

>> Oregon medical marijuana
program operations and
compliance assessment May, 2018

Report to the oregon cannabis commission.

Acknowledgments

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Executive summary

HB 2198, passed during the 2017 legislative session established the Oregon Cannabis Commission (“the Commission”) with the Oregon Health Authority (OHA). One of the duties of the Commission is to provide advice to the OHA with respect to the administration of the Oregon Medical Marijuana Act (OMMA)¹. The following assessment of the Oregon Medical Marijuana Program (OMMP) provides the Commission and public health leadership with information about operations and functions of the program. This report specifically highlights the program’s challenges and strengths and outlines areas to improve the program’s implementation of the OMMA.

The OMMP, established within the Public Health Division (PHD) of the OHA, registers and regulates medical marijuana patients, medical marijuana growers, grow sites, processors, dispensaries and caregivers, and promulgates cannabis testing rules.

Since the inception of full legalization of marijuana in Oregon with voters’ approval of Ballot Measure 91 and the subsequent passage of HB 3400 (2015), the OMMP and its registrants have been significantly affected by changes to the OMMA. The OMMP has been confronted with several challenges while implementing and enforcing the OMMA and other laws related to full legalization.

These challenges are based upon:

- **Frequent legislative changes** affect OMMP’s ability to consistently regulate and monitor the medical marijuana market,
- **Early Retail Sales** that incentivized the use of OMMP by registrants to profit from the production and sale of medical marijuana, and
- **Insufficient funding and staffing resources** to meet the demands of robust regulation.

This assessment highlights the program’s challenges, strengths, and areas for improvement.

Challenges to the program:

- Insufficient and inaccurate reporting and tracking
- Inability to validate grow site locations
- Dispensary and processor inspections did not keep pace with applications
- Not enough inspections and enforcement of grow sites

¹ ORS 475B.961

- Resources unable to meet regulatory demand
- Existing data systems incompatible with legislative changes
- Lack of consistent process for testing laboratories and product destruction
- Addressing complaints from patients

Strengths of the program:

- Ability to facilitate access to medical marijuana
- Built framework to regulate growers and dispensaries
- Ability to implement numerous legislative changes with transparency
- Broad communication and outreach

OMMP management is also aware of the areas needing improvement and is working towards solutions to address the areas within its control. Actions OMMP is taking to improve its regulation of medical marijuana include:

- Implementing the use of the Oregon Liquor Control Commission's (OLCC) Cannabis Tracking System (CTS) by OMMP processing sites, dispensaries and certain growers.
- Implementing a new administrative process to require proof of addresses when processing cardholder applications will assist in validating grow site locations.

Adequate compliance and enforcement resources is another area of concern that needs to be addressed. A robust compliance system requires a visible enforcement presence, however current staffing levels do not sufficiently provide such a presence.

Regulatory stability and sufficient funding and staff resources would allow OMMP to consistently apply requirements of the OMMA to better serve patients and ensure access to medical marijuana as a therapeutic option. We recommend that policy makers consider actions in the following areas:

- Streamline regulation of growers, retailers and processors and make data more available to law enforcement and local jurisdictions.
- Enhance funding for OMMP compliance and enforcement to ensure marijuana production is preserved and directed to patients who count on it to address their medical conditions.

As policy makers work towards enhancing cannabis regulation, it is important to ensure that OMMP remains responsive to the needs of medical marijuana patients into the future.

Introduction

The purpose of the Oregon Medical Marijuana Program (OMMP) is to implement and administer provisions of the Oregon Medical Marijuana Act (OMMA)² to ensure Oregonians suffering from debilitating medical conditions have safe and well-regulated access to medical marijuana as a therapeutic treatment for those conditions. This report is an assessment of OMMP's operations since full legalization, identifying strengths, challenges, and opportunities for improvement.

Full legalization of marijuana in November 2014, when Oregon voters approved Ballot Measure 91, changed the OMMA and broadened OHA's regulatory responsibilities regarding medical marijuana. This shift in cannabis policy significantly impacted the OMMP and its registrants. Since full legalization, the program has been confronted with three main issues in administering the OMMA and ensuring medical marijuana patients have safe and legal access to medical marijuana. These challenges include implementing significant successive legislative changes to the OMMA, addressing the use of OMMP for profit from the sale of medical marijuana, and inadequate funding and staffing resources to meet the demands of robust regulation.

The first of the above challenges, specifically nine cannabis bills that passed in consecutive legislative sessions since 2016, brought significant changes, requirements and enhancements to the OMMP. The program, while implementing numerous legislative requirements, has not had time to fully evaluate the implementation of a particular legislative change before implementing new requirements in subsequent legislation. This environment of constant legislative change resulted in an inconsistent regulatory environment that made the program's ability to consistently apply rules and processes to its registrants challenging. The second challenge, arose from the early retail sales period, from October 2015 to October 2016, when OMMP registered dispensaries and processing sites were the only facilities allowed to sell marijuana to the general public prior to OLCC setting up its recreational use licensing system. This early start period attracted cannabis businesses interested in profit to participate in a system that was intended for compassionate and therapeutic purposes. Lastly, the third major challenge, inadequate funding and staffing, limited the ability of the program to sufficiently ensure compliance of its participants, especially in a rapidly changing regulatory environment.

Background and Legal Framework

Voters approve marijuana use for medical purposes

In November 1998, Oregon voters approved Ballot Measure 67, which allowed the use of marijuana for medical purposes. The OMMA:

- Provided legal protections for patients with a qualifying debilitating medical condition,
- Required a written physician statement of a patient's debilitating medical condition and that the patient could benefit from the medical use of marijuana,
- Allowed a caregiver to assist a patient with accessing marijuana, and
- Mandated an Oregon Health Authority (OHA) identification registration system.

Subsequently, the OMMP was created within the Public Health Division of the Oregon Health Authority.

Legislature expands access and regulations

In 2006, changes in state law added the ability for a registered patient to assign a grower to produce marijuana for that patient. In 2013, additional changes to state law gave OHA authority to register Medical Marijuana Dispensaries, which could provide medical marijuana to patients and their caregivers. In 2014, Oregon voters approved Ballot Measure 91, which allowed the production, sale, and possession of non-medical marijuana by persons over 21 years of age.

In the 2015 legislative session, HB 3400 and SB 460 expanded OHA's role in regulating both medical and non-medical marijuana. HB 3400 provided that in addition to regulating medical marijuana, OHA would set requirements for testing, labeling and dosage of all cannabis products, whether medical or non-medical. SB 460 authorized medical marijuana dispensaries to sell limited marijuana retail products for non-medical adult use from October 1, 2015 through December 2016, and for OHA to regulate these limited early retail sales. These legislative changes required OMMP to significantly increase its regulatory oversight of medical cannabis access, production and sale.

The program's organizational structure evolved to include four principal program areas:

- A **card registry unit** that registers medical marijuana grow sites and issues registry identification cards to patients, caregivers, and growers;
- A **law enforcement unit** that provides technical assistance to applicants and registrants, and responds to inquiries by law enforcement, counties, cities, and water masters; and
- **Compliance and analysis units** that are responsible for regulating and tracking the sale and production of medical marijuana by medical marijuana dispensaries, processors, growers and grow sites.

In subsequent legislative sessions, the legislature made further changes and amendments to the cannabis regulatory structure. Nine cannabis bills passed between 2016 and 2018. These bills made significant regulatory changes that generally expanded patient and consumer access to marijuana, loosened restrictions on growers and established additional responsibilities of the OMMP. Implementation of each bill required extensive rule promulgation, policy and procedure creation, technology changes and additions, and extensive outreach to OMMP registrants and stakeholders. As the number of registered patients, growers and dispensaries dramatically increased, OMMP staffing did not increase.

Some of these bills and their provisions include:

2016

- **HB 4014** modified residency requirements; added the requirement to issue a temporary receipt the day a complete application is received from a patient; reduced the application fee for veterans; and removed the limit to the number of patients at a grow site addresses.
- **SB 1511** expanded early retail sales to include the sale of one single-serving low dose edible and one prefilled receptacle of an extract to a retail customer per day, and enacted a stay on plant count limits for growers that had applied to the Oregon Liquor Control Commission (OLCC).
- **SB 1598** allowed a patient or caregiver to provide marijuana to a processing site and for the processing site to transfer the products made back to the patient or caregiver; allowed a person to be designated to report inventory for all growers located at a grow site; and allowed OHA to adopt rules to implement non-profit dispensaries.
- **SB 1524** allowed veterans with a disability rating of 100 percent (which

directly resulted from active duty) to renew their OMMP registration without documentation from an attending physician.

- **SB 1601** exempted retail sales of marijuana items to OMMP patients and caregivers from taxation.

2017

- **HB 2198** established the Oregon Cannabis Commission (OCC); allowed an annual transfer of 20 lbs. of usable marijuana from certain OMMP grow sites into the OLCC recreational market; allowed OMMP caregivers to assist with production and processing of usable marijuana, cannabinoid concentrates, and medical cannabinoid products; made adjustments to plant limits for specific grow sites; changed the acceptable format of an ‘address’ considered sufficient to identify a grow site location; and clarified previous restrictions on marijuana retailers’ proximity to schools.
- **SB 1057** allowed OLCC marijuana producers to grow medical marijuana for OMMP cardholders at the same location as their producer license; directed OMMP to establish and maintain a database of information on OMMP participants and grow sites, to be accessible by the OLCC and the Department of Revenue (DOR); transferred the responsibility of labelling from OHA to the OLCC; made adjustments to plant limits for specific grow sites; required OMMP to develop and implement a means for specific grow sites to begin tracking in the OLCC’s Cannabis Tracking System (CTS); and directed OMMP to no longer renew grow sites that do not begin tracking in either CTS or OMMP’s internal tracking system on or before July 1, 2018.
- **SB 56** required OMMP to develop and maintain a hotline for certain local government and interagency officials to use to confirm whether a specific address is a current or proposed location of an OMMP grow site, processing site, or medical dispensary.

2018

- **SB 1544** passed and will take effect July 1, 2018. The bill allows OLCC producers to transfer immature plants to OMMP growers, patients, and caregivers; changes the acceptable ‘address’ format considered sufficient to identify a grow site location; makes adjustments to plant limits for specific grow sites; changes the criteria used to determine whether a grow site is required to report using CTS; adjusts the timeline of certain directives of the OCC; changes previous restrictions on marijuana retailers’ proximity to schools; and establishes a grant program for funding local law enforcement investigation of illicit marijuana activity.

Challenges to the Program

- Insufficient and inaccurate reporting and tracking
- Inability to validate grow site locations
- Dispensary and processor inspections did not keep pace with applications
- Too few grow site inspections
- Resources not meeting demands
- Existing data systems incompatible with legislative changes
- Lack of consistent process for testing laboratories and product destruction
- Addressing complaints from patients

Insufficient and inaccurate reporting and tracking

Medical marijuana growers are required to report their inventory of usable marijuana and other marijuana items as well as transfers made each month (ORS 475B.816). Similarly, medical processors and dispensaries are required to report itemized transfers made each month (ORS 475B.846, 475B.867). To comply with the monthly reporting requirements, a reporting system was developed for applicable registrants to report usable marijuana and cannabis product transfers and inventory. However, the system that was developed was limited to registrants self-reporting monthly aggregate amounts of usable marijuana and cannabis products. That system was built to the OHA's tracking authority provided in law, and is limited in its ability to measure and accurately account for the amount of medical marijuana produced and transferred. In addition, the reporting requirements do not allow for the collection of data that can accurately identify or track patients' medical marijuana needs.

SB 1057, passed during the 2017 legislative session required certain growers and all dispensaries and processors to use CTS by July 2018. Before the passage of SB 1057, OMMP did not have the statutory authority to require any of its growers, processors, or dispensaries to use a more accurate "seed-to-sale" tracking system similar to OLCC's CTS.

Compliance with monthly reporting by applicable registrants is consistently low. As shown in Table 1, compliance with reporting peaked at 42% in July and August of 2017. Upon implementation of mandatory reporting, growers were confused about the requirements to still report during non-growing seasons, which contributed to lower rates of reporting. Although growers who did not report were in noncompliance with the law, OMMP's compliance strategy focused on educating non-compliant growers about reporting rather than penalizing them.

	Growers who reported	Growers who did not report	Rate of compliance
January, 2017	6,028	9,829	38%
February, 2017	5,584	9,701	37%
March, 2017	5,265	9,460	36%
April, 2017	5,085	8,825	37%
May, 2017	5,262	8,630	38%
June, 2017	5,703	8,292	41%
July, 2017	5,804	8,038	42%
August, 2017	5,769	7,861	42%
September, 2017	5,290	7,776	40%
October, 2017	4,658	7,638	38%
November, 2017	3,693	7,634	33%
December, 2017	2,717	7,643	26%

Table 1

As of January 2018, the program had 25,615 growers who were growing at 20,025 grow sites. With approximately 33% or about of those growers required to report, the volume of citations needed to address non-reporters would be impractical considering OMMP’s staff resources and the impact on the Department of Justice’s resources to assist with thousands of potential contested administrative hearings. The program simply does not have the staff resources to issue civil penalties for the number of non-reporting growers shown in Table 1, let alone to afford each cited party their due process rights, including their opportunity to appeal a citation.

Compliance with reporting has also been comparatively lower for dispensaries and processors, as can be seen in Tables 2 and 3. OMMP also took an educational approach and did not impose civil penalties for not reporting.

	Dispensary count	Dispensaries who reported	Rate of compliance
January, 2017	172	45	26%
February, 2017	149	32	21%
March, 2017	110	23	21%
April, 2017	90	15	17%
May, 2017	49	14	29%
June, 2017	43	13	30%
July, 2017	31	13	42%
August, 2017	28	11	39%
September, 2017	23	10	43%
October, 2017	21	10	48%
November, 2017	21	9	43%
December, 2017	19	9	47%
Table 2			

	Processing site count	Processing sites who reported	Rate of compliance
January, 2017	106	24	23%
February, 2017	75	19	25%
March, 2017	61	11	18%
April, 2017	10	8	80%
May, 2017	13	6	46%
June, 2017	13	5	38%
July, 2017	13	5	38%
August, 2017	13	5	38%
September, 2017	13	6	46%
October, 2017	12	4	33%
November, 2017	12	5	42%
December, 2017	12	4	33%
Table 3			

However, current compliance rates indicated in Table 3 for both dispensaries and processors are skewed lower than the true rate of compliance because these numbers include facilities that have active registrations, but which have ceased operating and/or intend to transition to participation in the OLCC’s recreational market.

OMMP is currently taking steps to address non-compliance with reporting. As part of implementing SB 1057, OMMP will revoke the registrations of participants

who are not complying with their reporting requirements by July 1, 2018, whether reporting in CTS or in OMMP's internal monthly reporting system. Between March and July 2018, OMMP is communicating with all growers, dispensaries and processors and outlining the requirements that must be followed. Communication will be sent through bulletins, targeted letters, emails, and in-person overviews and coordinated efforts with advocacy groups. The OMMP is striving to ensure growers, dispensaries and processors know the requirements of reporting and the steps they must follow to comply, or face revocation.

Another issue with tracking and reporting is that the units of measure used for reporting cannabis and cannabis products are inconsistent. The OMMP online system requires reporting in metric units (either grams or kilograms). However, the OMMP observed that some growers appear to select "grams" as the units being reported when entering amounts in kilograms and vice versa. This has skewed data and potentially inflated the amount of product reported to be on hand at grow sites. The current tracking and reporting system was built without limitations or maximum allowable quantities. OMMP is developing a system to warn growers in real time if they attempt to report unusually large amounts of inventory or transfers. This warning system should help reduce erroneous reporting data, and is expected to increase the accuracy of the amount of cannabis being reported.

Another challenge with reporting is the lack of standardization around the reporting of concentrates, extracts, and other cannabinoid products. Current interpretation of statute requires that participants report a count of an item, with no standard unit size. For example, the size, amount and measurement of "1 unit" of a given item remains undefined.

Potentially erroneous reporting coupled with low reporting compliance makes it difficult to accurately track how much product is in the medical system. This limits OMMP's ability to successfully identify and address potential diversion. This also adversely affects OMMP's ability to understand how much product is in the medical system and consequently severely limits OMMP's capability to address issues of patient access and product availability.

The implementation of SB 1057 will directly address these limitations by bringing more OMMP participants into the comprehensive reporting regime of the seed-to-sale OLCC Cannabis Tracking System (CTS), and by allowing for the revocation of the registrations of all participants who do not comply with their reporting requirements. However, growers may simply grow less plants to avoid meeting the requirements for tracking in CTS. Finally, OMMP database improvements are underway and should increase the reliability of reporting data.

Inability to validate grow site locations

An area of concern in the card registration program is validating the location of grow sites. There is no straightforward method for the OMMP to verify an address without physically visiting each newly registered site, which would simply be beyond the ability of the program. This lack of validation can lead to duplicate or inaccurate address entry, limits the program’s ability to enforce allowable plant limits, and complicates the transition of grow sites from the OMMP to the OLCC. Improved validation of addresses is an important step in detecting and addressing attempts to circumvent plant and possession limits.

Currently, the OMMP is attempting to verify questionable addresses through each county’s online property data tools. This process is time consuming and each county has different tools to locate and verify addresses., The program is considering the use of third party software to assist in determining the validity of an address.

While general confidentiality of grow site addresses is protected in statute, grow site confidentiality presents a barrier to the program’s ability to comply with some requests from local and county law enforcement and land use bodies. Despite the sensitive nature of balancing participant confidentiality with public safety and land use regulation, OMMP currently provides pertinent information permitted by statute and rule to assist with requests from these and other partners across Oregon. This includes maintaining a hotline for counties, cities, and watermasters to use to verify grow sites. It also includes responding to law enforcement requests to verify specific grow sites. These law enforcement calls are tracked by the program, and the data show that they significantly decreased after recreational legalization, as can be seen in Table 4. Despite the decrease, OMMP is still available via phone to legally verify all grow site addresses that law enforcement and local jurisdictions have questions about.

Year	Law Enforcement Calls
2012	2,695
2013	2,539
2014	2,155
2015	1,036
2016	546
2017	531

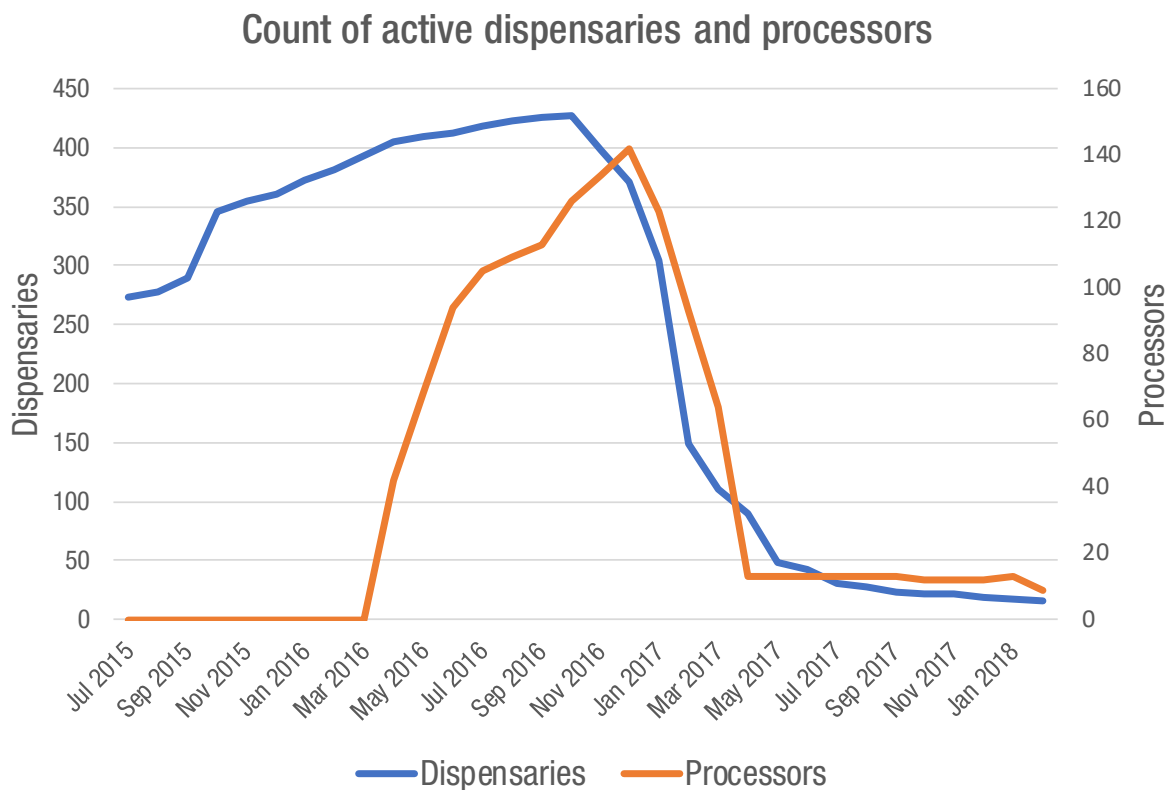
Table 4

Dispensary and processor inspections did not keep pace with applications

The OMMP management team developed a compliance inspection roadmap in late 2015 and early 2016, setting compliance priorities to ensure safe and legal access to medical marijuana. Consideration was given to the number of staff, volume of work, and priorities of the section. OMMP management determined that compliance inspectors would first prioritize registering dispensaries to ensure safe and legal sales to the public, then address processor applications and, after those were addressed, begin prioritizing grow site compliance. Prioritization was necessary considering limited staffing and resources.

From the onset of the early retail sales period in October 2015, OMMP compliance resources were stretched thin dealing with the volume of new dispensary applications. Dispensary registrations renew on an annual basis, and given that the dispensary program began in April 2014, most renewals occurred in March and April of each year. Those early-established businesses had to submit renewal documentation and compliance staff needed to review those renewals and perform on-site inspections. Along with this, new dispensary applications were steadily coming into the program and required complete application review and pre-issuance inspections.

In April 2016, medical marijuana processors began submitting registration applications. Processor applications are complex and require extensive staff training prior to review. Review of processor applications did not begin until July 2016. Available compliance staff were initially unable to keep up with the volume of work. Figure 1, below, provides a visual of the overlap and volume of applications for dispensaries and processors.



OMMP was conservative with filling compliance positions because of other funding obligations, declining registrations which decreased revenue, and the impact on revenue from facilities moving to licensure with OLCC. The program concluded that it would not be fiscally responsible, nor reasonable, to hire additional staff into the program without sustainable funding for the program. In addition, the use of temporary or limited duration staff was not a viable option due to the extensive and lengthy training required of compliance staff. This resulted in not enough compliance staff to address all compliance issues.

Limited grow site inspections

Grow site inspections began in the fall of 2016 when OMMP staff began conducting inspections on larger outdoor grow sites. The inspection process was further developed and refined in 2017 using the knowledge gained from the 2016 inspections. In the fall of 2017, compliance staff resumed grow site inspections, again concentrating on larger outdoor grow sites and those near harvest season. This time of year was selected because observing mature plants allows for a more accurate determination of compliance within allowable plant limits.

OMMP staff conducted eighteen inspections utilizing procedures that incorporated the newly passed legislation of plant limits at a patient's residence under HB 2198. The grower community, largely unaware of the new plant limits, expressed vocal opposition to the changes made to the laws and a decision was

made by OMMP to pause on inspections until the OMMP further communicated the growers on the implication of HB 2198. The feedback from growers highlighted opportunities for improvement, and led to further training and process refinement within the compliance unit. Inspections resumed and the compliance unit conducted a total of fifty-eight inspections before the 2017 harvest season ended.

According to the January 2018 Statistical Snapshot, (<https://go.usa.gov/xUKbr>) there are 20,025 registered grow sites statewide. OMMP determined that, given the current staffing, the compliance program will proactively inspect grow sites in all regions of the state, making sure to also conduct complaint based investigations with concerns to public health and safety. The overarching objective is to perform enough inspections with limited staff resources to create an effective deterrent against non-compliance with the OMMA.

OMMP estimates that to perform a sufficient number, or percentage, of grow site inspections to ensure broad-based compliance the program would have to establish five regional bases, each staffed with three to five compliance and support personnel. Currently, OMMP is not staffed a sufficient level to attain this goal.

Program resources unable to meet regulatory demands

Another challenge that OMMP faces is the potential lack of funding and resources to effectively serve and regulate its participants. SB 1057, passed during the 2017 legislative session, required medical growers to pay an additional tracking fee to utilize the OLCC's cannabis tracking system (CTS) in addition to the existing grow site registration fee. Increased registration costs for growers and the opportunity to expand into the retail market, the OMMP projected that medical growers with three or four patients would move to the OLCC. The fiscal impact statement for SB 1057 indicated a negative revenue impact due to the projection that growers would move to OLCC. The OMMP was required to show reductions in expenditures to match the revenue loss. The largest expenditures to the program are legislatively mandated so the program could only reduce expenditures in personnel. OMMP fee revenue has been allocated by the legislature to fund other PHD programs over the last few biennia. In the 15-17 biennium, \$18 million was allocated to fund other public health programs and in the 17-19 biennium \$7.2 million was allocated to fund state support for public health. The program couldn't make up those expenditures with fee increases so it had to eliminate positions in the compliance and analysis units of the program to offset this loss of funds.

Despite a reduction in funds and resources, OMMP is still responsible for enforcing the Oregon Medical Marijuana Act. To adequately perform this work,

it's necessary for compliance staff to conduct site visits and investigate complaints of medical grow sites, processing sites and dispensaries that remain registered with OHA. Through a rebalance in 2018, the program could restore three Compliance Specialist 3 positions and some of the analysis unit positions. However, the compliance positions are not at a level to adequately perform inspections or enforce compliance with a significant regulatory or deterrent effect.

Existing data systems incompatible with legislative changes

In some circumstances, the OMMP is unable to make established technology systems meet new legislative requirements. The OMMA designed the OMMP registration system to be patient-centered. A patient submits the application and chooses to have a caregiver and a grower/grow site, and provides information on all participants and locations. If a patient chooses to have a grower, the product belongs to the patient and must be returned to them if the patient requests. OMMP registers growers that grow at registered grow sites whereas OLCC licenses producers (growers) that are established as a business. There is often a disconnect between the language in law and how the OMMP registrants practically operate. For example, legislation mandates actions at a grow site level as if medical marijuana grow sites were businesses similar to the OLCC. In reality the grow site may be a community garden comprised of multiple growers who do not interact with one another.

Additionally, the OMMP relies on outdated third-party software PrintMachine and NeoPost machine for printing all the card registrant cards. It is an expensive system to maintain and places OMMP in a vulnerable situation when there are issues with functionality. The OMMP is required to send cards to patients within five days of approval (ORS 475B.797 (5)(a)).

Lack of consistent process for testing laboratories and product destruction

Oregon Health Authority (OHA) contains two programs that are responsible for cannabis testing. OMMP is responsible for cannabis testing rules that apply to both the medical and retail market. Any marijuana or marijuana item intended to be sold at a dispensary or retail shop must have been sampled and tested according to the testing rules.

ORELAP is a program under the Center for Public Health Practice at the Oregon Public Health Laboratory and accredits qualified laboratories for testing under the Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act, Safe Drinking Water Act and Cannabis testing under ORS 475B.550 to

475B.590. ORELAP is recognized by The NELAC Institute's (TNI) National Environmental Laboratory Accreditation Program. ORELAP's primary role in cannabis is to oversee the accreditation of testing laboratories to ensure they meet testing standards and proficiencies. Through on-site assessments performed, ORELAP ensures that laboratories meet TNI accreditation standards. OLCC is responsible for licensing laboratories

Marijuana items must receive passing compliance test results for pesticides, water activity/moisture content, solvents, and meet potency requirements, as applicable, before being transferred to a dispensary or retail shop. The product type and the intended next transfer destination for the item determines what test will be performed at which stage. Only one compliance test may be ordered for the same marijuana item. This eliminates someone from going from laboratory to laboratory to get the "best" possible results. Laboratories are required to enter testing result data in the Cannabis Tracking System (CTS) for licensees and starting July 1, 2018 for qualifying medical marijuana growers. For medical marijuana growers not required to use CTS, a laboratory only needs to report failed test results to OMMP.

Accreditation is just a snapshot of time and does not ensure that a laboratory is not performing outside required parameters of licensure but not necessarily violating accreditation standards. For example, standardization of protocols for potency testing isn't a requirement of accreditation. A state reference lab could set standardized protocols in place for testing for potency, pesticides and solvents. Additionally, the program and ORELAP often receive complaints from labs or licensees that cannabis potency isn't as advertised and the lab results are manipulated to reflect an artificially high level of THC. There is a need for a state reference laboratory to assist with investigations into labs and licensees manipulating lab results and to act as an objective referee when there are disputes between the state and a registrant or licensee over the validity of cannabis testing results. Also, a state reference lab could randomly audit laboratories or tested samples to determine accuracy and ensure the product sold to the consumer is reasonably safe and free of adulterants.

Initially, after legalization a need developed for OHA, OLCC and ODA to ensure destruction of tainted cannabis. The agencies were tasked with developing consistent protocols to guide the destruction of tainted product. Entities registered with OHA did not have the same requirements as OLCC licensees regarding security (e.g. OHA was not allowed to require security cameras on grow premises whereas OLCC licensees have security camera requirements) and development of consistent destruction protocols was slow moving and difficult to develop. A viable destruction protocol has now been finalized by the OMMP's compliance program, and it is being implemented.

Addressing complaints from patients

Lack of standardized complaint tracking

The program does not have a standard repository for all complaints. The card registration database has tracked and addressed complaints on administrative matters from patients, caregivers, and growers since the Oregon Medical Marijuana Registry (OMMR) database was implemented. Individual complaints are entered as notes in each registration. It is not possible to extract the data to determine types or number of complaints received by the card registration program.

The compliance unit began in 2015. There was not an existing system to track complaints so they were tracked in an excel spreadsheet. It wasn't until fall 2017 that the compliance unit began using CASPER to track complaints. The data from the excel spreadsheet cannot be uploaded to CASPER so the section has three different mechanisms to track complaints.

The program is looking towards utilizing CASPER for all complaints received. However, staff will still need to add notes to the OMMR as well as create a file in CASPER.

Limited statutory authority to address complaints

Initially, the program lacked statutory authority to investigate or inspect grow sites or growers until mid-2016 so any complaints prior to this authority from a patient, caregiver or grower were closed as 'no authority'.

Many complaints that came in early 2017 were determined to be outside the scope of authority to respond as the program did not have rules in to investigate grower and patient relationship based complaints. The plants and the useable marijuana are the property of the patient, unless a patient has given a portion of the grow to a caregiver or grower via a personal agreement. Patients frequently complain that growers are not providing marijuana or not in the anticipated quantity they expected. As with any crop, there are variables outside of their control, weather, infestations of bugs, molds and these can affect the amount of marijuana a grower provides to the patient. However, the program has modified the rules to clarify the legal grower/patient relationship and to provide specific expectations of the registrants within that relationship that now enable the program to address valid complaints where a grower may have violated the legal relationship with a patient, for example not allowing the patient to access her marijuana.

Strengths of the Program

- Effectively facilitate access to medical marijuana
- Built framework to regulate growers and dispensaries
- Implement legislative changes and provide transparency
- Broad communication and outreach

Effectively facilitate access to medical marijuana

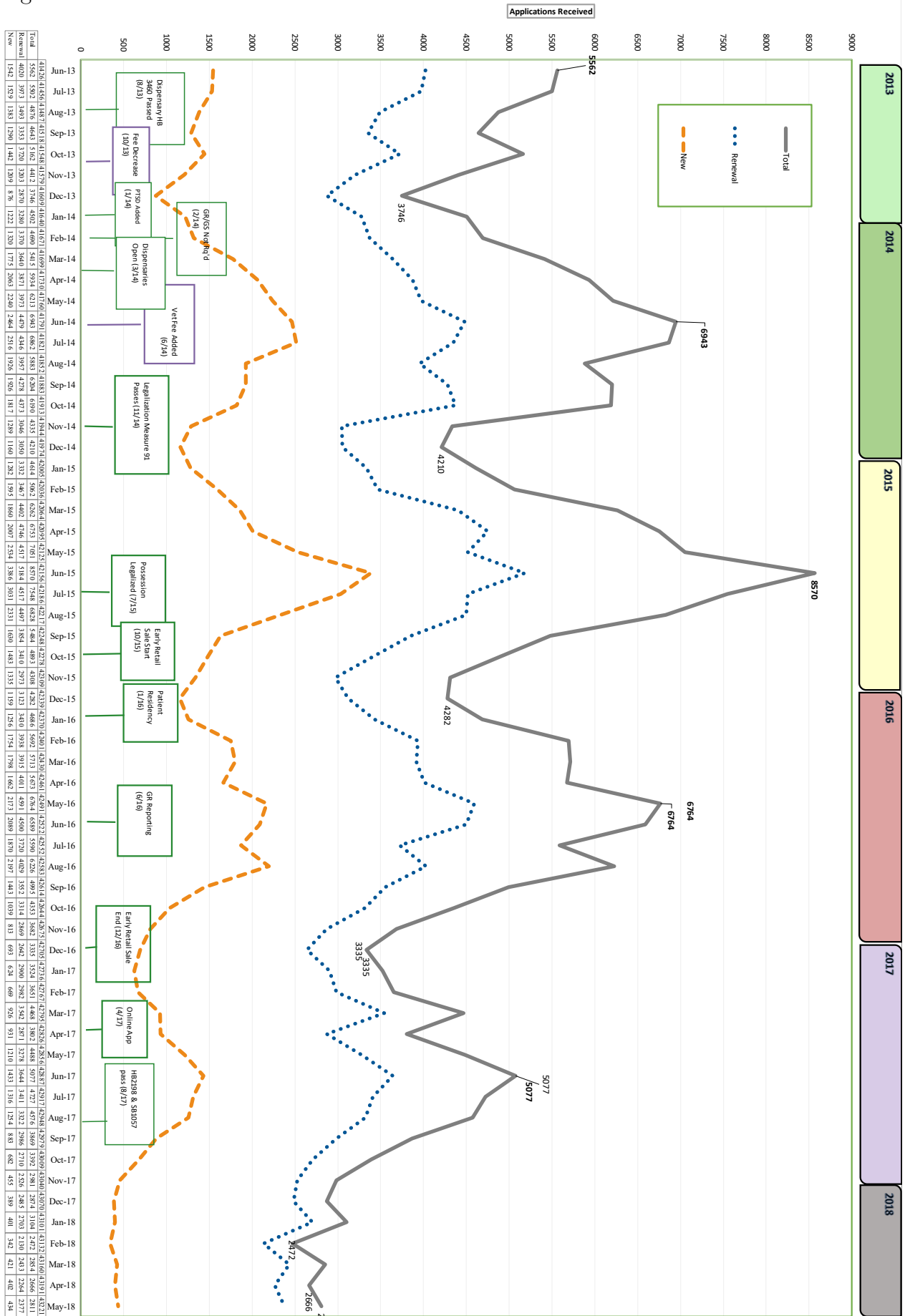
The goal of the card registry program is to meet the needs of patients in a timely manner within the evolving framework of rules established by the legislature. The changes to the OMMA have had a significant impact on program registrants' understanding of how these changes affect them and what they are required to do to remain compliant and protected with the law. OMMP staff addressed the numerous changes in rule, process and procedure with a deliberate and systematic approach. Throughout the OMMP's implementation of changes to the OMMA, OMMP staff have implemented necessary modifications to rules and processes within funding limitations, while focusing on the needs of patients. The Card Registry Program (card program) assisted patients, caregivers, and growers with every new rule and regulation and answered a wide variety of questions to help cardholders navigate the regulatory requirements.

The card program is responsible for receiving and processing applications, processing change requests and renewals from patients both online and by mail, assisting law enforcement, counties, cities and water districts and the general public with inquiries; as well as assisting patients, caregivers, and growers with technical support and questions through a call center or by email. The call center staff receive hundreds of calls each week and assist with various programmatic and non-programmatic questions. In addition to assisting medical marijuana registrants through the call center, the card program added an email account for direct inquiries. The email account reduced call volume and provided registrants with an alternative and efficient method to obtain information on the program or their application status.

The card program has a statutory mandate to approve or deny an application for a medical marijuana card within thirty days of receiving the application (ORS 475B.797 (4)(b)). Historically, the program struggled to meet the requirement to decide on an application within thirty days. Until April 2016, the program relied on a completely paper based application system and stored approximately 278,000 paper copy files for patient registration information.

Figure 2 shows monthly applications that were processed over the last five years and demonstrates the cyclical aspect of the volume of applications received. During months with less volume, the program could meet or get close to compliance but in peak months, staff were unable to keep up with the increased workload. The program regularly brought on temporary staff to achieve compliance with the thirty-day application processing requirement. However, historic funding levels have not been sufficient to enable the program to maintain adequate capacity to meet patient demand

Figure 2



Applications may still be submitted by mail and all medical marijuana cards and communication to patients are provided in paper form and are mailed out. Through process improvement initiated in 2016, the card program moved from creating and keeping paper files to converting and retaining files electronically in a database. The implementation of HB 3400 (2015) necessitated the development of an online system for OMMP growers to use to report their growing activity. It was determined that it would be fiscally responsible to incorporate the patient application process into this new online system.

In April 2017, the program deployed a new patient online application system. This online application offered patients a faster and more efficient method to apply for a medical marijuana card, provided them a receipt to use at a dispensary for thirty days, and increased staff productivity in reviewing applications. Additionally, the online application system streamlined the registry application process by reducing data entry, allowing direct upload of documents to the database; and providing staff additional tools to assist them with the application review. Currently, the online application system accounts for 24% of the applications received.

Due largely to the continued process improvements described above, the program operated within the thirty-day application review statutory requirement for all of 2017. In 2017, the program processed 47,000 applications; received 76,000 pieces of mail; sent 235,000 pieces of mail; and, assisted approximately 30,000 customers.

Built framework to regulate growers and dispensaries

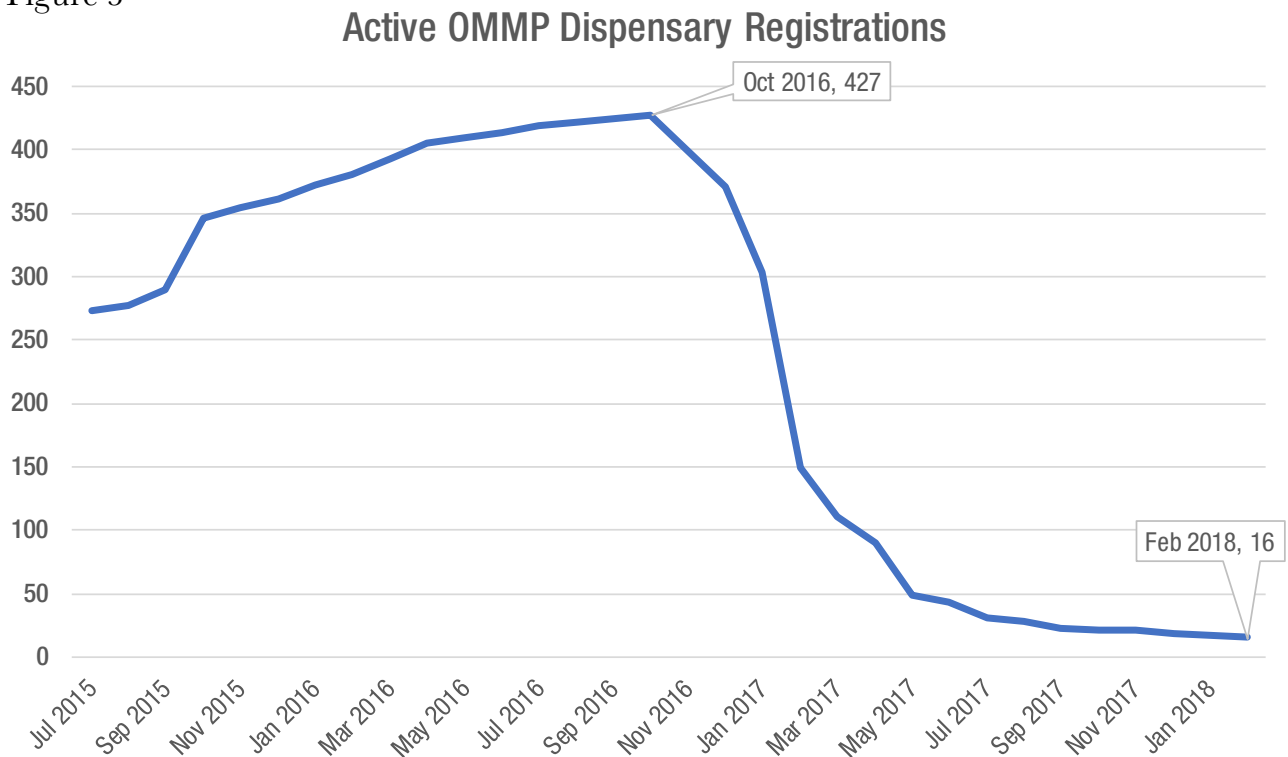
In June 2015, with the passage of HB 3400, OHA received position authority to create the compliance program to register and inspect medical marijuana facilities and regulate early recreational sales that began on October 1, 2015. Compliance staff were on-boarded in October 2015 that included a manager, seven inspectors, three other compliance specialists to process applications, an operation and policy analyst, and one support staff.

The focus for the new compliance program was multifaceted with a short implementation timeline. The program had to gain an understanding of existing laws and rules, develop new rules relating to regulating processors and dispensaries, develop a processor application and process for approval, review and approve dispensary applications, and complete inspections of dispensaries. With the ability for medical marijuana dispensaries to sell to the non-medical retail market through early recreational sales (October 2015 – December 2016), applications for new dispensaries rapidly increased. Active registrations increased from 250 in July 2015 to 427 in October 2016. From July 2015 to April 2016, the priority of the compliance program was to review and inspect dispensaries. Early recreational sales ended December 31, 2016.

Those dispensary operators with intentions to move into the OLCC’s recreational/ adult use retail system understood that OLCC would begin licensing recreational marijuana retailers in October 2016 and that those locations would have to adhere to the same minimum distance requirements (no closer than 1,000 feet of each other or to schools) that applied to OMMP registered dispensaries. Therefore, due to the ability to secure a location under the medical program that could then be held for the OLCC licensure process, business operators that intended to transition into the recreational system were incentivized to apply to become OMMP dispensaries during the early sales period.

Figure 3, below, illustrates the increase in the number of registered dispensaries until the OLCC began issuing retail licenses in October 2016.

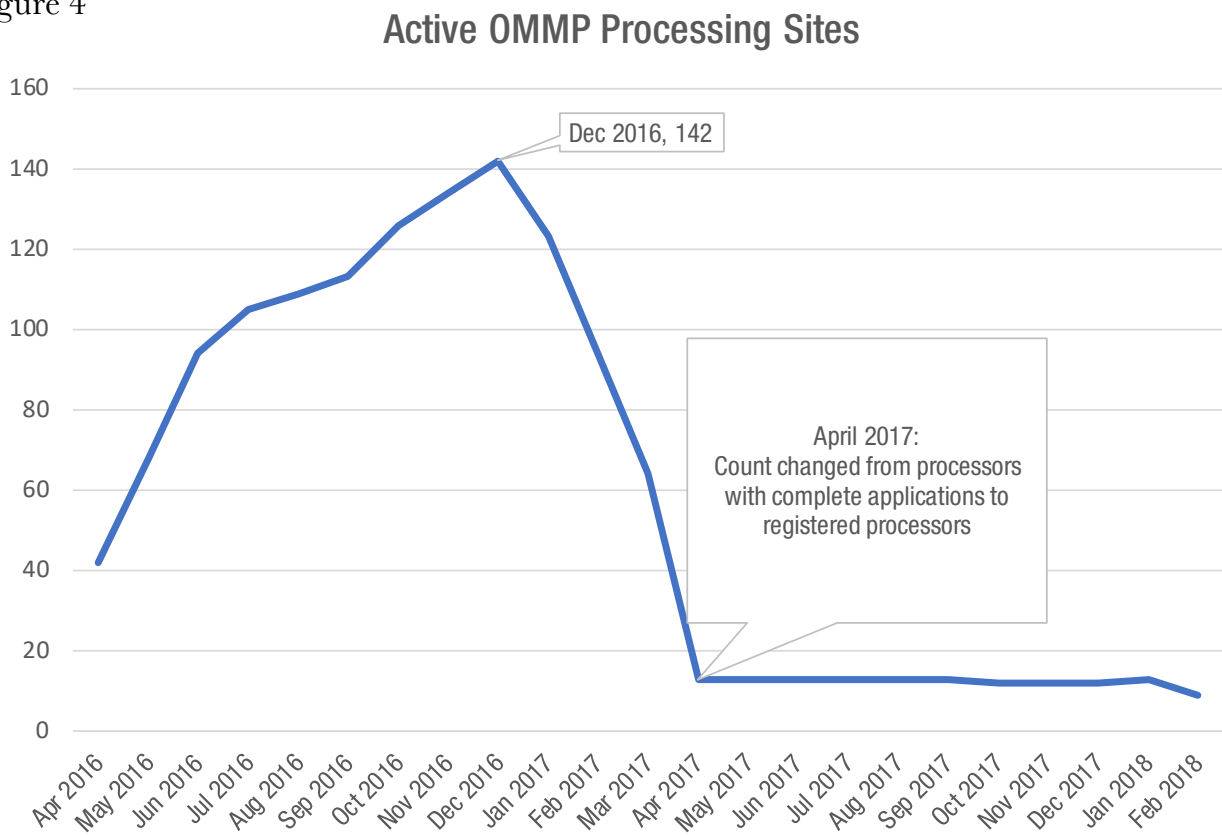
Figure 3



In April 2016, medical marijuana processing sites (processors) began applying for registration with OMMP. In July of 2016, the compliance program prioritized reviewing processor applications to ensure applicants had submitted a complete application while also continuing dispensary application reviews and inspections. Until March 2017, a processing site could process marijuana with only verification that a complete application had been submitted, pursuant to ORS 475B.907 [formerly 475B.475]. Thereafter, due to a change to OAR 333-008-1620, a processor had to be fully registered with OMMP to process marijuana.

Just as OLCC began to license recreational retail facilities in October 2016, they also began to license recreational processors at the same time. Figure 4 illustrates the number of OMMP medical processors increasing through December 2016 and then steadily decreasing as OLCC licensed recreational processors.

Figure 4



Following the end of the early recreational sales period on December 31, 2016, the compliance program was tasked with ensuring that all dispensaries that had been authorized to participate in early recreational sales only sold to cardholders. In January 2017, OMMP compliance inspectors completed 206 unannounced spot inspections statewide to confirm cessation of recreational sales.

Although previously unregulated, inspection of medical marijuana grow sites came under the authority of OMMP in 2016 (ORS 475B.810 to 475B.828). The development of the grow site inspection procedure began in the fall of 2016 and finished in August 2017. In the fall of 2016, OMMP inspectors conducted fourteen pilot inspections at larger registered outdoor locations to gain an understanding of the variety of site conditions. That experience, along with visits to several indoor grow facilities and input from numerous other growers and professional organizations, contributed to the development of a formalized inspection process. The resulting process and procedures currently consist of more than 70 individual steps from initial research to case close-out. The compliance team also incorporated personal safety training, predicated on consultation with DAS Risk Management and Oregon OSHA, designed to mitigate exposure to potential on-site hazards. One inspection can necessitate up to twenty-five hours of preparation, travel, execution and close-out, and may involve as many as five different compliance staff members.

From August through December of 2017, the compliance team conducted fifty-eight grow site inspections, with the goal of observing the fall harvest at potentially high plant sites across a region. As of July 2017, there were 25,130 total OMMP grow sites, but only about one-third of these were subject to tracking and reporting. Still, with such a large number of sites, the team focused efforts on larger grow sites (i.e., sites with sixty or more plants). The focus was placed on outdoor grow sites because the timing of these inspections happened to align with the fall harvest season, indicating that these sites were more likely to have the highest number of mature plants during this time. Like the fourteen pilot inspections in 2016, the fifty-eight inspections conducted in 2017 were not intended to fully assess or estimate the compliance of all OMMP grow sites. Instead, these inspections were undertaken to broaden the experience base on which to refine the inspection process.

Proactive and complaint-based inspections of grow sites are anticipated to remain the primary focus of the compliance program. In the late summer of 2018, the compliance program will implement an outreach campaign intended to make the compliance staff accessible to registrants, applicants and citizens outside of inspection related contacts. To this end, compliance inspectors and the program manager will be hosting open forum sessions as they travel throughout the state.

Implement legislative changes and provide transparency

The analysis staff duties and functions consisted of: drafting rules pertaining to the tracking of medical marijuana; developing the tracking system for growers, processors, and dispensaries; developing the management system for growers and processors; testing the tracking system; creating training materials for staff as well as growers, processors, and dispensaries pertaining to tracking; conducting statewide training for registrants on how to use the tracking system; providing technical assistance with tracking; developing a manual reporting mechanism for growers without internet access to be able to comply with the law; creating a DataMart to analyze data from all registrants around tracking; developing tracking reports; creating and implementing the patient online application portal; developing all training materials for the patient online system for staff and patients; providing webinar and in-person trainings to patients regarding the application portal, and providing technical assistance to growers through email. Every year this program is responsible for creating new systems or modifying existing systems to meet legislative requirements or changes.

Since full legalization in 2015, OMMP has sought to expeditiously implement all legislatively required mandates. This effort has been complex, as every year new legislation passed which modified existing systems or created the need for new systems to be developed, tested, and deployed. OMMP implemented each of these system changes by the date stipulated in the relevant piece of legislation. The following completed tasks not only satisfied various statutes and rules, but also improved patients' ability to access medical marijuana:

- Decreased wait times for submitted applications and phone/email assistance by reclassifying existing staff into positions that directly contact registrants.
- Developed a Patient Online Application portal for new and renewal applications
- Revised the Website to be more user friendly
- Created a new database for processor applications;
- Developed a system to track early retail sales;
- Created a new application to track propagation and sales of medical marijuana for dispensaries, processors and growers;
- Created an internal management database system for the new tracking system;
- Created a DataMart to query all reporting;
- Developed reporting and tracking documents;
- Created a hotline for counties, cities, and watermasters to use to verify grow sites;

- Created a web-based system for Oregon Liquor Control Commission and Department of Revenue to have access to the medical marijuana registry system; and
- Made numerous enhancements and changes to the new and existing systems and processes due to changes made in legislation.

Broad communication and outreach

At each stage of change, OMMP was also responsible for communicating relevant changes to all its affected registrants, and stakeholders. This information was communicated by mail, email, press-release, in-person outreach, webinars and opt-in listserv news blasts. An archive of previous informational bulletins can be found on OMMP's public website (<https://go.usa.gov/xUKWd>).

Conclusion

Assessment of a program, system or process is essential to program improvement and the goal of this report is to highlight the opportunities for improvement to OMMP. This report discusses the program's resource limitations, its areas for improvement and strengths.

Since full legalization of marijuana in July 2015, the 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 excellent 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, insufficient grow site address verification, and low staffing in the compliance unit. Utilizing the CTS tracking system will assist in addressing reporting compliance, as will having the authority to revoke growers, processors and dispensaries for not reporting. Implementing new steps when processing applications to require proof of addresses will assist in validating addresses. 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. Program staff are taking the following steps to address those issues:

- Overseeing the utilization of the Oregon Liquor Control Commission's (OLCC) Cannabis Tracking System (CTS) by OMMP processing sites, dispensaries and certain growers and addressing non-compliance of registrants required to report in CTS but do not. Applicable registrants must begin using the CTS by July 1, 2018.
- Implementing a new process to require proof of addresses when processing cardholder applications will assist in validating grow site addresses.

Adequate staffing to address compliance issues 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.

Additionally, regulatory stability and sufficient funding and staff resources would allow OMMP to consistently apply requirements of the OMMA to better serve patients and ensure access to medical marijuana as a therapeutic option. We recommend policy makers consider actions in the following areas:

- Streamline regulation of growers, retailers and processors and make data more transparent to law enforcement and the community.
- Enhance funding for OMMP compliance and enforcement to ensure marijuana production is preserved and directed to patients who count on it to address their medical conditions.

As policy makers work toward determining which agency is responsible for which components of the law in this newly legalized market, it is important to ensure that OMMP remains responsive to the needs of all patients into the future.



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