on the smallest amount of particulate that labs could be expected to detect with their equipment. All but two of the high-risk pesticides are illegal to use on marijuana. The following year, in the lead up to implementing statewide marijuana testing requirements, the Oregon Department of Agriculture created a guide list of pesticides that are not illegal for Oregon’s marijuana growers to use.

Starting on October 1, 2016, all marijuana sold through retail shops and dispensaries was required to pass a panel of compliance tests that included potency and pesticides. As of that date, only two labs had been accredited, though 17 more were accredited by December 2016.

Despite additional controls, a 2017 media investigation of marijuana products sold by Portland retail stores claimed to have found unacceptable levels of pesticide contamination in three out of 10 sampled extracts. The resulting article stated that all the extracts had previously passed state mandated testing.¹³

Testing requirements now cover both recreational and medical marijuana for sale

All marijuana and derived products for sale in Oregon are now required to be tested for potency and a range of contaminants to protect public health. The purpose of state-mandated testing is to ensure product on retail and medical dispensary shelves is safe and states accurate potency levels. Currently, OHA testing requirements include THC and CBD potency, 59 pesticides considered high risk, 24 solvents potentially used during processing, and moisture content and water activity levels. Water Activity tests typically measure the partial vapor pressure of water in a substance and are used to assess the risk for microbial growth. OHA and OLCC can also order random testing for microbiological

Oregon marijuana labs

In Oregon, 22 labs were accredited and licensed to perform marijuana compliance testing as of October 2018.

¹¹ “How potent are marijuana edibles? Lab tests yield surprising results.” Oregonian, June 4, 2015, accessed at https://www.oregonlive.com/marijuana/index.ssf/2015/03/how_potent_are_marijuana_edibl.html

¹² The established action level marks tests as having failed (for pesticides and solvents) and should trigger a response from OLCC or OHA once they have been alerted of the failed test result.

¹³ “Testing marijuana for pesticides: How we did it.” Oregonian, June 7, 2017, accessed at https://www.oregonlive.com/marijuana/index.ssf/2017/06/testing_marijuana_for_pesticid.html

contaminants, such as E. coli and salmonella, and heavy metals like lead and arsenic, though those tests are not currently required.

In Oregon, 22 labs were accredited and licensed to perform marijuana compliance testing as of October 2018. These labs, like other licensees, are private sector businesses and work directly with growers, processors, and other licensees that are licensed by OLCC or registered with OMMP. Labs perform every step of testing, including collecting and processing samples, performing compliance tests, and reporting those results to their clients.

All test results for recreational marijuana are required to be tracked in Metrc and reported to OLCC, and all marijuana in the recreational system must be tested.

Testing in the medical marijuana program is comparatively limited. Medical product that enters the commerce stream through the small number of remaining medical dispensaries and processors must be tested, and failed test results are required to be reported to OHA. However, usable marijuana transferred directly to patients from growers is not required to be tested.¹⁴

When pesticides and solvents are detected above the action level by a marijuana testing lab, the test is counted as a failure. Tests that fail for solvents can be remediated; the extract or concentrate batch will be reprocessed to remove the solvent, then retested. However, in most

Why do we test for THC and CBD?

THC (tetrahydrocannabinol) is the principal psychoactive constituent in marijuana. This is the component that produces a 'high' and may affect motor skills and other cognitive functions in users.

CBD (cannabidiol) is a compound considered by many to have a range of medicinal benefits. It is not intoxicating and may prevent seizures and nausea, and provide pain relief.

cases, batches of usable marijuana that fail for pesticides cannot be remediated, though retests can be performed to verify the results. The Oregon Department of Agriculture is alerted after a pesticide testing failure and may perform an investigation of the originating grower. Marijuana batches with pesticide contamination must usually be destroyed by the grower if remediation is not possible.

All items for sale from a retailer or medical dispensary must include documentation of passing test results. Medical growers serving patients, patients growing for themselves, and home growers among the general population are generally exempt from testing requirements. They may cultivate and use product that has not undergone any compliance testing.

¹⁴ Medical growers using Metrc that choose to have their product tested are required to have those test results entered into Metrc.

Objective, Scope, and Methodology

Objective

This audit had two objectives. The first was to determine whether Oregon has adequate controls in place to deter diversion of marijuana from the recreational and medical systems to the black market. Our second objective was to determine whether the State is adequately overseeing marijuana testing to ensure test results are accurate.

Scope

This audit focused on controls related to marijuana diversion and laboratory testing in OLCC's recreational marijuana program and OMMP managed by OHA, as well as marijuana laboratory accreditation policies and procedures in ORELAP, which is also part of OHA.

Methodology

To address our objectives, we used a methodology that included, but was not limited to: conducting interviews, analyzing marijuana tracking and laboratory testing data, and reviewing documentation.

We conducted interviews with OLCC's executive director, other directors and managers, policy and data analysts, licensing staff, and inspectors. We also met with managers, inspectors, and assessors with OMMP and ORELAP.

To learn about the views, opinions, and perspectives of stakeholders, we met with managers or staff from the Oregon Department of Agriculture, Oregon Association of Counties, the Governor's Office, the City of Portland, the chair of the Oregon Cannabis Commission, and other stakeholders. We also met with attorneys and officers from law enforcement agencies, including the United States Attorney for the Oregon District, Oregon State Police, Oregon-Idaho High Intensity Drug Trafficking Areas program, and several local law enforcement agencies around the state. Additionally, we met with industry representatives and advocacy groups, such as the Oregon Cannabis Association, Compassionate Oregon, and some OLCC license holders.

To gain an understanding of internal controls for diversion and laboratory testing, we reviewed state laws and administrative rules, as well as policies and procedures, inspection checklists, and other control documentation from OLCC, OMMP, and ORELAP. Additionally, we observed some OLCC and OMMP compliance inspections, and observed an accreditation assessment at a marijuana laboratory with an ORELAP assessor. To look for indications of diversion or problems with laboratory testing, we requested and analyzed marijuana tracking data stored in OLCC's data tracking system, Metrc, for the period of January 2017 to July 2018. We concluded that Metrc data on adjustments were not reliable enough for our purposes, based on our audit objectives, as errors in the data make it difficult to use in aggregate to identify diversion. We have made recommendations that address these data errors. While the Metrc data on marijuana lab testing included some outliers, we concluded it was reliable enough for our purposes, based on our audit objectives.

To gain an understanding of practices in other states, we interviewed and surveyed state officials and reviewed supporting documentation from the following states: Washington, California, Colorado, Nevada, Michigan, Maryland, and Rhode Island.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions

based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

We sincerely appreciate the courtesies and cooperation extended by officials and employees of OLCC and OHA during the course of this audit.

Audit Results

OLCC has made progress implementing a regulatory structure for recreational marijuana, but data errors and a lack of inspections hamper the agency's ability to deter diversion. With no authority to cap licenses and only a short period to establish rules and begin licensing, the agency was overwhelmed by rapid market growth and unable to gradually increase staff, licenses, and inspections to the levels required for adequate oversight.

In contrast to OLCC, OMMP has only a minimal regulatory structure in place, which greatly increases the risk of diversion. The program lacks the authority to require medical growers to implement more controls, has few inspectors, and is hindered by dropping fee revenues and high turnover among inspectors. By addressing their regulatory gaps, OLCC and OMMP could forestall additional federal scrutiny and benefit public health and safety in Oregon.

Oregon's marijuana testing regime has evolved since the advent of legal recreational marijuana. Current testing requirements address some public health risks, but do not address others, like those that can be caused by heavy metals and some microbiological contaminants. While all retail marijuana must pass compliance testing, there is no mechanism in place for verifying the accuracy of test results produced by private labs. Both OHA and OLCC have the authority to conduct random testing to confirm test results, but no action has yet been taken to perform such testing.

Oregon's lab accreditation program can do more to ensure that labs meet and maintain accreditation standards to safeguard public health. Not all active labs are fully accredited for the full spectrum of testing responsibility, and when issues arise that threatens a lab's accreditation status, ORELAP struggles to respond quickly and effectively.

Though OLCC has made progress developing its recreational marijuana regulatory program, weaknesses exist that could increase the risk of diversion

While OLCC has implemented security, surveillance camera, and marijuana tracking requirements, accuracy errors in the tracking data make it difficult to use in aggregate to identify potential compliance problems or diversion. After marijuana businesses are licensed, proactive compliance and harvest inspections are used to verify that licensees' inventories match what they have entered into the tracking system. However, only 3% of retailers and 32% of growers have received a proactive inspection or harvest inspection, respectively, though OLCC reports that inspectors visited most licensees in 2018.

Since marijuana licensing began in 2016, OLCC has received many more license applications than forecasted. As a result, staffing and inspections have lagged. OLCC's data system also contains few controls to prevent errors, and the agency has not set inspection goals or reviewed inspector workloads to determine if they have enough inspectors.

OLCC has made progress establishing a regulatory framework for recreational marijuana

Since Measure 91 passed, OLCC has been developing the rules governing how recreational marijuana is produced and sold in Oregon. However, because only Washington and Colorado had legalized recreational marijuana before Oregon, OLCC had few examples on which to model its regulatory program and no established best practices to follow.

Many of the rules and controls OLCC has put in place help reduce the risk that recreational marijuana licensees will divert marijuana to the black market, either in Oregon or in other states. There are three key regulatory components to help prevent diversion: surveillance cameras, seed-to-sale tracking, and compliance inspections. When agency staff or inspectors observe

anomalies in a licensee's tracking data, they can inspect the licensee's property and inventory, and use surveillance camera footage to observe what was happening at the licensee's facility when the anomalies occurred. In this way, these components all work together to deter diversion by licensees.

Surveillance cameras and security systems. Like other states with legal recreational marijuana, OLCC requires all licensed businesses to have properly functioning security equipment in place, including:

- surveillance cameras that cover all entrances and rooms;
- battery backup capable of powering surveillance cameras for at least an hour;
- storage capacity for at least 90 days of camera footage, kept in a separate room with limited access;
- actively monitored alarm systems, with sensors on all exterior doors and windows; and
- commercial grade doors and locks.

OLCC inspectors conduct pre-license inspections to ensure that license applicants meet all security and surveillance camera requirements — as well as many other requirements — before they can begin operating as licensed OLCC businesses.

Seed-to-sale tracking system. OLCC uses Metrc to track all marijuana in the recreational system from its beginning as a seed or immature plant to the point when it is sold in a licensed retail shop. Colorado, Nevada, and Maryland, among other states, also require their licensees to track their marijuana products using Metrc. This tracking system allows OLCC to see the origin and destination of all marijuana in the recreational system. Gaps or anomalies in a licensee's tracking data could indicate product that has been diverted out of the regulated system.

Starting in July 2018, OLCC began sending out automated email warnings to licensees when information they entered into Metrc appears to indicate a violation of certain OLCC rules, such as selling more product to an individual than is allowed under the law. These email warnings are sent once a day and include any and all potential rule violations that have been flagged by the system. As of October 2018, OLCC had also hired additional data analysts to help review and make sense of the large volume of data contained in Metrc. These staff are working on creating data “dashboards” for each regional office that highlight licensees whose Metrc data appears to contain a relatively higher number of potential violations. These dashboards are being designed to give regional compliance managers a quick snapshot of these licensees so inspectors can prioritize them for follow-up visits or inspections.

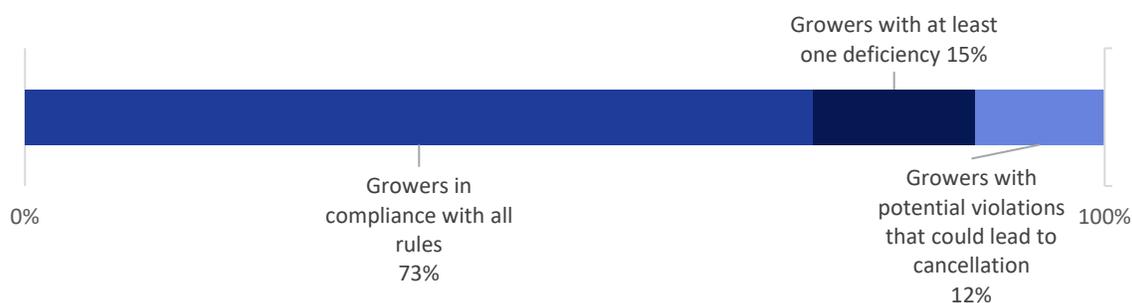
Compliance inspections. Inspectors recently began conducting proactive compliance inspections of some licensees. Also known simply as proactive inspections, they are performed at facilities that already have a license, to determine whether the licensee is still in compliance with OLCC rules. Facilities are proactively chosen for inspection based on their Metrc tracking data. Compliance inspections are similar to pre-license inspections in that they verify facilities have all required security equipment in place and that these systems are still in working order. However, in a proactive inspection, inspectors also review a sample of a licensee's inventory to ensure that marijuana plants and products on hand match what the licensee has entered into the Metrc system. Compliance inspections were a prominent regulatory feature in other states we spoke with.

We observed five proactive inspections of retail shops. Inspectors followed prepared inspection checklists to see that security systems, surveillance cameras, and battery backup systems were functioning properly. They also reconciled a sample of marijuana products against licensees' inventories in Metrc, reviewed product labels, and checked that all products had correct Metrc ID tags. Each of the inspections we observed had some deficiencies identified, including discrepancies between Metrc tracking data and product on hand.

Because the risk of diversion increases during harvesting, OLCC has also begun conducting harvest inspections during the outdoor harvest season, typically September and October each year. When outdoor growers are ready to harvest, OLCC requires them to notify the agency through Metrc. Those notifications are routed to a regional compliance manager, who then assigns inspectors to conduct unannounced inspections at a portion of the growers that are harvesting. Other than their timing, the agency describes these inspections as similar to proactive inspections. However, according to OLCC, harvest inspections provide the best “bang for the buck,” as inspectors are able to conduct many inspections over a short period of time, all at a point in the process when the risk of diversion and other compliance violations are high.

For 2018, OLCC conducted 354 harvest inspections across the state, equal to 32% of all 1,094 licensed growers and 56% of the 628 outdoor and mixed outdoor-indoor growers as of October 2018. About three-fourths were in compliance with all rules, and roughly a quarter had at least one deficiency, though some had potential violations that could result in license cancellation.

Figure 8: While most licensed growers that received a harvest inspection were in compliance with all OLCC rules, a small percentage had violations that could lead to license cancellation



Source: OLCC.

In addition to proactive and harvest inspections, OLCC inspectors are also in contact with licensees for other types of compliance work. For example, inspectors also perform minor decoy operations to help ensure retail shops are not selling to minors, alteration inspections when a licensee makes a change to a licensed facility, compliance investigations, and pre-license inspections.

Data errors and a lack of performance benchmarks reduce OLCC’s ability to use the Metrc tracking system to help prevent diversion

According to OLCC, the Metrc system tracks marijuana in the legal recreational system and points out red flags and risks in a licensee’s compliance with marijuana regulations. Those red flags and risks could be the result of user mistakes, or they could stem from potential compliance violations, which could range from a minor omissions or misunderstanding of the rules to major violations that result in license revocation. OLCC data analysts can run queries of the Metrc data to pull out those errors for further examination. However, data inconsistencies make it extremely difficult to differentiate errors or mistakes from potential compliance violations when reviewing the data in aggregate.

For example, we reviewed 12 months of data on adjustments of marijuana packages¹⁵ tracked in the Metrc system. Adjustments can be made to account for changes in weight due to waste, spoilage, moisture loss, entry error, or various other factors. Because adjustments, like all other data in Metrc, are self-reported by licensees, adjustments are a key way in which a licensee could attempt to falsify their data. The Metrc data we reviewed included 37,550 adjustment records. In

¹⁵ Once a marijuana plant is harvested, the harvested marijuana is separated into different “packages” that are tracked in Metrc.

examining the adjustment data, we found a number of obvious errors in some adjustments. For example, a marijuana testing lab had reported having destroyed 81,273 pounds of marijuana samples — an unlikely amount, given that a sample is generally only a few grams. We also found other examples of adjustments that were logically inconsistent, such as packages with an increase in weight due to waste or spoilage.

While these adjustment errors were relatively easy to identify, without examining individual licensees' data in Metrc, there is no way to know if other adjustments, or even the marijuana packages themselves, are being correctly and honestly tracked in the system. Without looking in-depth at a licensee's data and ultimately reconciling that data back to their inventory on hand through an inspection, it is difficult to tell whether outliers in the data are related to errors or larger compliance issues, such as diversion.

OLCC also has not yet established baselines or other performance measures that can be used to help identify licensees whose Metrc data differs significantly from other similar licensees. However, the agency only has about two and a half years of Metrc data to work with, which along with the data errors and rapid growth in the number of licensees makes it difficult to identify baselines for how licensees' data should look in the system. The data dashboards mentioned previously may represent a first step in that direction.

OLCC's marijuana tracking system contains few controls for preventing data entry errors

Data inconsistencies are due in part to the Metrc system having few automatic checks or controls to prevent users from making data entry errors. According to the agency, Metrc just provides “the rules of the road” for licensees, but does not put up any barriers to prevent them from breaking those rules. However, these data errors, and the resulting adjustments that have to be made in order to correct them, make it difficult to use the data in aggregate to identify potential diversion. Potential data errors can require OLCC to follow up with a licensee, or may even require a visit by inspectors in order to determine whether the licensee just has a problem with their data or if the information in Metrc is pointing to larger compliance problems.

Another potential error source that can make it difficult to work with aggregate-level Metrc data are third party point-of-sale systems.¹⁶ These systems sometimes have problems communicating with Metrc, causing errors that later have to be corrected. We observed proactive inspections at five marijuana retail shops. In three of those inspections, the retailers either mentioned encountering problems with their software communicating with Metrc or inspectors saw discrepancies between the system and Metrc that appeared to indicate a communication issue.

Previous audits in Oregon and Washington, as well as general guidance on data management from the Government Accountability Office (GAO),¹⁷ recommend improvements in data tracking and benchmarking. The Audits Division's information technology audit of OLCC released in February 2018 noted that problems with the reliability of OLCC's Metrc data could hinder the agency's ability to ensure licensees' comply with agency rules.¹⁸ An audit by the Washington State Auditor's Office recommended that Washington's Liquor and Cannabis Board create reasonable data ranges, or benchmarks, to help identify higher risk transactions.¹⁹ GAO's Internal Control Guide affirms the importance of accurate data that can be used for tracking and

¹⁶ Point-of-sales systems help merchants record product sales and track their inventory.

¹⁷ The GAO is an independent, nonpartisan agency within the legislative branch of the federal government that examines how tax dollars are spent and provides objective, reliable information to help government work more efficiently. It also establishes standards for federal and state auditors around internal controls, financial audits, and other types of government audits.

¹⁸ “Cannabis Information Systems Properly Functioning but Monitoring and Security Enhancements are Needed,” Oregon Secretary of State: February 2018, <https://sos.oregon.gov/audits/documents/2018-07.pdf>.

¹⁹ “Improving Cannabis Risk Management Tools Using Business Transaction Data.” Office of the Washington State Auditor: August 2018, accessed at http://www.sao.wa.gov/state/Documents/PA_LCB_Improving_Cannabis_Risk_Management_ar1022033.pdf

monitoring. It recommends that data entry features in government systems be designed in a way that supports data accuracy, and that incorrect data be identified, investigated, and quickly corrected. As noted previously, OLCC also has not yet established benchmarks that can be used to help identify licensees with unusual Metrc data when compared to their peers.

Lack of inspections weakens OLCC efforts to prevent diversion

Because the Metrc system relies on licensees self-reporting their marijuana products and transfers, inspections are essential for ensuring that inventories and transfers of marijuana products are consistently and correctly tracked in Metrc. OLCC staff have noted that inspections are a key enforcement component to help push licensees to remain compliant with the agency's tracking requirements.

Though all licensed businesses are inspected prior to receiving a license, OLCC has lagged in performing proactive inspections once those businesses have opened. OLCC began conducting proactive inspections in June 2018. As of October 2018, the agency had only completed 16 proactive inspections of licensed retail shops, amounting to roughly 3% of the 591 licensed retail shops. OLCC managers are not certain of the total number of retail shops that have been inspected because those inspections have not been tracked consistently. However, they believe a new case management system that rolled out in late 2018 will help with inspection tracking. Additionally, OLCC has not conducted proactive inspections of other licensees, including 196 processors, 133 wholesalers, or 24 labs.

OLCC has conducted proactive inspections at just 3% of licensed retailers

Of the 591 licensed marijuana retailers, only 16 had received a proactive inspection as of October 2018, or 3%. OLCC managers are not certain of the total number of retailers that have been inspected because those inspections have not been tracked consistently.

Growers likely represent Oregon's largest diversion risk among all licensees, given that they are most negatively impacted by the drop in marijuana prices. However, only 354 licensed growers have ever received harvest inspections — just 32% of all 1,094 licensed growers. Furthermore, no indoor growers have had a harvest or proactive inspection. By comparison, other states we contacted conduct regular inspections of all marijuana businesses. For example, Nevada inspects all recreational marijuana licensees annually, and Maryland conducts quarterly inspections of all medical marijuana licensees.

Counting all contacts inspectors had with licensees, OLCC reports having visited roughly 1,290 licensees in 2018, though there is some uncertainty around that number, as contacts with licensees were not consistently tracked until late 2018. The agency also reports having conducted about 400 pre-license inspections in 2018.

OLCC generally has fewer inspectors than other states with recreational marijuana and has not analyzed inspection staffing needs

OLCC may not have enough inspectors to conduct regular proactive inspections, which could affect its ability to deter diversion on the part of licensees.

As of October 2018, OLCC had 23 inspector positions for roughly 2,038 licensees, a ratio of about one inspector for every 88 licensees. Additionally, despite the agency imposing a moratorium on new applications in June 2018, there are still roughly 1,400 pending applications that are ready for pre-license inspections, adding to inspectors' workloads. The agency plans to ask the Legislature for authority to hire eight additional inspectors, to decrease the expected ratio of inspectors to licensees to about one inspector for every 75 licensees, but they do not plan to do so until the next legislative session in February 2019.

Other states have lower ratios of inspectors to licensees, which allows them to inspect licensees on a regular basis. In Maryland’s medical marijuana program, the ratio is 1:8, with all licensees receiving quarterly inspections, though the state has comparatively few licensees.²⁰ Rhode Island inspects licensees twice a year and has an inspector to licensee ratio of 1:11, while Nevada inspects all licensees at least annually and had a ratio of 1:48 as of September 2018.

The GAO’s Internal Control Guide also provides guidance on determining program staffing levels. The guide recommends identifying program objectives that include measurable criteria, assessing performance measures over time, and ensuring adequate staffing.

OLCC managers have indicated a desire to conduct annual inspections of all licensees, as well as annual minor decoy operations at all licensed retail shops to ensure these shops are not selling marijuana to minors. However, that goal has not been formalized. An inspector to licensee ratio of 1:75 could potentially allow OLCC to adequately inspect and monitor its licensees on an annual basis. However, the agency has not analyzed inspector responsibilities and workloads to determine how many inspections each inspector can complete in a year. Without a set goal for how frequently they plan to inspect licensees and an analysis of inspector workloads, agency managers cannot know if they have enough staff to meet that target. OLCC needs to set inspection goals and analyze workloads to determine whether current staffing levels will allow the agency to achieve its desired outcomes.

Depending on the results of OLCC’s analysis, the agency could re-assess recreational marijuana licensing fees if additional revenues are needed to continue building the regulatory structure. State marijuana licensing fee structures can be complex and consist of differing elements making direct comparisons challenging. However, OLCC’s fees are lower than in some other states, as shown in Figure 9.

Figure 9: Oregon’s marijuana licensing fee is low compared to some other states

State	Overall range of licensing fees for all types of marijuana businesses	Retailer license tiered?	New retailer license fee	Annual retailer license renewal fee
Oregon	\$1,000 to \$5,750	No	\$4,750	\$4,750
Nevada	\$10,000 to \$30,000	No	\$20,000	\$6,600
California*	\$135 to \$200,000	Four tiers based on estimated maximum dollar value of planned operation	Ranges from \$4,000 to \$120,000 depending on Tier	Same as initial licensing fee
Washington	\$250 to \$1,480	No	\$1,480	\$1,480

Note: *California licensing fees include both medical and recreational licenses.

Source: State-provided data to audit questionnaire; California data was collected from their website, accessed at <https://cannabis.ca.gov/faqs/>

With a short timeframe to implement a program and no cap on the number of licenses, OLCC initially lacked resources to perform inspections and other core regulatory functions

After the Legislature implemented Measure 91, OLCC had just six months to write all the temporary rules needed to implement the legislation. At the same time, the agency had to borrow both staff and funding from the liquor program to start standing up a regulatory

²⁰ As of August 2018, Maryland had 14 medical growers (capped at 22 licenses), 14 medical processors (also capped at 22 licenses), and 65 medical dispensaries (capped at 102 licenses).

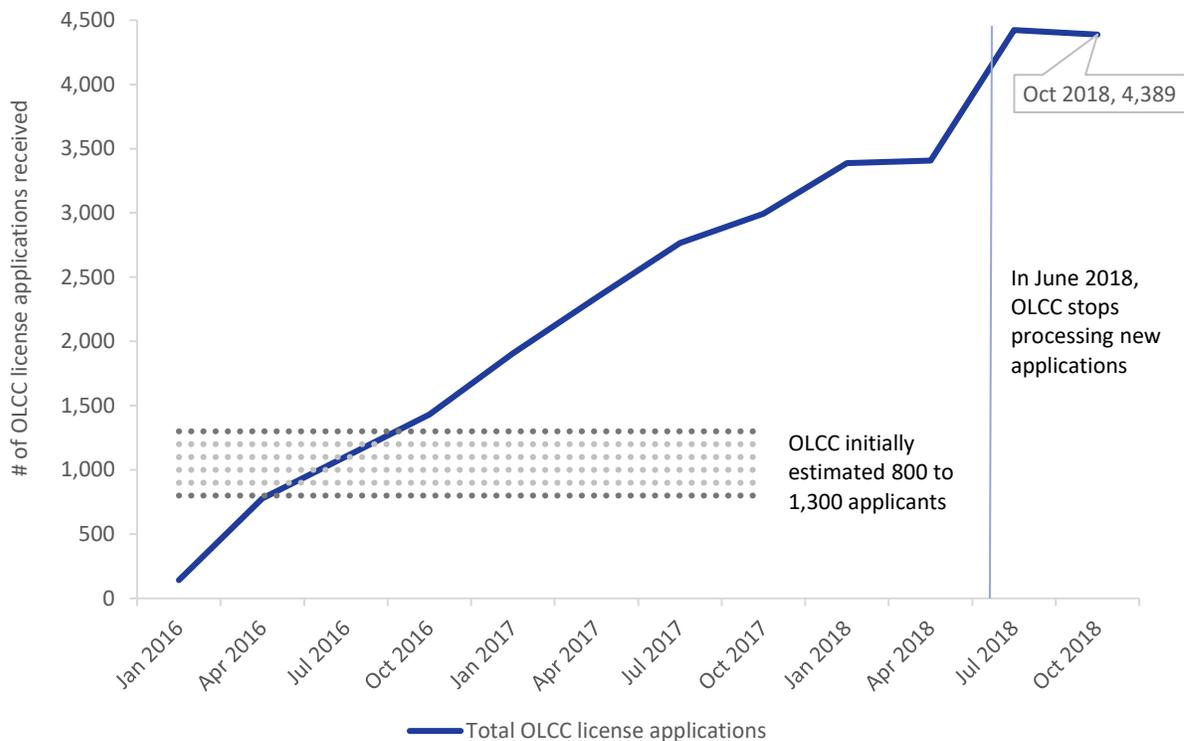
structure for recreational marijuana. At the time, OLCC had not received any funding for the program and had not yet received enough licensing fees to cover the program’s start-up costs.

One factor that complicated the rollout of the recreational marijuana program is that OLCC did not have the authority to limit the number of licensees or number of plants a licensed grower can have. Other legal states, such as Washington and Nevada, have either limited the number of licenses allowed or capped the number of plants some licensees can grow. Although OLCC tried to forecast the number of license applications they expected to get, the agency could not limit those applications in order to allow for a smooth and gradual increase in staffing and implementation of licensing and inspections.

Prior to accepting license applications, the agency forecast that it would license approximately 826 marijuana businesses through the end of the 2015-17 biennium, based on the number of licenses Colorado and Washington issued during the first year of their programs. In actuality, they ended up issuing 1,308 licenses by July 2017, or 58% more than forecast for that period. This resulted in an immediate strain on the program’s ability to comprehensively issue licenses, conduct proactive inspections, and implement other critical elements of the regulatory framework. Overall, the agency had received more than twice as many license applications as they expected to as of December 2017, and that number grew to 4,389 by October 2018, as shown in Figure 10. This volume has required inspectors to conduct more pre-license inspections and prevented them from conducting more follow-up compliance inspections.

Due to workload concerns, the agency put a moratorium on processing any new license applications received after June 15, 2018. OLCC has continued to struggle with processing a high volume of renewal applications while introducing certain OMMP grow sites to Metrc starting in July 2018. These OMMP grow sites also require inspections.

Figure 10: Number of total OLCC applications exceeded initial estimate and has trended upward since 2016



Source: OLCC.

Structural weaknesses within OMMP greatly increase the risk of diversion in Oregon’s medical marijuana program

Only a minimal medical marijuana program regulatory structure has been put in place by OMMP, due in part to statutory limitations. Growers are not required to have security systems or surveillance cameras because the program lacks the authority to mandate them. By statute, less than 10% of medical grow sites are required to track marijuana plants and transfers of product to patients in Metrc, and reporting requirements for other medical grow sites are limited. From January 2017 to September 2018, only 2.9% of medical grow sites received an inspection, due to a combination of decreasing fee revenues, an apparent lack of inspector positions, and personnel issues, including high turnover among inspectors. OMMP also has not set inspection goals or targets for how many inspections should be completed each month.

In contrast to OLCC licensing requirements, OMMP registration requirements for medical marijuana growers are limited

While OLCC is developing a structure for regulating the recreational marijuana system, the medical marijuana program overseen by OHA has few rules or controls in place to prevent diversion to the black market. OHA published an assessment of OMMP in May 2018 that pointed out a number of the program’s weaknesses, including poor data tracking and lack of inspections. Moreover, as shown in Figure 11, the program lacks several other controls required by OLCC and other states.

Figure 11: OMMP lacks many of the grow site registration requirements OLCC has implemented

Registration Requirements	OLCC Recreational Marijuana	OMMP Medical Marijuana
Criminal background checks	Required for all licensees	Required for all grow site administrators
Pre-Registration inspections	Required for all licensees	Not required
Surveillance camera systems with battery backup	Required for all licensees	Not required
Security systems with active monitoring ²¹	Required for all licensees	Not required
Seed-to-sale tracking system	Required for all licensees	Only required for some grow sites

Source: OLCC and OHA.

OMMP does not conduct any inspections before a medical grower is registered and does not require growers to have surveillance cameras with battery backups or either actively monitored security systems or security guards.

Limited tracking of medical marijuana heightens diversion risks

Unlike OLCC licensees, most registered medical marijuana growers are not required to track their plant totals or transfers to patients in Metrc. Of the 13,959 registered grow sites as of October 2018, about 6,230 were smaller home or personal medical grow sites legally exempt from any tracking. Of the remaining 7,729 grow sites, only 879 were required to report in Metrc,

²¹ Not required for licensees that have authorized personnel on site at all times.

or about 11%. There may be additional grow sites that should be tracking in Metrc that are not because the vast majority of them have not been inspected.

In April 2018, OMMP initially identified roughly 2,301 grow sites that needed to begin tracking in Metrc and began an outreach campaign to notify them, including sending letters to each of them. As of July 2018, that number had dropped to 1,320 grow sites, as 800 grow sites reported dropping the number of patients they grow for (which would require a drop in the number of marijuana plants they have on hand) and 181 reportedly left the program. However, OMMP has only conducted inspections of 44 of these grow sites, so the program cannot confirm that they have actually dropped patients or are no longer growing. Of the remaining 1,320 grow sites, 670 had registered in Metrc as of July 2018, while 280 were exempted from tracking because they had applied to convert to an OLCC licensee and 365 were out of compliance with the law. As of December 2018, OMMP had moved to revoke the registrations of 211 of these grow sites.

Medical growers and grow sites who do not track in Metrc, but who grow for patients other than themselves, are required by statute to submit monthly reports to OMMP.²² According to the program, there were 6,850 of these grow sites in October 2018. However, OMMP notes that only about 40% actually submit monthly reports as required. These reports must include mature and immature plant counts, amounts of usable marijuana on hand, and any marijuana transferred to patients. Without these reports, OMMP does not know how much marijuana these growers are producing. Additionally, because this information is only reported once a month and is not tracked from seed to sale, as it would be in Metrc, there is a greater risk of diversion.

Several other states with medical marijuana systems, like Maryland, Nevada, and Michigan, require licensed medical marijuana growers to track plants and product using Metrc or another seed-to-sale tracking system.²³

Similar to recreational marijuana, regular inspections of medical marijuana are needed to ensure compliance and prevent diversion

OMMP has a team of compliance inspectors that began in 2015 with a mandate to inspect medical dispensaries, and later processors. As dispensaries and processors moved over to the recreational system, the compliance unit shifted its focus in fall 2016 to inspections of medical grow sites, though it still also inspects the few remaining medical dispensaries and processors. The unit began with seven compliance inspectors, but had just six as of December 2018.

From January 2017 to September 2018, OMMP inspected just 2.9% of grow sites required to submit monthly reports. During that time, inspectors conducted inspections at just 201 of the 6,850 medical grow sites required to submit monthly reports.

From January 2017 to September 2018, OMMP compliance inspectors inspected 201 of the 6,850 registered grow sites required to submit monthly reports (though they also inspected 173 medical dispensaries and 26 processors over that time). This amounts to just 2.9% of these medical grow sites receiving an inspection over that period.

OMMP is hindered by limited regulatory authority, a sharp decrease in fee revenues, a lack of inspectors, and challenges with performance management

Oregon statutes prevent OMMP from requiring medical growers to implement many of the controls OLCC requires of its licensed growers. For example, Oregon law expressly prohibits the agency from requiring medical grow sites to have any sort of security system, including

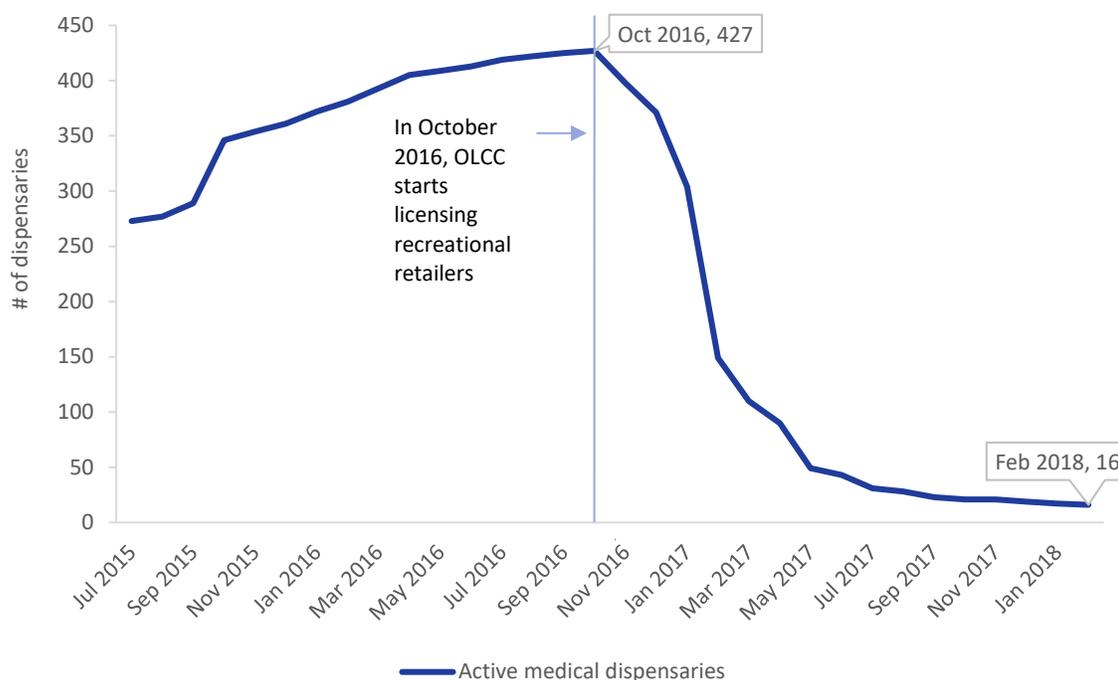
²² Oregon Revised Statutes, Chapter 475B, Section 816.

²³ Some of these states may not require caregivers who grow for patients or patients who grow for themselves to track marijuana plants and products from seed to sale.

surveillance cameras, alarm sensors, or physical barriers.²⁴ Similarly, data reporting requirements for medical growers are set by statute, restricting OMMP's ability to require additional medical growers to report data in the Metrc system or to push growers to provide more comprehensive reporting in its Oregon Medical Marijuana Online System.²⁵ By comparison, some other states we surveyed, such as Maryland, Rhode Island, and Nevada, require their licensed medical marijuana establishments to have security systems, surveillance cameras, and to track marijuana plants and products using a seed-to-sale tracking system like Metrc.

The fee revenues that fund OMMP come from registered dispensaries, processors, growers, and patients. A decrease in all types of registrants since 2015 and 2016 has caused significant reductions in fee revenues. Nearing the end of the early recreational sales period (October 2015 through December 2016), active OMMP medical dispensary registrations began to drop dramatically as OLCC started licensing retailers in late 2016.

Figure 13: Active OMMP dispensary registrations dropped dramatically as OLCC started licensing retailers in October 2016



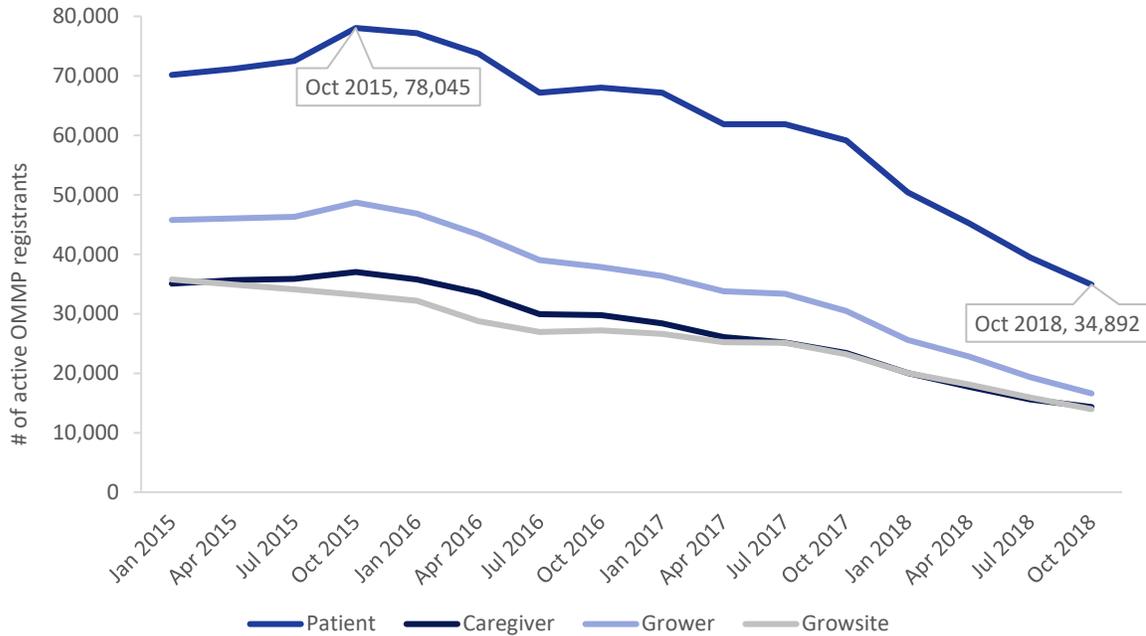
Source: OMMP.

Active dispensary registrations dropped from a peak of 427 in October 2016 to 16 in February 2018, as dispensaries converted to retail marijuana stores that sell to both recreational customers and medical cardholders. A similar trend occurred for OMMP registered processors, with medical processing sites peaking at 142 in December 2016, then falling dramatically as OLCC began licensing processors. Other OMMP registrants have also decreased since 2015, as shown in Figure 14.

²⁴ Oregon Revised Statutes, Chapter 475B, Section 828.

²⁵ Oregon Revised Statutes, Chapter 475B, Section 816.

Figure 14: Since 2015, the number of active OMMP patients, caregivers, growers and grow sites has trended downward



Source: OMMP.

OMMP is unsure of the reasons for the significant decline in these registered cardholders, though some have obtained OLCC licenses and moved to the recreational market. Moreover, OMMP patient registry cards enable patients to purchase medical marijuana tax-free from any licensed retail shop or dispensary, but require patients to pay a \$200 annual fee. Depending on how much they purchase, the tax savings for some consumers may not make up for the cost of this fee, which could partially account for the drop in OMMP registered patients and their associated caregivers. OMMP plans to send a survey to prior and current OMMP registered patients in early 2019 with some questions aimed at gauging why many have let their registration lapse.

As of October 2018, only five OMMP medical dispensaries and three processing sites were registered in Oregon. Registered patients and growers have dropped by more than 50% since October 2015. As noted previously, this has led to a large decrease in fee revenue. In addition, some of the fee revenue OMMP collects has been reallocated to other programs within OHA. The program reports that in the 2015-2017 biennium, the Legislature reallocated \$18 million to fund other public health programs. In the current 2017-2019 biennium, another \$7.1 million has been reallocated to fund state support for public health programs. As OHA also reported, OMMP could not increase fees to make up for both the loss of fee revenues and reallocations, forcing the program to cut all positions in its compliance unit, though some positions were later restored.

Despite the cuts in its funding, OMMP is still responsible for overseeing the medical marijuana program, including conducting compliance inspections of registered grow sites. However, the program has just four permanent inspector positions, with another two limited duration inspector positions that expire in June 2019 (along with the compliance unit manager’s position, which expires at the same time). In total, the unit has just six inspector positions to cover 6,850 grow sites who grow for patients other than themselves, an inspector-to-grow site ratio of 1:1,142. As OMMP notes in its assessment, this number of positions cannot adequately enforce compliance or provide a significant deterrent effect, which greatly increases the risk of medical growers diverting marijuana to the black market.

High turnover has affected the compliance unit's staffing, as well. As of December 2018, the unit had just three of its six inspector positions filled due to resignations and job rotations. In each year since 2015, at least two inspectors have either resigned or taken job rotation positions in other agencies. Inspectors we spoke with cited a perceived lack of support for the program within OHA, low morale, and a lack of effective internal management as key factors driving turnover. As an example, staff noted that the unit spent several months in both 2017 and 2018 revising inspection procedures for medical processors and dispensaries, even though very few of those registrants remain. Staff also noted that inspectors must manually transfer data between databases when performing investigations because the program was unable to retain support staff to perform this administrative function.

OMMP Compliance Staffing

The OMMP compliance unit has just six inspector positions to cover 6,850 grow sites who grow for patients other than themselves, an inspector-to-grower ratio of 1:1,141.

Additionally, like OLCC, OMMP has not set any goals for inspection frequency and has no targets for how many inspections should be completed each month. The program reports that it would need five regionally-based teams of three to five inspectors in order to adequately ensure compliance among medical grow sites.

Addressing regulatory gaps at both OLCC and OMMP would reduce the risk of diversion and federal action, and better protect public health and safety

In addition to possibly heightening the risk of federal action against Oregon marijuana businesses, diversion of marijuana to the black market could potentially affect public health and safety. Diverted legal marijuana provides additional marijuana supply for criminal operations and illegal processors, and could potentially allow unsafe, untested marijuana into Oregon's black market, where it could make its way into the hands of minors.

As noted previously, OLCC is in the process of developing its regulatory framework, and still needs more accurate Metrc data, established baselines and timeframes, and enough inspectors to ensure licensees are regularly inspected. OMMP has only a minimal regulatory framework in place in the medical marijuana system, with limited security requirements, data tracking, and inspections. Without improvements in these areas, both agencies face an increased risk that compliance violations, potentially including diversion, could go undetected.

Addressing these regulatory weaknesses would demonstrate that Oregon is serious about preventing and reducing diversion and is taking steps to improve the regulatory environment around legal marijuana. On the other hand, not addressing the regulatory vulnerabilities in the recreational and medical marijuana systems could contribute to increased skepticism from federal authorities about the sincerity of Oregon's efforts to effectively regulate marijuana. This could lead to increased federal scrutiny of marijuana businesses in the state.

Black market activity and diversion in Oregon could theoretically diminish tax revenue if substantial amounts of product are diverted elsewhere. Diversion could also increase public safety risks. Putting more controls in place to help prevent diversion could potentially allow law enforcement to focus more resources on purely black market marijuana operators, which often engage in other criminal activity. Black market operators, including illegal processors linked to several explosions, would also be deprived of a possible source of marijuana. This could prevent untested, unsafe marijuana from entering Oregon's black market, where it could potentially fall into the hands of underage marijuana users.

Oregon’s marijuana compliance testing requirements fail to address some important public health concerns

Compliance testing is critical to ensuring that marijuana in Oregon is free of harmful contaminants and is safe for consumption. Oregon’s current compliance testing regime and reporting requirements have contributed to the declining presence of pesticides above acceptable levels in recreational marijuana. However, Oregon does not require testing for heavy metals or specific microbiological contaminants. Medical marijuana is also largely exempt from testing requirements, despite serving patients who may be more vulnerable to contamination than the general population.

State enforcement efforts and improved cultivation methods contribute to the declining presence of pesticides in compliance tests

The declining rate of pesticide testing failures in an industry that continues to grow indicates that compliance testing can be an effective tool for protecting consumer health. Compliance testing in Oregon has shown that pesticides are present in the state’s supply of recreational marijuana. Pesticides are the most common and most serious reason for testing failures, and are frequently used during marijuana cultivation. However, the number of tested packages with pesticide presence above the acceptable level decreased from 5.6% in January 2017 (104 out of 1,857 packages failed) to 2.1% in July 2018 (60 out of 2,835 packages failed). Most types of marijuana product showed lower rates of pesticide contamination in the first half of 2018 than in 2017.

Figure 15: The 10 most common pesticide failures among Oregon marijuana

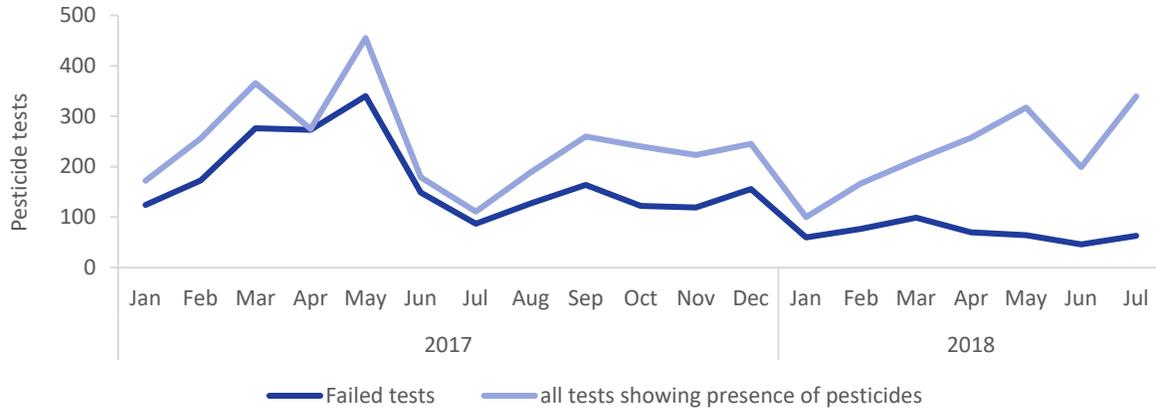
Pesticide	Failed tests (above action level)	Total tests (presence detected)	Percentage of tests failed
Bifenazate	100	180	56%
Malathion	100	147	68%
Chlorpyrifos	110	199	55%
Spiromesifen	141	224	63%
Spinosad	162	271	60%
Chlorfenapyr	176	297	59%
Bifenthrin	191	279	68%
Myclobutanil	225	333	68%
Pyrethrins	310	550	56%
Piperonyl butoxide	479	1,288	37%

Note: All of the 59 high-risk pesticides the state requires testing for, and 15 of the 24 solvents, showed up in compliance tests between January 2017 and July 2018. Some pesticides showed up in hundreds of tests, occasionally in amounts that greatly surpassed established action levels, though others were only present in a handful of tests and are of less concern.

Source: OLCC.

OLCC and OHA refer growers with pesticide failures to the Oregon Department of Agriculture, which works with growers to take steps to comply with state law. The department takes an educational approach to most initial violations, requiring that growers participate in a compliance assistance program. Growers who continue to fail pesticide testing may have to pay fines up to \$10,000 and risk losing their OLCC license. From October 2016 to June 2018, 143 recreational growers and 122 medical growers were referred to the Oregon Department of Agriculture for failed pesticide tests. OLCC made 12 more referrals from July through September for 11 different kinds of high-risk pesticides. Approximately 75% of recreational growers and processors in Oregon had no documented pesticide test failures between January 2017 and July 2018.

Figure 16: Rates of pesticide detection vary, but both the number and rate of failed pesticide tests has dropped over time



Note: This chart excludes pesticide testing data from Evio Labs Medford. While the overall presence has not notably declined, pesticides are showing up in marijuana in increasingly small amounts.
Source: OLCC.

Lab staff we spoke with expressed concern about the continuing presence of pesticides in Oregon marijuana, as well as concerns around questionable lab practices that may lead to contaminated product passing compliance tests and reaching the market. However, greater general awareness of the effects of pesticide use among growers and evolving cultivation methods have likely contributed to a decline in the presence of pesticides above acceptable levels in compliance tests. Some licensees told us that cultivation methods have shifted in recent years as some growers adopt more sophisticated growing techniques and were better able to time the pesticide application to reduce potential contamination.

Even low levels of certain pesticides could be unsafe, particularly for frequent or heavy users. While pesticide contamination continues to be an area of concern for recreational marijuana products, testing and agency efforts to educate growers help to reduce the associated public health risk. When pesticides are detected, it increasingly tends to be in minimal amounts. The impact on consumer health, and whether or not there is one, is not known.

Heavy metal and specific microbiological testing are not required in Oregon even though these contaminants could pose a risk to consumers

Contaminants including heavy metals such as chromium and microbiological contaminants such as salmonella may pose a risk to consumers. Tests for these are not required in Oregon, though other states include them in their compliance testing panels.²⁶

The risks of microbiological contaminants and heavy metals being present in marijuana have been noted in other reports.²⁷ In addition to pesticides and solvents, OHA determined in 2015²⁸ that microbiological contaminants such as E. coli and salmonella were areas of concern for marijuana products. Marijuana is also prone to growing molds that could contain carcinogenic

²⁶ Compliance panel includes required tests discussed on page 14.

²⁷ In addition to the 2015 OHA Technical Report and 2016 Association of Public Health Laboratories report (both discussed in text and referenced below), the American Herbal Pharmacopoeia identified contamination risks for marijuana. Risks were also identified in *Cannabis sativa L. – botany and biotechnology*. Other states have referenced the Pharmacopoeia in their testing rules. Upton, R., Craker, L., in ElSohly, M., Romm, A., Russo, E., Sexton, M., & American Herbal Pharmacopoeia. (2014). Cannabis inflorescence: Cannabis spp.; standards of identity, analysis, and quality control.

McPartland, J. M. & McKeron, K. J. (2017). Contaminants of concern in cannabis: microbes, heavy metals and pesticides. In *Cannabis sativa L. - botany and biotechnology* (pp. 457-474) Springer International Publishing AG.

²⁸ Farrer DG. Technical report: Oregon Health Authority’s process to decide which types of contaminants to test for in cannabis. Oregon Health Authority. 2015 December.

toxins and yeast, though Oregon’s water activity tests are considered a proxy for preventing exposure to mold.

In 2016, the Association of Public Health Laboratories published a report for state medical marijuana testing programs that recommended testing for heavy metals in addition to solvents, pesticides, and microbiological contaminants.²⁹ Heavy metals may accumulate in the body; some are carcinogenic and considered to cause a variety of diseases. Marijuana is efficient at absorbing and storing heavy metals and other pollutants found in soil and water, which increases the risk that that marijuana users could ingest or inhale heavy metals.

California has adopted testing requirements for recreational marijuana that include panels of microbiological contaminants and certain heavy metals. Medical marijuana in Michigan requires both harvest and final product screening that includes heavy metals and microbiological contaminants in addition to pesticides and solvents.



Maryland’s medical marijuana program introduced microbiological contaminant and heavy metals compliance tests in early 2018. During the first several months of testing, up to 30% of the marijuana tested failed for yeast, mold, and chromium. That failure rate had dropped to 5% to 10% by September 2018.

As of October 2018, only two marijuana testing labs in Oregon were accredited to perform microbiological contaminant testing, and Oregon does not accredit marijuana labs for heavy metals. From January 2017 to July 2018, approximately 100 E. coli tests were conducted on marijuana in Oregon — meaning that less than 0.11% of tested packages received microbiological tests. There are no records in Metrc of marijuana testing labs performing heavy metals tests.

While the scope of risks for consumers from microbiological contaminants and heavy metals is not clear without further research and testing, some frequent users may be unusually vulnerable to product with any kind of contamination.

Medical marijuana is largely excluded from testing requirements, creating potential health risks for users

Unlike marijuana sold through the recreational market, growers in the medical market are exempt from most testing rules and are not required to test usable marijuana product before it is transferred to a medical patient, which could expose patients to contaminants. Medical marijuana is typically only required to be tested when it is sold through a dispensary or processed by a medical processor. Registered patients may be more vulnerable than comparatively healthy adults, and the lack of pesticide testing requirements for medical grows leaves patients at higher risk for exposure than recreational consumers. Roughly 10% of Oregon’s medical marijuana patient community includes children under 18 years of age and seniors over 70. The patient community also includes individuals with conditions such as cancer and HIV that can directly compromise their immune systems.

Approximately 12% of recreational retail sales have been untaxed sales to registered medical patients. These patients have some assurance that marijuana they purchased through a recreational retail shop has been tested for pesticides and is reasonably safe for consumption. However, despite decreasing enrollment in the medical program, there are still thousands of registered medical patients likely obtaining marijuana directly from medical growers.

²⁹ Association of Public Health Laboratories. Guidance for State Medical Cannabis Testing Programs, May 2016.

Testing medical product may not be common outside of the small number of remaining dispensaries and medical processors. One lab we spoke with estimated that 80% of their compliance tests were for recreational marijuana. About 10% came from the medical program, and the rest was a mixture of hemp growers and private home growers.



Other states require testing for contaminants, including microbial and heavy metals, for medical marijuana. In Washington, test requirements are more stringent for medical marijuana than they are for recreational. While recreational and medical marijuana must be tested for microbiological contaminants, only medical marijuana must be tested for pesticides and heavy metals.³⁰ Medical marijuana programs in Michigan, Rhode Island, and Maryland require testing for pesticides, solvents, microbiological contaminants, and heavy metals.

Improved testing coverage could help ensure that vulnerable patient populations are not exposed to dangerous contaminants that may further jeopardize their health and undermine the potential medicinal benefits of marijuana.

What could exposure to contaminants mean for marijuana consumers?

Both acute and long term exposure to certain contaminants can result in a range of adverse health effects

Pesticides

Chlorpyrifos can cause the nervous system to malfunction during brief exposure and is linked to developmental delays in children of mothers with the pesticide in their blood. Bifenthrin may be a carcinogen and ingestion can cause headaches, vomiting, and respiratory irritation. Pyrethrins can cause difficulty breathing, vomiting and diarrhea when inhaled, and over prolonged periods may cause tissue damage in respiratory passages, and tremors.

Microbiological Contaminants

Salmonella, which was recommended for testing but is not specifically tested for in Oregon, can cause serious infections in young children and people with weakened immune systems. Mycotoxins found in fungi and aspergillus mold are nephrotoxic and carcinogenic, but mold is so common to the environment that OHA recommended not testing for them, instead opting for a proxy water activity test. The agency also recommended including a warning about the risk to persons with suppressed immune systems.

Heavy Metals

Chromium, detected in marijuana tests in Maryland, may be carcinogenic to humans. Lead has been found in marijuana in tests performed in Germany and has no level of safe exposure. It can affect the nervous system, cause kidney damage, slow brain development, and cause miscarriages. Arsenic is present in some groundwater sources and fertilizers that could be used on marijuana. Long-term exposure to arsenic can cause cancer and skin lesions, and acute exposure may cause vomiting, diarrhea, and even death.

Marijuana testing requirements in Oregon emphasize protecting public health, but broader testing coverage and more research are needed to protect consumers

The decisions OHA made for marijuana testing in 2015 factor in some of the known dangers of pesticides and solvents, and the OHA workgroup report addresses the possibility of some forms of microbiological contamination of marijuana product. However, the report does not include a discussion of heavy metals and Oregon's current testing regime leaves out sources of potential contamination that could impact consumer health. Additionally, the Labs Technical Advisory

³⁰ Washington allows patients and their designated providers to grow limited amounts of marijuana for medical use but homegrown marijuana for recreational use and sale remains illegal.

Committee convened by OLCC in July 2015 recommended mandatory testing for E.coli, Salmonella, several varieties of Aspergillus mold, and heavy metals, in addition to tests currently included on the compliance panel. Several testing recommendations from both the OHA workgroup and the advisory committee are not included on the current compliance panel.

There are barriers to expanding Oregon’s compliance testing requirements. Testing is costly, with a full compliance panel costing between \$300 and \$400 per batch. The cost of testing may already be prohibitive for many individual growers, particularly patients that qualify for reduced card fees. Some licensees identified testing as one of their most significant operating costs. Introducing heavy metals and microbiological contamination tests to the current compliance panel would likely increase the cost of testing. One lab owner estimated that an expanded compliance panel would cost both labs and their clients about 30% more than current panels.

Another barrier is lack of research around how marijuana interacts with contaminants. Research on the potential interactions of pesticides with marijuana is very limited, and there are no established exposure thresholds for marijuana and pesticides due to the federal ban. The lack of previous testing and research on heavy metals means there may not be reliable information on whether they are present in Oregon’s supply. The wide variety of products available also complicates testing, as different products would likely require setting different health risk action limits for heavy metals. Action limits set by other states tend to apply only to smoking marijuana, and may not be adequate for other methods of consumption.



Marijuana sample contaminated with mold found at retail shop. Retail staff identified the mold and removed the product from the shelf.

Marijuana testing is still evolving, and states with legal or medical marijuana programs have different testing requirements. Risk areas may also vary from state to state, depending on differences in cultivation and processing methods, and preexisting environmental concerns. Risk areas may also vary by region in Oregon, which could be a factor in researching and establishing testing requirements. OHA may consider reviewing its current testing panel and reevaluating the risks of consumer exposure to certain pesticides, microbiological contaminants, and heavy metals.

OLCC can better ensure product safety by taking steps to verify test results

While testing is critically important to protecting public health, pressure on labs to provide high potency test results, coupled with test subcontracting practices, increase the risk of inaccuracies and misreporting. By taking steps to verify test results reported by Oregon’s marijuana labs, OLCC can better ensure products sold in the recreational marijuana market are safe for consumption

Industry pressures may influence lab practices and affect the accuracy of reported results

The marijuana “gold rush” in Oregon has led to a swiftly growing marijuana industry and tight competition across the market. Labs are not shielded from these industry trends, and there has been substantial growth in testing since the expansion of marijuana testing requirements in 2016. Labs are in competition with other labs, and both OLCC and ORELAP report receiving complaints from labs, including accusations that competitors are not following testing rules or are manipulating potency results to retain and attract customers. Marijuana testing is a nascent industry, and unlike other kinds of environmental lab testing there is a general lack of guidance available to these labs; no standard methodologies are in place for testing, for example.

Potency drives sales and may affect testing practices

According to lab staff and others in the industry, the pressure to produce and sell high potency product sometimes translates to pressure on labs to produce high potency results for their clients.

Potency results are posted on package labels, and retailers report that high THC potency is highly sought after and a strong driver of sales. With production across the state creating a supply that may outstrip demand, there is a great deal of pressure in the industry to produce and sell marijuana products that are desirable, lucrative, and potent.

Several labs we spoke with expressed concerns about lab shopping, which happens when clients jump from lab to lab seeking desired test results. Labs also told us that it was not

unusual to lose clients to other labs. Among OLCC licensees, using the services of multiple labs is not uncommon; 24% of growers and 43% of processors used three or more labs between January 2017 and July 2018. During the same period, 38 growers and processors used five or more labs, and one processor used nine separate labs. There are several possible reasons for clients to move from one lab to another; the quality of services offered may vary, the closure of a few labs has required clients to seek other services, and some labs have changed ownership. However, the frequent use of multiple labs is consistent with that reported by industry members and concerns remain that some clients are seeking out labs that will give them desired results.

Average THC potency reported by labs increased from 25% in 2017 to 28% for the first half of 2018 for all marijuana products. Though extracts and concentrates are significantly more potent on average, most of the increase was due to increases in THC potency test results for marijuana flower. Several factors may play into increasing product potency, including its importance in terms of sales and the increasing sophistication of growing and processing methods. Without appropriate controls in place to verify the accuracy of test results, there is higher risk of manipulation of samples or potency tests to artificially increase potency results.

Other test types more closely connected to product safety, in particular pesticide testing, may also be at risk for misreporting. Batches that fail pesticide testing are supposed to be destroyed. This could create a substantial burden on the grower or processor who will lose that source of revenue.

There are few reliable indicators in the testing data to determine whether sample and test result manipulation is occurring. If a package has more than one test result entry in Metrc, it could indicate an attempt to alter the original test result, though it is also possible that it is a retest, or that the original entry was a mistake.

According to lab staff and ORELAP lab assessors, there are numerous ways to intentionally or unintentionally manipulate test results at multiple points along the testing process, including:

- **Sample collection:** While samples should be representative of the batch from which they are taken, lab technicians who fail to follow appropriate sampling procedures could collect product that is not representative, and potentially more or less potent, than the rest of the batch.
- **Sample preparation:** When samples are prepared for analysis, they are often heated to remove excess moisture. Heating the sample beyond a certain window of time can artificially inflate potency results.
- **Interpreting data:** The lab scientist who analyzes the sample must interpret complex sets of testing data, but labs may not have a sufficient process in place to confirm that the analysis was sound and accurate. How the scientist interprets the output and reports the results is up to them.
- **Data tracking and sharing:** While some labs have Laboratory Information Management systems that can automatically populate test results into Metrc, others use manual entry. As discussed in more detail on pages 40-41, labs that subcontract services also share test

results with each other outside of Metrc. Shared results are only reconciled with Metrc entries on an ad hoc basis by OLCC.

Ultimately, the integrity of testing data relies heavily on the professionalism and expertise of lab staff. The majority of workers in Oregon's marijuana industry are required to obtain worker permits from OLCC. In order for applicants to obtain a worker permit, a \$100 fee must be paid, they must take a test demonstrating an understanding of applicable laws and rules, provide valid photo identification, and pass a background check. However, labs and research facilities personnel are not required to obtain worker permits. As a result, apart from an estimate of staff numbers, not much is known about who is employed at Oregon marijuana labs. ORELAP staff also expressed concerns that poor lab practices and a lack of consistent testing methodologies may contribute to potentially inaccurate test result reporting.

Verifying compliance test results can provide greater assurance of marijuana product safety and testing accuracy

Despite having the authority to order random testing of marijuana, OLCC has not developed procedures for random testing methods, such as shelf audits where product is removed from retail shelves and tested, that could be used to verify the accuracy of reported test results. Neither OLCC nor OHA³¹ have ordered any shelf audits or other random testing to verify the accuracy of reported test results. Verification could help ensure that product on the shelf is reasonably safe and uncontaminated with pesticides or solvents, that the reported levels of THC and CBD potency are reasonably accurate, and that testing lab practices are sufficient to produce accurate test results.

As detailed earlier, shelf audits were conducted by a media organization in 2015 and 2017 and alleged to have found several issues with marijuana being sold, even after product had passed a required compliance panel. A similar shelf audit conducted in 2017 by a media outlet in California purported that that 93% of the products purchased in retail shops and then submitted for testing had unacceptably high levels of pesticide contamination.³² At the time of the report, California did not require pesticide testing. California has since introduced testing requirements covering pesticides, solvents, heavy metals, and microbiological contaminants. Myclobutinal, a pesticide that converts into highly toxic hydrogen cyanide gas upon combustion, was notably present in several of the California shelf tests. Myclobutinal has also showed up in hundreds of pesticide tests in Oregon, and above the action level in many cases.

None of the states we talked with reported conducting formal shelf audits of marijuana product, random testing happened rarely, and only two reported conducting routine testing verification. However, after concerns arose in Colorado about the consistency and accuracy of labs' test results, the state approved the development of a state-funded marijuana reference lab. The lab, approved to open in 2019, will serve both recreational and medical marijuana programs and is projected to be fully functional by late 2019. The lab will work with Colorado's private labs to verify test results, provide technical assistance, and establish analytical standards for marijuana analysis. Colorado labs, like Oregon labs, have had to develop their own testing procedures independent of the kind of oversight that other types of environmental labs experience.

Industry members we spoke with told us they thought testing in Oregon had become more consistent over time. However, this cannot be confirmed as the state currently does not have a mechanism to verify test results and has not ensured consistent practices among licensed labs. OMMP and ORELAP have both endorsed establishing a state-funded and independently functional reference lab that could support Oregon's marijuana labs by providing guidance on

³¹ OHA can also order random testing of medical marijuana.

³² "Pesticides and Pot: What's California Smoking?" NBC4, February 22, 2017, accessed at <https://www.nbclosangeles.com/news/local/I-Team-Marijuana-Pot-Pesticide-California-414536763.html>

testing methodologies. A reference lab could also participate in random testing with state agencies to ensure that reported test results are trustworthy and that marijuana sold in Oregon is reasonably safe for consumption.

Subcontracting testing services between labs complicates test tracking

Subcontracting testing services complicates OLCC’s ability to track test results and hold labs accountable for inaccuracies and misreporting. Because primary labs enter all the test results into Metrc, the audit team was unable to verify which labs performed which specific tests when subcontracting occurred. Test results do not tie directly to the specific lab that performed the test. The team was also unable to identify whether there were discrepancies and outliers in the data that could indicate misreporting or poor testing practices on the part of labs.

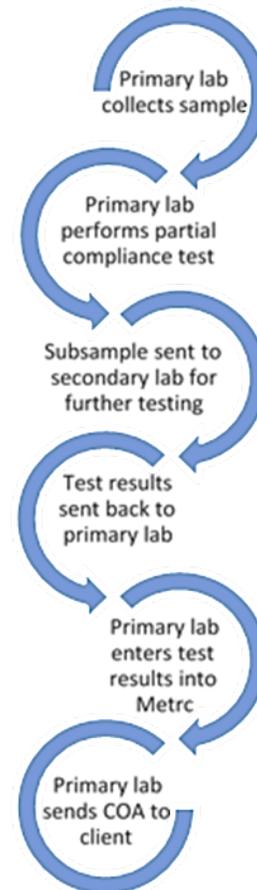
Oregon requires labs to be accredited for at least one type of test in order to be licensed by OLCC, but does not require labs to be accredited for a full compliance panel.³³ As of October 2018, only four of Oregon’s 22 labs were fully accredited for all required tests. The lack of full accreditations has likely contributed to frequent subcontracting. From January 2017 to July 2018, 87,800 packages were tested and the results entered into Metrc. In that time, 19 labs subcontracted testing services on more than 11,000 of those packages. Several hundred more packages also appeared to have been transferred between labs for testing.

When subcontracting, the primary lab works directly with the client, collecting samples from marijuana growers, processors, and wholesalers. The sample is prepared and initial testing is conducted by the primary lab. A subsample is sent to a secondary (subcontracted) lab to complete part or all of the full compliance panel.

The primary lab is responsible for entering all the test results into Metrc and sending a final combined certificate of analysis to the client. Secondary labs are not required to be notified of results reporting by primary labs, and apart from testing subsamples may have no interaction with licensees and no way of confirming whether the test results they reported to the primary lab reconcile with the results the primary lab reported to the client.

The methods by which test results are shared between primary and secondary labs is another concern. Labs share certificates of analysis in different ways; some labs use Confident Cannabis, which acts as a storage platform and allows labs to both share and access certificates directly. Other labs share certificates via email. Certificates are not stored in Metrc, and OLCC only makes ad hoc requests to labs for individual certificates. The agency does not have a comprehensive record of all Oregon’s certificates of analysis, or a mechanism for reconciling test results shared between labs with test results that are entered into Metrc and shared with clients.

Figure 17: Sample sharing and test result communication in subcontract relationships



³³ A compliance testing panel includes all tests required for a specific marijuana product. All products should receive pesticide and potency tests, and processed marijuana should also receive a solvent test.

Oregon’s testing regime can detect contaminated product before it reaches consumers. However, neither OHA nor OLCC are able to confirm that compliance panels adequately prevent contaminated or inaccurately tested product from reaching the point of sale. Developing a testing verification program and an independent reference lab to assist with testing accuracy verification would provide assurance that labs are accurately conducting and reporting test results.

ORELAP can better safeguard public health by ensuring that marijuana testing labs meet and maintain accreditation standards

As noted, all of Oregon’s marijuana labs have met at least some of the accreditation standards required to perform marijuana testing. However, ORELAP lacks a strategy and capacity needed to ensure that all marijuana labs have been fully assessed and consistently meet accreditation standards. Several marijuana labs have been allowed to operate, despite lacking an onsite assessment of their sampling practices. Lab failures to maintain accreditation standards have not been addressed in a timely manner. This increases the risk that underperforming labs are able to access and test marijuana, which could lead to contaminated product entering the market and compromising consumer health.

Progress has been made to introduce robust lab accreditation standards to Oregon marijuana labs

Oregon has made substantial progress toward creating a consistent marijuana testing program. Labs that perform those services are required to obtain accreditation from ORELAP. It was noted in some interviews with industry members that prior to 2016, marijuana testing in Oregon was an unregulated “wild, wild west,” and that issues with inaccurate testing and unprofessional lab practices were rampant. Interviewees also noted that the situation had improved since then, though there continue to be some issues that have not been fully or adequately addressed.

Labs must be accredited by ORELAP for at least one test type in order to be licensed by OLCC to test marijuana. ORELAP accredits labs under standards developed by The NELAC Institute (TNI), known as TNI standards,³⁴ which they consider to be more stringent than standards other states use. As of October 2018, 22 labs were accredited, though there has been considerable fluctuation as labs have opened, closed, and consolidated with other labs.

In order to maintain their accreditations, labs must participate in a full on-site assessment with an ORELAP assessor every two years and participate in proficiency tests every six months. Proficiency tests ensure that labs can produce test results within an acceptable margin of error on a blind sample. Oregon opened a five-year contract with Phenova in 2017, a Colorado-based proficiency test provider. According to Phenova, Oregon marijuana labs are becoming more consistent over time and are producing more routine and accurate proficiency test results than when they started.



An ORELAP Assessor observes a sampling procedure during an on-site assessment.

The conditions for proficiency tests have also become closer to those present in compliance tests, improving the relevancy of proficiency tests to determine whether labs can produce trustworthy compliance

³⁴ The NELAC Institute is a national accreditation program for environmental testing labs. They establish accreditation standards for state and regional accrediting bodies.

test results. Phenova has shifted from using “alternate” matrix proficiency tests, performed with a proxy sample such as hops flower, to “real” matrix tests that are performed with marijuana samples prepared by Phenova at an in-state location. Real matrix proficiency tests more closely mimic real world testing conditions. Only solvent tests are still performed using an alternate matrix. Solvents present a unique challenge, as they are only used during processing. There is a wide variety of marijuana products that use processed extracts and concentrates, and preparing and performing “real” matrix proficiency tests on each of those product types for every lab accredited to test for solvents may not be feasible.

Competing priorities undermine ORELAP’s ability to perform timely marijuana lab accreditations and respond decisively to potential violations

Despite overall improvements, ORELAP has struggled to fully implement marijuana lab accreditation requirements in Oregon.

ORELAP receives federal funds through the EPA to accredit drinking water and other environmental labs, but has not received federal or state funds for accrediting marijuana labs. ORELAP’s scope of duties has expanded in recent years to include marijuana lab accreditations and a variety of other environmental lab accreditations in Oregon and out of state. In addition to marijuana, ORELAP accredits labs under the Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act, and the Safe Drinking Water Act. Based on the current fee schedule, accreditation fees charged to marijuana labs cover the cost of the application fee, the on-site assessment fee, but do not account for other ORELAP responsibilities to those labs. Despite the frequent issues that ORELAP has run into with marijuana labs, accreditation work for those labs is not ORELAP’s only pressing priority. ORELAP accredited laboratories must have assessments to maintain their accreditations.

Marijuana sampling methods

Oregon allows labs to collect either random or representative samples of marijuana from growers and processors. The marijuana batch is divided into units, and a portion of the full sample is collected from either at random or from each unit. Each portion is weighed, and the sample transported to the lab.

As of October 2018, ORELAP had not completed on-site assessments of lab sampling practices for 12 of Oregon’s 22 operating marijuana labs, a critical and required component of the accreditation process. These labs were among several that sought accreditation in 2016 and 2017 and were granted provisional sampling accreditations. These labs submitted standard operating procedures and other necessary documents, but ORELAP, overwhelmed with an expanding workload and the loss of key staff, did not perform on-site assessments that included lab sampling practices to ensure that they were following acceptable sampling procedures. Labs with provisional sampling accreditations have been allowed to perform sampling and testing with no limitations, with the understanding that an assessment of sampling procedures would eventually be performed. By October 2018, only eight labs had been granted full sampling accreditations.

Additionally, ORELAP’s response to proficiency testing failures has been slow, and has allowed labs that may be underperforming to continue conducting crucial tests. Most of Oregon’s accredited marijuana labs have participated in proficiency testing. When labs fail a proficiency test, they have the option to redo the test. It is not uncommon for labs to fail a round of proficiency tests. Pesticide proficiency in particular is a challenge, as labs must accurately identify 59 unique pesticides within an acceptable margin of error. In August 2017, only 42% of pesticide accredited labs passed the first round of pesticide proficiency tests. By 2018, this amount had increased to 47%.

The majority of labs that failed initial pesticide proficiency tests in 2017 passed retests; however, two labs that failed the initial testing round did not participate in or pass retests. In

both cases, the labs continued to perform testing for several months after failing their proficiency tests. ORELAP eventually issued corrective action letters requiring that both labs pass pesticide proficiency tests or risk losing their accreditations, but not before both labs had performed numerous compliance tests for pesticides over several months for their clients.

In the first case, the lab was contacted by ORELAP four months after failing to test properly for 11 pesticides. The lab chose not to retest, but never formally withdrew their accreditation, and ORELAP never formally revoked it. Ultimately, the lab opted to subcontract out pesticide testing to another lab and reportedly stopped performing pesticide tests in February 2018, six months after failing the proficiency test. They retained the pesticide accreditation, with the exception of the 11 pesticides that failed in proficiency testing. We were unable to confirm that this lab had stopped performing pesticide tests. Tests that are subcontracted to a secondary lab are still tracked under the name of the primary lab in Metrc, which gives the appearance that the primary lab conducted the test.

In the second case, the lab was not contacted by ORELAP for a full year after failing their August 2017 pesticide proficiency test. Additionally, the second lab did not participate at all in the required tests in the spring of 2018. In the year between failing the August 2017 proficiency test and receiving the corrective action letter, the second lab continued to operate as a subcontractor to several other labs, receiving and presumably testing over 1,000 packages between August 2017 and July 2018. This lab was only accredited to perform pesticide tests. The lab reported to ORELAP in September 2018 that they were taking steps to address their proficiency testing deficiencies, but had failed to enroll in further proficiency tests as of December 2018.

Limited authority, inadequate staff coverage, and inefficient processes reduce ORELAP's ability to ensure Oregon marijuana labs consistently operate under accreditation standards

A case of potential sampling fraud

In early 2018, ORELAP received a video that appeared to show a lab technician participating in sampling fraud with staff working at a grow site. The lab technician observed grow site staff separate out a portion of a larger batch, then add an unidentified powder to the separated portion. The technician collected the sample only from this portion of the batch. ORELAP began an administrative review of the lab, scheduling a court hearing with the assistance of the Department of Justice. The lab appealed after the hearing but ultimately settled with ORELAP in October 2018. The lab's sampling accreditation was then suspended until the lab could prove that improvements had been made. The lab was active during the full 10-month period leading up to the suspension. As of December 28th, 2018, the lab had not completed the required corrective action plan.

ORELAP can revoke or suspend lab accreditations for proficiency testing failures. For other types of accreditation deficiencies, ORELAP's authority is bound by Oregon's Administrative Procedures Act. Addressing these concerns triggers a protracted administrative process during which ORELAP is prohibited from curtailing any of a lab's activities until after a court hearing. If labs choose to appeal the decision of the court, that can delay action almost indefinitely. While ensuring that individuals and businesses have the benefits of due process is critically important, the state may consider reexamining the limits of ORELAP's authority in egregious cases, such as sampling fraud, which could involve a potential public health concern. Additional oversight authority in such cases could prevent product that should not have passed a compliance panel from reaching retail shelves.

High workloads and inefficient, incomplete, and time-consuming tracking processes have likely impacted ORELAP's ability to respond to issues arising in Oregon's marijuana labs in a timely manner. ORELAP lost two key managers in early 2017 and has struggled with low staff numbers and high workloads for the past two years. ORELAP has five full time staff, including three assessors, a program manager, and a program

support position. The program was only recently able to staff fully, and was down to three people for over a year. They gained some position authority after taking over accreditations for drinking water labs in California and the introduction of marijuana lab accreditations, and are currently participating in a workload study to determine their true staffing needs.

ORELAP performs lab assessments on over 150 labs in several states and other countries. Of these labs, 86 are outside of Oregon. A single on-site lab assessment at a large lab can take up to 100 hours of staff time and could include substantial additional travel time. ORELAP staff duties also include answering questions from laboratories regarding regulatory requirements and investigating and substantiating complaints. Staff reported putting in double time and being unable to meet all their responsibilities under their current workload. One assessor said that they were frequently on the road, and in the month of July 2018 assessed labs in Oregon, California, and Fiji, and had to delay work related to Oregon marijuana labs in order to perform those assessments.

ORELAP's process for tracking and monitoring marijuana lab proficiency test data is not efficient. The proficiency test provider is required to send copies of proficiency test results to ORELAP when sending the results back to the labs. An ORELAP official stated that the provider had neglected to send copies of proficiency tests conducted to the program for some time, though how long is unclear. The provider recently began sending ORELAP the results concurrently with the labs after being reminded that doing so was a condition in the contract.

ORELAP stores proficiency test results in individual lab folders, but they have not been compiled into a searchable database that would aid timely tracking. As of this report writing, marijuana proficiency test results were being copied into a spreadsheet for staff use, though that spreadsheet was itself not yet complete. Tracking the receipt and status of lab's proficiency test results from the provider is time consuming and inefficient. In comparison, ORELAP has a fully developed and searchable internal database for tracking drinking water proficiency test results that is programmed to accept test results from outside entities and is less labor intensive for staff.

Recommendations

To help prevent diversion of marijuana from OLCC licensees to the black market, OLCC should:

1. Continue to improve data controls within Metrc, such as establishing automatic checks to prevent entry errors before they happen;
2. Continue to develop baselines, dashboards, and other data monitoring practices, such as setting reasonableness thresholds to help identify higher-risk marijuana transactions;
3. Establish inspection frequency goals and metrics and determine how many inspectors are needed to meet those goals. If the current number of inspectors is too low, work with the Legislature to identify additional funding options. Periodically reassess inspection goals and metrics, and whether the number of inspectors aligns with them; and
4. Work with the Legislature to review its licensing fees for marijuana businesses and consider whether licensing fees could be adjusted to support capacity building for the marijuana regulatory program.

To help prevent diversion of marijuana from medical registrants to the black market, OHA-OMMP should:

5. Enforce existing data reporting requirements for medical marijuana growers;
6. Establish inspection frequency goals and metrics and determine how many inspectors are needed to meet those goals;
7. Under the guidance of the Governor's office and the Legislature, review the level of authority OMMP needs to improve its regulatory framework for security, product tracking, and bolster resources for inspections, or consider placing the medical marijuana compliance program within the existing OLCC authority and control framework; and
8. Evaluate the reasons behind high inspection staff turnover and implement management strategies to reduce turnover.

To help ensure the accuracy of testing results, OHA should:

9. Perform a thorough study on the potential impacts and presence of microbiological and heavy metal contaminants in marijuana products, to make an informed decision on adding them to testing requirements, potentially in consultation with a reference lab;
10. If microbiological and heavy metal testing are added to testing requirements, work with testing labs and ORELAP to accredit labs for microbiological and heavy metal testing;
11. In consultation with the Legislature, review options for medical marijuana testing and take action to better ensure product safety for medical marijuana patients. Potential actions could include:
 - a. Implementing a public health campaign with assistance from other state agencies to educate medical growers and patients on ways to avoid, reduce, or eliminate marijuana product contamination;
 - b. Requiring testing for all medical marijuana to ensure it is free of contaminants that may impact patient health;
12. Consider developing a reference lab focused on standards and methodology setting, additional compliance testing and random testing of marijuana products, and assessing the overall risk of marijuana product contamination; and
13. In consultation with OLCC, perform random compliance testing, or shelf audits, to independently validate test results and assure product safety.

To help improve the accuracy of lab testing data, OLCC should:

14. Update test result tracking requirements for subcontracted tests to ensure that results can be directly traced in Metrc to the lab that performed a specific test;
15. Require that all marijuana certificates of analysis be stored in Metrc, where they can be reconciled with the reported lab test results

16. Examine whether requiring lab staff to obtain OLCC worker permits would increase lab accountability; and
17. Work with ORELAP and the Legislature to ensure appropriate and sufficient staff coverage to better monitor lab practices and review test result data.

To help improve testing lab accuracy and accreditation, OHA-ORELAP should:

18. Continue transitioning alternate matrix solvent proficiency tests in Oregon to real matrix solvent proficiency tests;
19. Complete all provisional accreditation assessments to ensure that sampling procedures taken by labs are appropriate;
20. Streamline the proficiency test tracking process for marijuana labs;
21. Review its level of authority to address lab issues related to upholding accreditation standards to determine what level is needed, and work with the Legislature to make necessary adjustments;
22. Work with OLCC and the Legislature to ensure appropriate and sufficient staff coverage to better monitor lab practices and review test result data; and
23. Develop a strategy to meet established response timelines for addressing proficiency test failures and other lab accreditation deficiencies.



January 25, 2019

Kip Memmott, Director
Secretary of State, Audits Division
255 Capitol St. NE, Suite 500
Salem, OR 97310

Dear Mr. Memmott,

This letter provides a written response to the Audits Division's final draft audit report titled *Oregon's Framework for Regulating Marijuana Should Be Strengthened to Better Mitigate Diversion Risk and Improve Laboratory Testing*.

The Oregon Liquor Control Commission (OLCC) appreciates the timely audit of the marijuana program from the Secretary of State's Audits Division (SOS Audits Division) and generally agrees with the recommendations.

The OLCC was tasked with the regulation of the recreational marijuana program with the passage of Measure 91 in 2014. Each year since, subsequent legislation has passed modifying the program and OLCC's roles and responsibilities.

As we enter 2019 the agency is able to focus more on streamlining policies and procedures and better utilizing our data to manage the marijuana control systems intelligently, ensuring that any growth or change is socially responsible, responsive to citizens' needs, and encourages the development of all Oregon industry.

Below is OLCC's detailed response to each recommendation in the audit.

RECOMMENDATION 1		
Continue to improve data controls within Metrc, such as establishing automatic checks to prevent entry errors before they happen.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1, 2019 and ongoing	TJ Sheehy 503-872-5017



Narrative for Recommendation 1

OLCC agrees with the high importance of data accuracy and fidelity in the Cannabis Tracking System. The Metrc system has developed greater controls to prevent entry errors since recreational licensure began in 2016. The OLCC agrees that more controls can be instituted based on the nature of entry errors that have been seen to date.

OLCC will develop a list of system changes to institute additional controls to prevent entry of impossible values (for example, lab results that exceed 1,000 milligrams per gram). OLCC will also solicit input from Metrc users on reports and additional “checks and balances” within Metrc that would better enable licensees to audit their own data and confirm the accuracy of items they receive from others. OLCC will work with Metrc to develop cost estimates and a timeline to implement the software changes in the Cannabis Tracking System. This implementation plan is expected to be completed by July 1, 2019.

Aside from direct data entry in the Cannabis Tracking System, licensees may enter data via file upload (e.g. CSV files) or Application Programming Interface (“API”). API data transmission occurs from third-party software and, although Metrc validates all software for integration with the Cannabis Tracking System, there is much less ability to directly influence or control the quality of data that is entered through either file upload or the API. The OLCC will continue to work with Metrc to develop protocols to audit the quality of data entered via file upload and/or the API on an ongoing basis.

RECOMMENDATION 2		
Continue to develop baselines, dashboards, and other data monitoring practices, such as setting reasonableness thresholds to help identify higher-risk marijuana transactions.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1, 2019 and ongoing	TJ Sheehy 503-872-5017

Narrative for Recommendation 2

The OLCC has begun to create a unit of compliance analysts charged with bringing the initial vision of the tracking system to life. The Cannabis Tracking System (CTS) is at the heart of creating a comprehensive approach of using data to create a system of violation prevention, deterrence and detection through the automated and manual identification of data anomalies in CTS. Central to the system is the ability to flag activities for warnings and violation tickets followed by inspectors in the field who inspect or survey licensee activities. Utilizing basic algorithms and programming, the regular production of data reports will unleash the tremendous value of the data reported into CTS.

In addition to the work already completed to warn licensees of data anomalies and potential violations, OLCC will implement formal procedures for utilizing data from CTS in its compliance activity. OLCC has begun to develop a compliance dashboard that relies on data entered into CTS that is out of the expected norm. When completed this dashboard will be utilized by compliance managers to identify high-priority cases and licensees that may warrant greater scrutiny and follow-up. This dashboard will include baselines of “reasonableness thresholds” and will be implemented by July 1, 2019.

RECOMMENDATION 3		
Establish inspection frequency goals and metrics and determine how many inspectors are needed to meet those goals. If the current number of inspectors is too low, work with the legislature to identify additional funding options. Periodically reassess inspection goals and metrics, and whether the number of inspectors aligns with them.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1, 2019 and ongoing	Shannon Hoffeditz 503-872-5212

Narrative for Recommendation 3

It was not until 2018 with the integration of marijuana enforcement into public safety that compliance really took hold. While there are more resources necessary to complete this process, OLCC has established a management structure that is integrated within the Public Safety Division and in regional field offices. OLCC has made progress on training staff and developing field procedures for enforcement inspections of each license type.

Compliance inspections vary based on the reason for the inspection, and the level of licensee compliance. Inspections generally fall into the following categories:

- Harvest inspections – producer licensees
- Minor Decoy Operations – retail licensees
- Compliance investigations – all licensees
- Alteration of licensed premises inspections – all licensees
- Pre-license inspections – all licensees

Currently recreational program inspectors are funded at a ratio of 100 licenses to 1 inspector. The agency believes this ratio is too low and is requesting additional staff so the ratio will be closer to 75 to 1 in the next two years.

In OLCC’s 2019-21 budget request, the agency has asked for additional staffing including 8 marijuana regulatory specialists to ensure regulatory compliance; 1 laboratory compliance specialist to focus on laboratory compliance, protocol and regulation; 3

office specialists to utilize the information stored on video to enforce compliance and prevent or detect diversion; and funding for continuing strategic and tactical communications support related to marijuana.

In order to monitor the number of inspectors needed to effectively regulate, the OLCC plans to utilize its case management system to help determine average inspection times. In addition to the case management system, OLCC staff tracks the outcome of all inspections to determine general workload based on the types of inspections being conducted in each region and identify inspections that require significant additional staff time, such as alleged cancellable violations.

RECOMMENDATION 4		
Work with the Legislature to review its licensing fees for marijuana businesses and consider whether licensing fees could be adjusted to support capacity building for the marijuana regulatory program.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1, 2019 and ongoing	Bill Schuette 503-872-5023

Narrative for Recommendation 4

The OLCC continues to work with Department of Administrative Services (DAS) and the Legislature on appropriate funding, budget and staffing requests. Based on the budget allocated to the agency, licensing fees are adjusted.

If license fees are to be increased, the OLCC may not do so unilaterally. While the fee levels are established in OLCC’s administrative rules, the agency requires approval to raise the fees and spend the revenues. OLCC’s marijuana program is exclusively fee-funded. Fee revenues may only be at a level to cover programs costs and a small operating reserve. If OLCC were granted budgetary authority to collect and spend more fee revenue, the agency would only be able to fund specific positions or agency costs. Without additional authority, OLCC could not raise fees.

The OLCC realizes this is an important conversation and will continue discussions with the Governor and legislators as the program matures.

RECOMMENDATION 14		
Update test result tracking requirements for subcontracted tests to ensure that results can be directly traced in Metrc to the lab that performed a specific test.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1, 2019 and ongoing	TJ Sheehy 503-872-5017

Narrative for Recommendation 14

OLCC’s Division 25 administrative rules (OAR 845-025-5045) specify what information labs must enter into the Cannabis Tracking System when testing marijuana items. Divisions 7 and 64 (promulgated by OHA) specify further requirements for lab testing and documentation. OLCC does exercise direct control over the test types from which labs select when entering results in the Cannabis Tracking System. While the level of effort to change these test types is minimal and would not require software development to implement, requiring subcontracted labs to enter specific information may require administrative rule changes and coordination between OLCC and OHA. By July 1, 2019, OLCC will identify rule changes that may be required in Divisions 7, 25, and 64 and develop an implementation plan and timeline for any required Division 25 rulemaking to meet this recommendation.

RECOMMENDATION 15		
Require that all marijuana certificates of analysis be stored in Metrc, where they can be reconciled with the reported lab test results.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1, 2019 and ongoing	TJ Sheehy 503-872-5017

Narrative for Recommendation 15

As in the case of implementing changes to requirements for subcontracted tests, requiring labs to upload additional information into the Cannabis Tracking System may require changes to administrative rules in Divisions 7, 25, and 64. Moreover, while the functionality to require uploads of certificates of analysis has already been developed by Metrc for a different state, if this feature were enabled in Oregon the number of files required to be stored within the Cannabis Tracking System would have significant implications for server capacity. By July 1, 2019, OLCC will develop an implementation

plan that identifies required amendments to administrative rules as well as changes to the Cannabis Tracking System and associated development or server expansion costs.

RECOMMENDATION 16 Examine whether requiring lab staff to obtain OLCC worker permits would increase lab accountability.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1,2019	Amanda Borup 503-872-5456

Narrative for Recommendation 16

ORS 475B.261 gives the OLCC authority to require worker permits for producers, processors, wholesalers and retailers. The authority to regulate labs and their employees is located in a different section of statute, ORS 475B.550, and does not include requirements for worker permits.

By July 1, 2019 the OLCC will examine the statute, and will work with Oregon Health Authority (OHA) and Oregon Department of Justice (DOJ) to determine if the OLCC has the authority to issue lab worker permits. If so, OLCC will work with OHA and the industry to determine if a worker permit for lab employees will benefit the industry and add a level of accountability.

RECOMMENDATION 17 Work with ORELAP and the Legislature to ensure appropriate and sufficient staff coverage to better monitor lab practices and review test result data.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 1, 2019 and ongoing	Amanda Borup 503-872-5456

Narrative for Recommendation 17

OLCC recognizes this is a critical issue for the accountability of the marijuana program in Oregon, and will dedicate staff to work with the other agencies and the Governor’s office to put in place a plan to strengthen regulatory oversight of the laboratory sampling and testing. Such a plan, including a funding mechanism and potential administrative rule adjustments, will require strong coordination between Oregon

Health Authority (OHA), Oregon Environmental Laboratory Accreditation Program (ORELAP), Oregon Department of Agriculture (ODA) and OLCC. The funding plan to implement controls will require approval from the Governor and the Legislature.

In the 2019-21 OLCC budget request, OLCC requested funding for 1 laboratory compliance specialist to focus on laboratory compliance, protocol and regulation. Compliance staff can spend a significant amount of time researching complaints against laboratories. Having a dedicated staff member to focus on laboratory compliance, protocol and regulation will assist the overall efficiency of OLCC's compliance program. Regulatory inspectors can get needed assistance in the field and OLCC will have the capacity to work with the OHA and ORELAP on detailed investigations and audits (provided OHA and ORELAP are also provided resources). ORELAP will benefit in having a contact person at the OLCC who understands laboratory protocol and the OLCC rules and regulations. OHA will benefit by having a staff member who works directly with labs and can track modifications of testing requirements and train and educate other inspectors on these change.

Even with its considerable imperfections, Oregon's aggressive testing standards are nation leading and important to marijuana regulation across the nation and internationally. Laboratory regulation is an important policy area for all states regulating both medical and recreational marijuana. Protecting health and safety in this area, and the consistency of standards between jurisdictions for measuring product qualities, is important to harmonize. Today, testing methodology varies from laboratory to laboratory and state to state. Regulators and the industry are looking to improve and standardize testing to protect consumers through consistent regulation. Even though interstate commerce is not available today, brands that consumers are familiar with are available through each state's regulatory systems and these products, with respect to testing are not equivalent for consumer use. This position will help the OLCC continue to manage to a best practices level of service.

Please contact Amanda Borup at 503-872-5456 with any questions.

Sincerely,



Steve Marks
Executive Director
Oregon Liquor Control Commission



OFFICE OF THE DIRECTOR

Kate Brown, Governor

Oregon
Health
Authority

500 Summer St NE E20

Salem OR 97301

Voice: 503-947-2340

Fax: 503-947-2341

www.Oregon.Gov/OHA

www.health.oregon.gov

January 25, 2019

Kip Memmott, Director
Secretary of State, Audits Division
255 Capitol St. NE, Suite 500
Salem, OR 97310

Dear Mr. Memmott:

This letter provides a written response to the Audits Division's final draft audit report titled *Oregon's Framework for Regulating Marijuana Should Be Strengthened to Better Mitigate Diversion Risk and Improve Laboratory Testing*.

The Oregon Health Authority appreciates the professional work of the Oregon Secretary of State's Office Audits Division staff as they conducted this audit of both the medical and retail marijuana markets. We understand and appreciate the magnitude of the assignment and your commitment to producing an accurate audit. Thank you for the opportunity to review and respond to the final draft report. OHA agrees with the recommendations put forth and the areas for improvement and outlined many of these areas in our report to the Oregon Cannabis Commission in May 2018. Some of the recommendations will require legislative changes and fall outside of the scope of OHA's current statutory authority. This includes recommendations 6, 7, 11, 12, 21 and 22. In the absence of statute change, the ability to comply with the recommendations is limited.

Since full legalization of marijuana in July 2015, the Oregon Medical Marijuana Program (OMMP) has expanded its focus to include regulation of marijuana while continuing to administer the card registry program. The program has grown to include compliance and analysis staff; developed and implemented databases and web-based applications to track product transfers and inventory on hand for growers, processing sites and dispensaries; enhanced all existing data systems; addressed multiple legislative changes each year; and implemented a grow site inspection process while maintaining inspections of dispensaries and processing sites.

The program's two primary objectives are to remain a patient-centered registry, and to efficiently and effectively regulate the production, transfer and testing of medical marijuana. The OMMP's strengths lie in timely processing of registrant cards, providing good customer service, and the design and implementation of necessary enhancements to new and existing systems to meet new legislative requirements. Areas for improvement include the need to improve reporting compliance and staffing in the compliance unit. Utilizing the Cannabis Tracking System (CTS) through the Oregon Liquor Control Commission (OLCC) has addressed reporting compliance for grow sites with three or more patients. Additionally, having the authority to revoke growers, processors and dispensaries' registrations for not reporting helps bring these registrants into compliance as well. Compliance Staffing remains an area that needs to be addressed. A robust compliance system requires a strong presence in the state, but current staffing levels cannot sufficiently provide such a presence. The program's management is aware of the constraints and challenges OMMP faces.

Additionally, regulatory stability, sufficient funding and staff resources would allow OMMP to consistently apply requirements of the Oregon Medical Marijuana Act to better serve patients and ensure access to medical marijuana as a therapeutic option.

The Oregon Environmental Laboratory Accreditation Program (ORELAP) was established in 1999 and operates under ORS 438.605 to 438.620 to assess over 120 laboratories. ORELAP accredits laboratories based upon standards established by the National Environmental Laboratory Accreditation Program and under the guidance of the Clean Air Act, Clean Water Act, Safe Drinking Water Act, the Resource, Conservation and Recovery Act and Oregon statute related to cannabis. Since full legalization of marijuana, ORELAP has expanded its focus to include Cannabis testing regulation under ORS 475B.550 to 475B.590. The program objective is to assure to the public that the accredited laboratories meet the minimum quality standards and generate data of known quality through the implementation of a quality assurance program that adheres to TNI Standards. ORELAP management is aware of the current challenges and areas of improvement and is consistently working towards this goal. Areas for improvement include the completion of provisional accreditation assessments for sampling, continue transitioning to a more representative in matrix proficiency test sample for residual solvent samples, to meet established response timeliness for addressing proficiency test failures and to have established standardized methods for cannabis testing. ORELAP capacity rests mostly on current staffing coverage to monitor lab practices and review test data. Additionally, the need for a state-funded and independent reference laboratory could establish standardized methods for cannabis testing which would provide guidance to ORELAP accreditation process on testing methodologies and to ensure that reported test results are dependable and consistent between cannabis labs.

Below is our detailed response to each recommendation in the audit.

RECOMMENDATION 5 (OHA-OMMP) Enforce existing data reporting requirements for medical marijuana growers.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 25, 2019	Carole Yann Section Manager 971-673-2507

Narrative for Recommendation 5

OMMP created a plan to address non-compliance with reporting for growers and grow sites using the monthly Oregon Medical Marijuana Online System (OMMOS) as well as grow sites with 3 or more patients that were required to track using the Cannabis Tracking System (CTS). The program’s enforcement priority was to target those registrants not complying with the CTS tracking requirements first as statute provided that OHA must revoke or not renew grow sites that did not comply with the law by July 1, 2018. At that time, there were 365 grow sites that were out of compliance with the law. Enforcing this tracking requirement was a time-consuming process and the

program is still addressing many enforcement actions through appeals, hearing, settlement agreements and follow-up to ensure the settlement agreements are being adhered to.

Enforcement of non-reporting for those using OMMOS will begin with warning letters sent to all growers at grow sites who do not report for the month. They will have 15 days to report or be charged a civil penalty. Notices of Intent to Impose Civil Penalties will be sent to those who do not comply. For those who still do not comply OMMP will issue a Notice of Intent to Revoke, followed by issuing a Final Order of Revocation if a hearing is not requested.

It is important to note the volume of citations needed to address non-reporters will strain OMMP's staff resources and also impact the Department of Justice's resources to assist with thousands of potential contested administrative hearings.

RECOMMENDATION 6		
(OHA-OMMP) Establish inspection frequency goals and metrics and determine how many inspectors are needed to meet those goals.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 25, 2019	Carole Yann Section Manager 971-673-2507

Narrative for Recommendation 6

The Compliance unit has four permanent and two limited duration Compliance Specialist's to conduct inspections, investigate complaints, and as of July 2018, complete enforcement actions resulting from OLCC inspections of growers at locations using the CTS tracking system. An inspection includes the time involved for preliminary processing, conducting the actual inspection, completing all post-inspection report writing and processing of any necessary enforcement action and follow up inspections.

Based on current position authority, OMMP has set an expectation of four grow site inspections per week per inspector, equating to 1,150 inspections with a reduction in following years due to the limited duration positions ending July 2019. Focusing on inspections with grow sites with 2 patients (2,610 grow sites) OMMP could conduct an annual inspection of approximately 40% of those grow sites.

OMMP will complete a monthly report on the number of inspections, complaint investigations, and enforcement actions the unit completes and will use that document to measure our success through analysis of inspection outcomes ensuring that we are meeting our goals.

Without legislation to increase position authority OHA would not be able increase the number of inspections conducted. OHA awaits direction from the Oregon legislature regarding this recommendation and will support decision making with data and evidence-based practice.

RECOMMENDATION 7		
(OHA-OMMP) Under the guidance of the Governor’s office and the Legislature, review the level of authority OMMP needs to improve its regulatory framework for security, product tracking, and bolster resources for inspections, or consider placing the medical marijuana compliance program within the existing OLCC authority and control framework.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree, but not allowed under current statute	TBD, pending provision of statutory authority	Holly Heiberg, OHA Government Relations 971-207-7767

Narrative for Recommendation 7

In our Operations and Compliance Assessment, submitted to the Oregon Cannabis Commission in May 2018, we acknowledge the shortcomings OHA has in regulation and that policy makers are working towards determining which agency is and should be responsible for specific components of the law.

OHA awaits direction from the Oregon legislature regarding this recommendation and will support decision making with data and evidence-based practice.

RECOMMENDATION 8		
(OHA-OMMP) Evaluate the reasons behind high inspection staff turnover and implement management strategies to reduce turnover.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 25, 2019 or TBD, pending position authority	Carole Yann Section Manager 971-673-2507

Narrative for Recommendation 8

The migration of registrants from OMMP to OLCC and the decline in patients and registered medical dispensaries and processors resulted in decreased revenue to support compliance operations and led staff to feel insecure about the stability of the program. SB 1057, passed during the 2017 legislative session, removed the entire compliance unit position authority effective July 1, 2018. OHA was able to request and receive permanent position authority for four compliance specialists, and limited duration authority for the manager, a compliance specialist 1 and an operations and policy analyst 1.

The limited duration positions end July 2019. As a result, staff are concerned about their employment status. Overall, without a stable program with permanent positions, we may continue to see staff turnover.

Management has also acknowledged staff morale and is beginning to address staff concerns. OMMP partnered with an Employee Assistance Program to provide employees an opportunity to bring forward their concerns and has implemented actions to address them. Management has taken classes and employees have received burnout prevention classes. Management is continuing to work with the staff to address their concerns and is implementing a performance system agency wide. Staff turnover is an important element of the performance measures.

RECOMMENDATION 9		
(OHA) Perform a thorough study on the potential impacts and presence of microbiological and heavy metal contaminants in marijuana products, to make an informed decision on adding them to testing requirements, potentially in consultation with a reference lab.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	January 25, 2020	André Ourso Center Administrator 971-673-0403

Narrative for Recommendation 9

While OHA agrees with this recommendation, there are currently no resources to conduct such a study. Resources would need to be allocated for this study to occur.

In the absence of dedicated resources to conduct a thorough study, OHA will reach out to other states with legalized marijuana to request their data related to testing for specific microbiological and heavy metal contaminants. OHA can also convene a rules advisory committee to seek guidance on testing for microbiological and heavy metal contaminants in marijuana products.

RECOMMENDATION 10		
(OHA) If microbiological and heavy metal testing are added to testing requirements, work with testing labs and ORELAP to accredit labs for microbiological and heavy metal testing.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 25, 2019, or TBD	Carole Yann Section Manager 971-673-2507

Narrative for Recommendation 10

Depending on the study and the findings received on the potential impacts and presence of microbiological and heavy metal contaminants in marijuana products, OHA will work with ORELAP, and testing labs to accredit them for these additional tests in the same manner as done for pesticides, solvents and potency.

<p>RECOMMENDATION 11 (OHA) In consultation with the Legislature, review options for medical marijuana testing and take action to better ensure product safety for medical marijuana patients. Potential actions could include:</p> <ul style="list-style-type: none"> a. Implementing a public health campaign with assistance from other state agencies to educate medical growers and patients on ways to avoid, reduce, or eliminate marijuana product contamination; b. Requiring testing for all medical marijuana to ensure it is free of contaminants that may impact patient health. 		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	TBD, pending provision of additional resources	Holly Heiberg, OHA Government Relations 971-207-7767

Narrative for Recommendation 11

OHA acknowledges the importance of public safety and implementing a public health campaign would be important. While OHA agrees with this recommendation, there are no resources to conduct a campaign. Funds would need to be allocated for the campaign to occur. OHA awaits direction from the Oregon legislature regarding this recommendation and will support decision making with data and evidence-based practice.

<p>RECOMMENDATION 12 (OHA) Consider developing a reference lab focused on standards and methodology setting, additional compliance testing and random testing of marijuana products, and assessing the overall risk of marijuana product contamination.</p>		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	January 25, 2020	André Ourso Center Administrator 971-673-0403

Narrative for Recommendation 12

The need for a reference lab has been acknowledged in the report to the Oregon Cannabis Commission in May 2018 as a necessary component to ensure the safety of marijuana in the market and accuracy of cannabis testing labs. The Oregon Cannabis Commission included a recommendation to create a reference lab in the report to the interim committees of the Legislative Assembly related to Health and Judiciary. Funds would need to be allocated for this to be implemented.

RECOMMENDATION 13		
(OHA) In consultation with OLCC, perform random compliance testing, or shelf audits, to independently validate test results and assure product safety.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 25, 2019	Carole Yann Section Manager 971-673-2507

Narrative for Recommendation 13

OHA will work with OLCC to implement this recommendation. In the absence of a reference lab, OHA and OLCC will partner with the Department of Agriculture to conduct the audit tests. In order to accomplish this recommendation, additional staff resources and funding for the tests will be needed.

RECOMMENDATION 18		
(OHA-ORELAP) Continue transitioning alternate matrix solvent proficiency tests in Oregon to real matrix solvent proficiency tests.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	June 2019	Alia D. Servin (503) 693-4122

Narrative for Recommendation 18

As of January 1, 2019, with the new testing rule changes, ORELAP requires in-matrix proficiency testing for pesticide and potency analyses. Currently, ORELAP is working with the proficiency test (PT) provider Phenova to continue transitioning to a more representative in matrix proficiency test for residual solvent samples. As a part of Phenova’s contract agreement, the contractor will continue to develop and provide other cannabis matrix PT standards to support the OHA lab accreditation program. These can include additional matrix standards (i.e., potency and pesticides in concentrates and edibles) as well as additional regulated analytes as they become promulgated.

RECOMMENDATION 19		
(OHA-ORELAP) Complete all provisional accreditation assessments to ensure that sampling procedures taken by labs are appropriate.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	June 2019	Alia D. Servin (503) 693-4122

Narrative for Recommendation 19

Currently, ORELAP is working towards this goal in collaboration with OLCC. In November of 2018, ORELAP requested through OLCC video footage of a selected day and time of sampling events. These dates were selected based on the laboratory's sampling plans and chain of custody documents to evaluate and assess sampling protocols and practices from 19 cannabis labs. As of January 23, 2019, ORELAP received confirmation of three video recordings. Based on the cannabis laboratories' failure to provide the requested video recordings, ORELAP is currently scheduling on-site assessments of the remaining ten laboratories with provisional sampling accreditation. Upon completion of the ten laboratories' observation assessments of sampling, there will be no provisional accreditation sampling thereafter.

RECOMMENDATION 20		
(OHA-ORELAP) Streamline the proficiency test tracking process for marijuana labs.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	June 2019	Alia D. Servin (503) 693-4122

Narrative for Recommendation 20

Currently, ORELAP is working on this process in collaboration with the PT Provider and OHA IT specialists. ORELAP has developed a summary document to keep track of laboratory's participation in PT studies and PT performance. It is ORELAP's intent to transition the PT evaluation to ORELAP's database in order to streamline the proficiency test tracking process for cannabis labs. Additionally, we are working closely with Phenova PT provider in order to receive PT final reports in a timely manner to ensure appropriate corrective actions are addressed in accordance with the TNI standards.

RECOMMENDATION 21 (OHA-ORELAP) Review its level of authority to address lab issues related to upholding accreditation standards to determine what level is needed, and work with the Legislature to make necessary adjustments.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree, but not allowed under current statute	TBD, pending provision of statutory authority	Holly Heiberg, OHA Government Relations 971-207-7767

Narrative for Recommendation 21

OHA awaits direction from the Oregon legislature regarding implementation of this recommendation. ORELAP will support the recommendation with time capture data staff is currently compiling for evidence-based practice.

RECOMMENDATION 22 (OHA-ORELAP) Work with OLCC and the Legislature to ensure appropriate and sufficient staff coverage to better monitor lab practices and review test result data.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree, but not allowed under current statute	TBD, pending provision of statutory authority	Holly Heiberg, OHA Government Relations 971-207-7767

Narrative for Recommendation 22

OHA awaits direction from the Oregon legislature regarding implementation of this recommendation. ORELAP will support the recommendation with time capture data staff is currently compiling for evidence-based practice.

RECOMMENDATION 23 (OHA-ORELAP) Develop a strategy to meet established response timelines for addressing proficiency test failures and other lab accreditation deficiencies.		
Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	June 2019	Alia D. Servin (503) 693-4122

Narrative for Recommendation 23

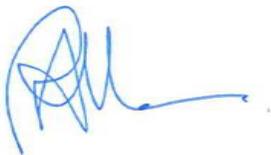
ORELAP is working on this strategy in collaboration with the PT provider to receive the final reports in a timely manner and to ensure the appropriate corrective actions are addressed in accordance to the TNI standards and ORELAP Program policies. Once the PT results are received from the PT provider, PT results will be evaluated for conformance to the TNI standard to determine the accreditation status of a laboratory within 60 days of the receipt of the final report from the PT provider.

ORELAP is currently developing a summary document that contains historical information about the cannabis labs PT results to meet the established timeline for the evaluation of proficiency test failures and to address cannabis labs PT failures in a timely manner and according to ORELAP Program policies.

The accreditation status is based on a laboratory maintaining a history of at least two successful performances out of the most recent three PT samples analyzed for the same accreditation FoPT. Upon any desk review, ORELAP sends a letter requesting information regarding the unacceptable performances. The ORELAP manager will notify the laboratory's director by registered mail, return receipt, of suspension of accreditation. The notification shall include the beginning date of the suspension, which elements are suspended and the reasons for the suspension. If the cause of suspension has not been corrected within six months or the period of accreditation, whichever is shorter, the status of the affected fields of testing will change to revoked.

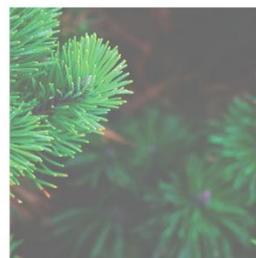
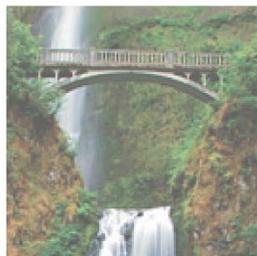
Please contact Carole Yann, Oregon Medical Marijuana Section Manager at 971-673-2507 with any questions.

Sincerely,



Patrick M. Allen
Director

- EC: Steve Winn
Andrew Love
Ariana Denney
William Garber
Kris Kautz
Andre Ourso
Carole Yann
Alia Servin
Jonathan Modie
Karen Slothower
Sarah Landis
Stephanie Ringsage



Audit Team

William Garber, CGFM, MPA, Deputy Director

Andrew Love, CFE, Audit Manager

Stephen Winn, MPP, Principal Auditor

Bonnie Crawford, MPA, Senior Auditor

Ariana Denney, MPA, Staff Auditor

About the Secretary of State Audits Division

The Oregon Constitution provides that the Secretary of State shall be, by virtue of his office, Auditor of Public Accounts. The Audits Division performs this duty. The division reports to the elected Secretary of State and is independent of other agencies within the Executive, Legislative, and Judicial branches of Oregon government. The division has constitutional authority to audit all state officers, agencies, boards and commissions as well as administer municipal audit law.

This report is intended to promote the best possible management of public resources.
Copies may be obtained from:

Oregon Audits Division
255 Capitol St NE, Suite 500 | Salem | OR | 97310
(503) 986-2255
sos.oregon.gov/audits