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Oregon Cannabis Commission Report

House Bill 2198

Acknowledgments

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Oregon Cannabis Commission members, public health officer included in statute and eight members appointed by Oregon Governor Kate Brown:

- Esther Choo, research faculty, Oregon Health & Science University (chairperson)
- Rachel Knox, attending physician (vice chairperson)
- Katrina Hedberg, state health officer, Oregon Health Authority, Public Health Division
- Anthony Taylor, OMMP registry identification cardholder
- Cedar Grey, OMMP grower
- André Ourso, Oregon Health Authority representative
- Jesse Sweet, Oregon Liquor Control Commission (OLCC) representative, resigned Oct. 26, 2018
- Amanda Borup, OLCC representative, appointment approved Dec. 17, 2018
- Pat Luedtke, local health officer, and
- Jeff Kuhns, deputy chief, Keizer Police Department

Oregon Cannabis Commission Report

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Executive summary

The Oregon Medical Marijuana Program (OMMP) was established in 1998, after passage of citizen's ballot initiative 67. The purpose of OMMP is to:

- Implement and administer provisions of the Oregon Medical Marijuana Act (1)
- Ensure that Oregonians suffering from debilitating medical conditions have safe and well-regulated access to:
    - Medical cannabis, and
    - Cannabis products as a therapeutic treatment for those conditions.

In its 20-year history OMMP has served approximately 300,000 individuals as patients, caregivers or growers. The program provides a vital service to many who have exhausted all other sources for relief from chronic pain, cancer and other debilitating conditions or who have found its benefits superior to pharmaceutical drugs. OMMP experienced steady growth from inception until 2015. Oregon, like other states, experienced a decline in medical cannabis program participation with the passage of Ballot Measure 91 legalizing recreational marijuana effective in July 2015. Legalization of recreational cannabis possession and increased grow site regulation changed the landscape of how cannabis and cannabis products are perceived and has changed the focus and duties of OMMP from being a patient registry program to include regulation of medical growers, grow sites, processing sites and dispensaries.

House Bill (HB) 2198 (2), passed during the 2017 legislative session, established the Oregon Cannabis Commission (the commission) within the Oregon Health Authority (OHA). Commission seats were created in a manner to ensure representation from the various stakeholders involved in cannabis. Representation includes:

- The state public health officer
- A registry identification cardholder (patient)
- A person designated to produce marijuana for a registry identification cardholder (grower)
- An attending physician
- An OHA representative
- An Oregon Liquor Control Commission (OLCC) representative
- A local health officer, a law enforcement officer, and
- A person knowledgeable in research and grant protocols.

The public health officer position is written into statute. The other eight members were appointed by Governor Kate Brown and confirmed by the Senate.

The commission is tasked with determining a possible framework for the future governance of OMMP. This includes proper oversight and regulation of each of the following:

- Registry identification cardholders, designated primary caregivers, attending physicians, marijuana grow sites, marijuana processing sites and medical marijuana dispensaries as those terms are defined in ORS 475B.791.
- Necessary amendments to the laws of the state pertaining to cannabis, including any necessary amendments to OLCC statues as ORS 475B.005 to 475B.778 and 475B.775 to 475B.968.
- The future role of the commission with respect to the possible framework.

Further, the commission is to determine steps that the state must take, whether administrative or legislative in nature, to ensure that research on cannabis and cannabis-derived products is being conducted for public purposes, including the advancement of:

- Public health policy and public safety policy
- Agronomic and horticultural best practices, and
- Medical and pharmacopoeia best practices.

The commission is required to submit a report to the interim committees of the Legislative Assembly related to health and judiciary on the findings and determinations made by the commission by Feb. 1, 2019. The commission may request that the interim committee ask legislative council to prepare legislative concepts for the commission's consideration. While the Oregon Health Authority convened and provided staff support to the commission, the statements in this report do not represent the opinion or recommendations of the agency.

In addition, the commission has a duty to provide advice to the OHA with respect to the administration of OMMP and provide advice to OLCC with respect to registry identification cardholders and designated primary caregivers. The commission is to:

- Develop a long-term strategic plan for ensuring that cannabis will remain a therapeutic option for persons with debilitating medical conditions
- Develop a long-term strategic plan for ensuring that cannabis will remain affordable for persons with debilitating medical conditions, and
- Monitor and study federal laws, regulations and policies regarding marijuana.

The commission must meet at least quarterly. OMMP maintains a website pertaining to the commission (3). The commission held meetings on Dec. 8, 2017 and January 30, March 21, May 21, July 23, October 4, November 9, November 27 and Dec. 19, 2018.

In addition to setting aside time at each commission and subcommittee meeting for public comment, the commission held a listening tour directly following the Oct. 4, 2018 meeting in Eugene to solicit feedback from OMMP patients, caregivers, growers, physicians and other members of the public. Over the next year, the commission plans to hold future commission meetings in Medford, Bend and Portland that include listening tours as part of those meetings.

The commission members engaged in an interactive identification of key issues and priorities, with an iterative consensus-building process which included input from the attending public, written public comments, significant discussion, and successive rounds of voting by the commission members. From this process, four key priority areas were identified which led to the creation of four subcommittees to work on the priority areas led by commission members with inclusion of both subject matter expert and public input. The four priority areas, goals and commission member leads are in Table 1, below.

Table 1. OCC subcommittees

Priority area	Priority goals	Commission subcommittee member leads
Product integrity	Minimize diversion Ensure product integrity	André Ourso and Jesse Sweet (resigned Oct. 26, 2018)
Research	Develop and integrate a research "toolkit" Fund medical cannabis research Small directed projects	Esther Choo and Katrina Hedberg
Clinical practice and training subgroup	Develop recommendations for clinicians Integrate cannabis education into pain management	Rachel Knox
Patient access	Establish and maintain access for low income patients Improve, streamline and expand program	Anthony Taylor

In addition to these four priority areas, the commission members committed to:

- A review of the current cannabis governance framework in Oregon
- Consideration of how different frameworks may assist with reaching goals of the identified priorities, and
- With better serving the medical cannabis registrants.

This report identifies barriers to addressing needs of patients in OMMP. It offers recommendations about possible ways to address identified barriers. Still, policymakers should engage further with the commission and other stakeholders on concrete solutions and implementation strategies.

Recommendations

The following is a summary of the barriers and recommendations the commission would like to bring forward. The main report overviews each one in more detail.

Cannabis governance framework

Barrier 1: Current regulation of cannabis by multiple state agencies with different mandates causes confusion, task duplication, and does not provide Oregon with centralized oversight.

Recommendation 1: The legislature, in coordination with the OCC and other agencies, should explore alternate forms of governance over cannabis, such as consolidating governance under a single body. This process will require a detailed examination of the costs and benefits of restructuring the programs, and how to implement such a change.

Funding

Barrier 2: OMMP needs a dedicated, stable, and consistent source of funding.

Recommendations 2:

- *A portion of the collected retail sales tax should be secured to fund OMMP and the recommendations in this report.*
- *OMMP fees should be used only for operation and administration of OMMP.*

Product integrity

Barrier 3: There is no mechanism for the state of Oregon to perform independent testing on cannabis and cannabis products to confirm private laboratory testing is accurate, in compliance with current rules and regulations, and to assist with other state regulatory duties.

Recommendation 3: Oregon should establish an independent state reference lab housed in the Department of Agriculture to objectively audit and investigate private laboratories and randomly test cannabis products to ensure testing accuracy, consistency and cannabis product integrity on a regular basis.

Barrier 4: Due to various reporting methods across law enforcement, OLCC and OMMP, and the lack of a central data repository for product movement and seizures related to diversion or potential diversion, the magnitude of the diversion issue with cannabis is unknown.

Recommendations 4:
Legislative

- *OMMP growers enrolled in OLCC's Cannabis Tracking System (CTS) should be subject to security requirements as appropriate for the scale of the grow site in order to ensure data entered into CTS is accurate and to mitigate opportunities for diversion.*
- *The OCC recognizes diversion is an issue and supports funding for additional resources for the Oregon State Police, OLCC and OMMP to investigate and develop enhanced data systems around cannabis diversion activities.*

Administrative

- *OMMP should continue enrolling applicable growers and grow sites into OLCC Cannabis Tracking System (CTS).*

Research

Barrier 5: There is a need for research that expands the science and knowledge related to the health effects of cannabis, including by product type.

Recommendations 5:

- *The state of Oregon will establish a Cannabis Research Center(CRC) to advance research on cannabis and cannabis-derived products.*
- *The CRC will be a collaboration across state academic, medical, and government agencies.*
- *The CRC will be funded by allocation of a minimum of $10 million to $12 million over a four-year period to fund establishment of the center, core staff, an experienced director, and substantial, high quality research and grant activities.*
- *The CRC will coordinate and support original research projects on the health effects of*

cannabis in the areas of public health policy and public safety policy, agricultural and horticultural best practices, and medical and pharmaceutical best practices, and will establish a competitive grant process with a rigorous external peer review.

- *The CRC will provide a report of expenditures and grants awarded and a summary of any original research findings at the end of year two and year four to the legislative assembly.*

Clinical practice and training

Barrier 6: Inconsistent assessment, consultation, and management of patients by Attending Providers.

Recommendations 6:

- *Develop or license existing materials to provide rigorous training in cannabis use in patient care in the state of Oregon.*
- *Require that all APs who wish to evaluate patients for OMMP-approval first complete this training.*

Barrier 7: Currently the only medical providers who may recommend cannabis to patients in Oregon are Medical Doctors (MDs) and Doctors of Osteopathy (DOs). This restricts patient access to cannabis as an individual's primary medical care provider may not be a MD or DO.

Recommendation 7:

- *Revise ORS 475B.791(1):*

  "Attending ~~physician~~ **provider**" means a physician **(MD or DO) or a physician assistant (PA)** licensed under ORS chapter 677**, an advanced registered nurse practitioner (ARNP) licensed under ORS chapter 678, or a naturopath (ND) licensed under ORS chapter 685,** who has primary responsibility for the care and treatment of a person diagnosed with a debilitating medical condition.

Barrier 8: Current statute limits an AP's ability to recommend medicinal cannabis to patients with debilitating conditions not on the current list, but who can likewise benefit from medical cannabis use, and requires a petitioning process to expand the debilitating medical condition list that in practice is onerous.

Recommendations 8:

- *Revise ORS 475B.791(6):*

  "Debilitating medical condition" means:

  (a) Cancer, glaucoma, a degenerative or pervasive neurological condition, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, or a side effect related to the treatment of those medical conditions.
  (b) A medical condition or treatment for a medical condition that produces, for a specific patient, one or more of the following:
  (A) Cachexia
  (B) Severe pain
  (C) Severe nausea
  (D) Seizures, including seizures caused by epilepsy, or
  (E) Persistent muscle spasms, including spasms caused by multiple sclerosis.

(c) Post-traumatic stress disorder, or
(d) Other medical conditions or side effects related to the treatment of a medical condition ~~adopted by the Oregon Health Authority by rule or approved by the authority pursuant to a petition filed under ORS 475B.946~~ **that a certified AP determines in accordance with evidence-based practice and professional judgement, may be mitigated with cannabis**.

- *Remove ORS 475B.946:*

~~Petitioning for disease or condition to be included as debilitating medical condition; rules. Any person may petition the Oregon Health Authority to request that a disease or condition be included among the diseases and conditions that qualify as debilitating medical conditions under ORS 475B.785 to 475B.949. The authority shall adopt rules establishing the procedure for filing a petition under this section and the manner by which the authority evaluates a request made under this section. Rules adopted under this section must require the authority to approve or deny a petition within 180 days of receiving the petition. Denial of a petition is a final agency action subject to judicial review.~~

Patient access

Barrier 9: OMMP patient fees are prohibitive to patient access; patients on reduced or fixed income are unable to access medical cannabis.

Recommendations 9:

- *Establish an alternative and stable funding source so OMMP may reduce annual application fees for patients, and not require medical patients to wholly fund OMMP. As suggested in Recommendation 2, this source could be from the retail tax receipts.*
- *Explore a Supplemental Patient Care Program that serves low income OMMP patients who do not already qualify for an OMMP reduced application fee but are below the federal poverty line.*

Barrier 10: OMMP patients do not have easy access to medical cannabis growers; grower fees are prohibitive; and growers do not have an avenue to transfer excess product.

- *Grow Site and tracking costs are too high to sustain a robust grower population.*
- *Complex and changing rules make compliance difficult.*
- *Restricted entry into the market for overproduction.*
- *Growers restricted from sharing with general patient population and are only allowed to transfer to patients registered at specific grow sites.*

Recommendations 10:

- *Establish an alternative and stable funding source so OMMP may reduce annual application fees for growers. As suggested in Recommendation 2, this source could be from the retail tax receipts.*
- *Allow registered growers that are currently required to track in CTS to transfer to any OMMP patient or caregiver cardholder.*
- *Develop and maintain an opt-in for growers to waive their confidentiality protections under current statute and appear on an online list with name, contact information, and product experience.*

Barrier 11: OMMP patients have limited access to affordable medical product in the current retail market system.

- *Lack of participation by OLCC licensees.*
- *Lack of clear direction from the state.*
- *Focus on diversion over adequate patient access.*

Recommendation 11:

- *Revise ORS 475B.873 to facilitate OLCC retail store participation in a non-profit patient access program, or*
- *Create incentives for OLCC licensees to participate.*

Commission next steps

The commission and subcommittees discussed many issues, ideas and suggestions that were not developed enough to be included into this report. Additionally, the commission would need additional time to consider specifics and detail of the Governance recommendations in this report.

Over the next year the commission has the following goals:

- Define the role of a medical marijuana program in a legalized market.
- Work with OMMP to develop and analyze a comprehensive survey of current and past OMMP patient participants to determine:
    - Reasons patients do not renew registration
    - Patients' ability to access medical cannabis product
    - How patients use medical cannabis to mitigate conditions, and
    - Patients' vision for the commission, OMMP and overall cannabis regulation in Oregon.
- Continue with listening tours throughout the state to open dialogue with stakeholders.
- Revisit the priority areas to add, revise, or eliminate priority areas as needed.
- Further explore and refine the vision of one body being responsible for cannabis in Recommendation 1.
- Highlight the commission's work in creating a path for how Oregon can continue to serve cannabis patients and create and fund cannabis programs, training, regulation, and research into the future.

Other commission discussions included:

- Patient issues with employment, drug screening, lease or rental agreements, health care treatment options, professional licensing restrictions, denial of public resources, research of existing poverty guidelines in other states to qualify more patients for reduced application fees and promote the knowledge of benefits of being a patient to the public.
- Grower issues with inability to transfer to any patient and have a verification mechanism, per-patient grow site registration fee, removing grow site registration fee and reporting requirements.

Background: Oregon Medical Marijuana Program

The Oregon Medical Marijuana Program (OMMP) was established in 1998, after passage of a citizen's ballot initiative 67. The purpose of OMMP is to implement and administer provisions of the Oregon Medical Marijuana Act (4) to ensure Oregonians suffering from debilitating medical conditions have safe and well-regulated access to medical cannabis and cannabis products as a therapeutic treatment for those conditions.

In its 20-year history OMMP has served approximately 300,000 individuals as a patients, caregivers, or growers. OMMP provides a vital service to many who have exhausted all other sources for relief from chronic pain, cancer and other debilitating conditions, or who have found its benefits superior to pharmaceutical drugs. OMMP experienced steady growth from inception until 2015. Oregon, like other states, experienced a decline in medical cannabis program participation with the passage of Ballot Measure 91 legalizing recreational marijuana effective in July 2015. From October 2015 to October 2018, OMMP experienced a 55 percent decline in patients, a 61 percent decline in caregivers and a 66 percent decline in growers. See Table 2.

The reasons for these significant declines in participation are not fully understood, although decreased access to medical cannabis products in the new regulatory and commercial environment and high annual OMMP participation fees (applicants paying full price, physician fees) are suspected to be major factors. The commission requested that OMMP conduct a survey of registrants to learn the most common reasons for not renewing a medical card. The initial draft of this survey was provided to the commission in November 2018.

Table 2. OMMP participant fluctuation (5)

	Patients		Caregivers		Growers		Grow sites	
October 2015	78,045	-	37,017	-	48,699	-	33,194	-
October 2016	68,032	⇩ -13%	29,770	⇩ -20%	37,847	⇩ -22%	27,200	⇩ -18%
October 2017	59,137	⇩ -13%	23,377	⇩ -21%	30,477	⇩ -19%	23,175	⇩ -15%
October 2018	34,892	⇩ -41%	14,313	⇩ -39%	16,600	⇩ -46%	13,959	⇩ -40%

Medical cannabis dispensaries started appearing in April 2014. After HB 3400 passed, OMMP saw an influx of new medical cannabis dispensary applications. As part of Senate Bill 460, OMMP was tasked with implementing early retail sales to Oregonians by October 2015. Most medical cannabis dispensaries were preparing to:

1. Participate in the early retail sales access, and
2. Transition to OLCC once OLCC started licensing locations.

OLCC began licensing retail stores in October 2016 and OMMP began to see a steady reduction in the number of medical cannabis dispensaries. As of January 2019, OMMP oversees four medical cannabis dispensaries in Oregon.

Medical cannabis processing site applications began in April 2016 and OMMP received a large number of applications for registration. When OLCC began licensing processors OMMP saw a decline in medical processing sites. As of January 2019, OMMP oversees two medical cannabis processing sites in Oregon.

Table 3 Fluctuation of medical marijuana dispensaries and processing sites

	Medical cannabis dispensaries		Medical cannabis processing sites	
October 2015	346	-	-	-
October 2016	427	+23%	126	-
October 2017	21	-95%	12	-91%
October 2018	5	-76%	3	-75%

Cannabis governance framework

As of May 2018, cannabis is fully legal in nine states and in the District of Columbia. Each jurisdiction also has a medical cannabis program. In discussing alternate frameworks for the governance of OMMP, the commission reviewed models of governance in states with recreational cannabis, all of which also maintain a medical cannabis program. The information was presented to the commission by OMMP in the document, Oregon Medical Marijuana Program Current Marijuana Regulatory Regimes (6), and is summarized in Table 4, below.

All US jurisdictions that currently have legalized recreational, adult-use cannabis already implemented medical cannabis programs before legalization occurred. Five states have two separate regulatory bodies that oversee their medical and recreational programs. Two states have or plan to have one body that oversees both programs. In those states, there remains a registry of medical participants administered separately by that state's public health body. Two states and the District of Columbia merely decriminalized recreational cannabis. Thus, they do not have regulators of recreational "programs."

Table 4. Other state medical cannabis program governance summary

Jurisdiction	One agency?	Med passed	Governance of medical	Rec passed	Governance of recreational
Alaska	No	1998	Division of Public Health	2014	Alcohol & Marijuana Control Office
California	Yes (planned)	1996	Department of Public Health (current)	2016	Bureau of Cannabis Control (future)
Colorado	No	2000	Department of Public Health & Environment	2012	Dept of Revenue (MJ Enforcement Div)
Maine	N/A	1999	Department of Health & Human Services	2016	TBD - "State Licensing Authority"
Massachusetts	No	2012	Department of Public Health	2016	Cannabis Control Commission
Nevada	Yes	2000	Div of Pub Health & Behaviorial Health (formerly)	2016	Dept of Taxation
Oregon	No	1998	Public Health Division of Health Authority	2014	Oregon Liquor Control Commission
Vermont	N/A	2004	Department of Public Safety	2018	Legalization of possession only
Washington	No	1998	Department of Health	2012	Washington State Liquor & Cannabis Board
Washington D.C.	N/A	2010	Health Regulation & Licensing Admin	2014	Legalization of possession only

Since inception in 1998, the OMMP model with its basic tenant of confidentiality and patient access through patient and grower relationship, has been referenced by many states. Oregon will need to be an innovator with respect to restructuring the governance of OMMP. Specifically, with the goal of strengthening the environment for its patients in context of legalization for recreational use. It is important to note this review occurred with the awareness that states are experiencing sharp declines in medical program participation; thus, evaluating restructuring options offers not a panacea to the challenges facing the OMMP, but examples of other models to consider. The commission discussed the unique position of Oregon as a leading model for the framework of how other states have set up their medical cannabis program.

Barrier 1: Current regulation of cannabis by multiple state agencies with different mandates causes confusion, task duplication, and does not provide Oregon with centralized oversight.

Cannabis is a complex and nuanced issue, making decisions about its governance far from straightforward.

Treated as a medicine, OMMP was placed under Oregon Health Authority's Public Health Division. OMMP served patients, caregivers and growers by administering the card program. Also, later, by registering and regulating medical dispensaries and processing sites, while developing a new compliance unit. OMMP then was required to develop a method of tracking cannabis plants and transfers. This was accomplished by creating the Oregon Medical Marijuana Online System (OMMOS) where certain growers are required to log in and report aggregate inventory and transfers once a month. These growers are subject to inspections as needed.

Treated as a substance to be regulated for the adult retail market, oversight and regulation of cannabis and cannabis derived products intended to enter a commercial market place was placed under a different agency, the Oregon Liquor Control Commission (OLCC). OLCC worked with a vendor to develop the Cannabis Tracking System (CTS). CTS is a detailed seed to sale reporting system. OLCC licenses:

- Producers
- Processors
- Wholesalers
- Retail stores, and
- Laboratories.

Legislation that passed later also placed OMMP grow sites with three or more patients under partial OLCC regulation by requiring these grow sites to use the CTS system to track.

Treated as an agricultural product, cannabis is also subject to oversight by the Oregon Department of Agriculture at specific stages of processing, including registration of grower, handler and seed production for industrial hemp, agricultural water quality, food safety, pesticides and cannabis weights and measures (scales).

Finally, the Oregon Health Authority's State Public Health Laboratory, Oregon Environmental Laboratory Accreditation Program (ORELAP) oversees the accreditation process for laboratories testing cannabis samples.

Each oversight agency has its own mission and mandate, and views cannabis from its own lens. Cannabis oversight does not neatly fit into any current state agency. This inconsistent vision and overlap of duties creates the potential for conflict but does not make regulation of each impossible.

On top of the varied and overlapping agency oversight, there are many stakeholders with very different interests in cannabis oversight. These include:

- Patients with debilitating medical conditions and their caregivers
- Hospice and residential organizations
- Medical and recreational growers
- Medical and recreational processors
- Medical community
- Academia
- Law enforcement (local, state, other state and federal)
- Cities and counties
- Water masters
- Those who benefit from revenue collected from the adult use market
- Public health officials
- Recreational users, and
- Many others.

Commission members noted that some stakeholders, specifically law enforcement and growers, find the multiple programs and differing rules regarding cannabis to be confusing and difficult to navigate.

Recommendation 1: The legislature, in coordination with the OCC and other agencies, should explore alternate forms of governance over cannabis, such as consolidating governance under a single body. This process will require a detailed examination of the costs and benefits of restructuring the programs, and how to implement such a change.

Such an exploration would require a detailed consideration of the following concerns:

- Improving patient access to cannabis in both the medical and retail markets
- Structured cannabis and hemp research
- Product integrity and diversion prevention in both the medical and retail markets
- Creation of medical training for attending providers, and
- Cultivation of cannabis and hemp.

Funding

A dedicated, stable and consistent source of funding must be found to support OMMP. Funding is needed for multiple priorities outlined in this report, including establishing the infrastructure for:

- Oregon to become a leader in cannabis research
- Better ensuring public health by creating an independent reference laboratory, and
- Creation of provider training to standardize cannabis-based medical care for Oregonians.

Following the increase in OMMP fees and creation of new fees in 2011, OMMP revenue has been transferred to help fund other Public Health Division programs over the last three bienniums. OMMP also

created and sustained the pending recreational market by oversight of dispensaries and processing sites during the early retails sales period from October 2015 through December 2016 giving OLCC time to create their recreational cannabis infrastructure and train staff.

With the significant decrease in participation, OMMP may become unsustainable as a program, because it is funded by the fees paid by its participants. The recommendations in this report may not come to fruition unless a stable and consistent funding source is secured.

In fiscal years 2016-17 and 2017-18 Colorado appropriated monies from their Marijuana Tax Cash Fund to support education and a variety of state programs including:

- Research at the Institute of Cannabis Research at Colorado State University-Pueblo
- Marijuana lab certification
- Health research grants
- Health effects monitoring
- Data collection, and
- A study of the impacts of the legalization of retail marijuana. (7)

In addition, California created the California Marijuana Tax Fund which funds support various departments, including the Department of Public Health for their duties implementing the Medicinal and Adult Use Cannabis Regulation and Safety Act as well as funding research to evaluate the implementation and effect of Adult Use of Marijuana Act. (8)

Barrier 2: OMMP needs a dedicated, stable, and consistent source of funding.

Recommendations 2:

- *A portion of the collected retail sales tax should be secured to fund OMMP and the recommendations in this report.*
- *OMMP fees should be used only for operation and administration of OMMP.*

Product integrity

The focus of the product integrity subcommittee included a review of the Oregon's current laboratory and testing programs, development of a compliance program for cannabis testing labs and cannabis product testing, and diversion of cannabis outside of the medical and recreational (adult use) regulatory systems.

The subcommittee members are:

- André Ourso, OHA representative
- Jesse Sweet, OLCC representative (resigned Oct. 26, 2018)
- Jeff Kuhns, deputy chief, Keizer Police Department

Invited Speakers:

- Sunny Summers, cannabis policy coordinator, Oregon Department of Agriculture
- Stephanie Ringsage, laboratory compliance manager, Oregon Public Health Laboratory
- Tyler Bechtel and Gregg Withers, Oregon State Police

The Product Integrity Subcommittee met on April 16, June 18, and Sept. 21, 2018.

Current Oregon cannabis laboratory compliance program and audit testing of cannabis products

Oregon's Environmental Laboratory Accreditation Program (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. (9) 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.

How accreditation works

A laboratory seeking accreditation applies with ORELAP for each testing method, analyte and matrix combination it wants to have the ability to perform. (10) These include testing for moisture content and water activity, potency, pesticides, solvents and biological contaminants. The lab submits an online application, a quality control manual, standard operating procedures, method validation, and performance testing data to ORELAP. Once the application is approved ORELAP conducts an initial on-site assessment. ORELAP assessors review how closely the laboratory follows their submitted documentation, equipment calibrations, how data review and analysis is performed, and how data reporting is performed. Once a laboratory meets the accreditation standards it will be granted accreditation approval and may apply for licensure with OLCC.

The laboratory must also participate in a Proficiency Testing (PT) program that offers in-matrix PT samples to show the lab is proficient at testing for a particular analyte or method. Laboratories must pass two out of the last three PT studies for every matrix and method-analyte for which they are requesting accreditation. These PT studies are to be done five to seven months apart. Results of the PT studies are reviewed by ORELAP and are required for a laboratory to maintain accreditation.

Current Oregon testing requirements

Cannabis and cannabis products must be tested to standards adopted in OAR by OMMP and must receive passing compliance test results for pesticides, water activity and 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 cannabis product. Laboratories are required to enter testing result data in the Cannabis Tracking System (CTS) for licensees and for qualifying medical cannabis growers. For medical cannabis growers not required to use CTS, a laboratory only needs to report failed test results to OMMP.

Table 5. Oregon testing requirements

Product type	Testing requirements if intended for sale from a retail shop or dispensary	Testing requirements if intended for further processing
Cannabis (usable marijuana)	Pesticides Water activity and moisture content THC and Cannabidiol (CBD) Microbiological (random)	Pesticides (if intended for use by a processing site making a cannabinoid product) Water activity and moisture content (unless processor uses sterilization

		method) Microbiological (random)
Extract or concentrate	Pesticides Solvents (exempt if meets requirements in OAR 333-007-0330(3)) THC and CBD Microbiological (random)	Pesticides Solvents (exempt if meets requirements in OAR 333-007-0330(3)) THC and CBD Microbiological (random)
Cannabinoid products intended for human consumption, ingestion, and cannabinoid suppositories, topicals and transdermal patches	THC and CBD Microbiological (random)	THC and CBD Microbiological (random)

All cannabis items must be sampled according to ORELAP sampling protocols and tested according to OAR 333-007-0300 to 333-007-0500 and OAR 333-064-0100 to 333-064-0110.

Failed test results must be reported to OMMP or OLCC by the testing laboratory within 24 hours of completion of the laboratory's data review and approval procedures and be reported at the same time or before reporting to the grower or processor. Depending on product type and reason for failure a batch may be destroyed, used in further processing, remediated, or retested. (11)

Barrier 3: There is no mechanism for the state of Oregon to perform independent testing on cannabis and cannabis products to confirm private laboratory testing is accurate, in compliance with current rules and regulations, and to assist with other state regulatory duties.

Recommendation for cannabis testing:

Accreditation is just a snapshot in time and does not continuously ensure that a laboratory is performing within its accredited parameters and complying with testing regulations. The establishment of a state reference lab would be a way to objectively audit laboratories and randomly test cannabis products to ensure testing accuracy, consistency and laboratory integrity on a regular basis. OMMP and OLCC have received complaints from licensees and registrants that there is inconsistency in test results between laboratories, especially for potency results, and that labs are manipulating results. Currently the state has very limited capacity to investigate these complaints to ensure the integrity of the testing process by private cannabis labs and whether cannabis products are mislabeled or adulterated.

Cannabis lab compliance and random or audit testing programs would further ensure Oregon's cannabis is reasonably safe and cannabis testing laboratories are held to legal and ethical conduct. Such a program would be able to investigate laboratory compliance issues, potential lab shopping on the part of producers and wholesalers, manipulation of testing results, serve as a reference for legal and compliance disputes related to testing, and establish standard reference methods for testing cannabis and cannabis products.

After discussing the establishment of a reference lab and a random or audit testing program the state agencies responsible for the regulation of cannabis (OHA, OLCC, ODA) concluded that a state reference lab would be best housed within the Oregon Department of Agriculture (ODA). ODA already has expertise in testing agricultural products for pesticides, including cannabis, and would be an objective agency without the appearance of a conflict of interest related to OREALP accreditation, which is conducted by OHA.

A state reference lab may also develop and provide standard methods of testing for all cannabis labs.

Funding for a state cannabis testing lab should include funds for laboratory equipment and instrumentation to test for potency, water activity and moisture content, solvents, pesticides, and contaminants, and an investigator to audit lab compliance issues. Approximately three full time employee chemists and an administrative laboratory staff member to perform testing, establish reference methods and perform administrative duties would be needed as well as additional full-time employees at the laboratory to train OLCC and OMMP compliance staff on proper sampling of cannabis products and utilizing standardized chain of custody procedures.

Recommendation 3: Oregon should establish an independent state reference lab housed in the Department of Agriculture to objectively audit and investigate private laboratories and randomly test cannabis products to ensure testing accuracy, consistency, and cannabis product integrity on a regular basis.

Control of diversion

On Jun. 18, 2018, the Product Integrity Subcommittee heard testimony from representatives from Oregon State Police (OSP) on data related to the illegal diversion of cannabis. While there is diversion from the medical cannabis and recreational cannabis markets as well as significant black-market activity, there is insufficient data to quantify exactly how much illegal diversion is occurring in each market. Data challenges exist with knowing how much illegal cannabis is seized. Due to various law enforcement jurisdictions having different reporting requirements, and the lack of a central data reporting repository for illegal cannabis seizures, the magnitude of the diversion issue with cannabis is unknown.

Barrier 4: Due to various reporting methods across law enforcement, OLCC, and OMMP, and the lack of a central data repository for product movement and seizures related to diversion or potential diversion, the magnitude of the diversion issue with cannabis is unknown.

Recommendations 4:

Legislative

- *OMMP growers enrolled in OLCC's Cannabis Tracking System (CTS) should be subject to security requirements as appropriate for the scale of the grow site in order to ensure data entered into CTS is accurate and to mitigate opportunities for diversion.*
- *The OCC recognizes diversion is an issue and supports funding for additional resources for the Oregon State Police, OLCC and OMMP to investigate and develop enhanced data systems around cannabis diversion activities.*

Administrative

- *OMMP should continue enrolling applicable growers and grow sites into OLCC Cannabis Tracking System (CTS).*

Research

The focus of the research subcommittee is to expand the science and knowledge related to the health effects of cannabis, including by product type. The subcommittee members are:

- Esther Choo, Research Facility, Oregon Health & Science University
- Katrina Hedberg, state health officer, Oregon Health Authority, Public Health Division
- Jane Ishmael, pharmaceutical sciences associate professor, Oregon State University
- Julia Dilley, Oregon Health Authority
- Peter Barr-Gillespie, professor of otolaryngology, Oregon Health & Science University

The Research Subcommittee met on Apr. 20, 2018, May 18, 2018 and Jun. 18, 2018. The subcommittee identified the lack of a centralized research center for cannabis in the state of Oregon. They explored research centers in other states and solicited input from medical, academic, and governmental community members to gauge the interest in creating a research center.

Sample research programs in other states

California has two cannabis-related research centers, the Center for Medicinal Cannabis Research which resides at the University of California, San Diego (12), and The Cannabis Research Initiative (13), University of California, Los Angeles which is supported by and sits with the UCLA School of Medicine Semel Institute for Neuroscience and Human Behavior.

The Center for Medicinal Cannabis Research was created by an initial appropriation of $9 million through legislation ($3 million per year for the first three years), funding through private gifts, and donations. In 2017, the Adult Use of Marijuana Act directed California created the California Marijuana Tax Fund which is directed to distribute two million dollars annually to the University of California San Diego Center for Medicinal Cannabis Research to further the objectives of the center, including the enhanced understanding of the efficacy and adverse effects of cannabis as a pharmacological agent.

In addition, California Marijuana Tax Fund earmarks 10 million dollars to a public university or universities in California annually from 2018 – 2029 to fund research on the implementation and effect of the Control, Regulate and Tax Adult Use of Marijuana Act. The research may include impacts on public health, cannabis effectiveness of different treatment programs, public safety issues, and cannabis use rates, among many other things. (14)

Colorado also has two cannabis-related research centers. Colorado began funding medical cannabis research under the Colorado Department of Public Health & Environment in 2014 using a budget surplus from their medical cannabis cardholder program and based on the California research bill. Initial funding was $10 million over a 5-year period, with $1 million of that earmarked for administrative costs. In the current legislative session there is a proposal to provide an additional $3 million dollars to fund studies specifically on pediatric conditions and autism. An additional $3 million was provided from the retail cannabis tax fund for research focused on public health issues. The second research center, established in 2016, is the Institute of Cannabis Research housed at Colorado State University (15) through a partnership between the University, the state of Colorado, and Pueblo county. Initial funding was provided by the state of Colorado and Pueblo county. Colorado legislature approved a $1.8 million budget for the Institute in fiscal year 2019.

Florida's Medical Marijuana Research and Education Coalition (16) was established within the H. Lee Moffitt Cancer Center, a nonprofit cancer treatment and research center. The Coalition has requested a state appropriation of $1.75 million for 2018 – 2019.

Washington State houses medical cannabis research in the University of Washington. (17) Washington's Initiative 502 directed a portion of the tax revenue from cannabis production and sales in Washington for research on cannabis use and research. For the 2015 – 2017 biennium, $454,000 was directed for this purpose. In November 2018 the Washington State Liquor and Cannabis Board issued its first state license to produce, process and possess cannabis for research purposes for a company conducting research on cannabinoid-based therapeutics. (18)

Pennsylvania has the Lambert Center for the Study of Medicinal Cannabis and Hemp located within Thomas Jefferson University. (19)

Barrier 5: There is a need for research that expands the science and knowledge related to the health effects of cannabis, including by product type.

Oregon lacks a structure, innovative, patient-focused body of ongoing research, placing it behind other states with medical cannabis programs.

Recommendations 5:

- *The state of Oregon will establish a Cannabis Research Center(CRC) to advance research on cannabis and cannabis-derived products.*
- *The CRC will be a collaboration across state academic, medical, and government agencies.*
- *The CRC will be funded by allocation of a minimum of $10 million to $12 million over a four-year period to fund establishment of the center, core staff, an experienced director, and substantial, high quality research and grant activities.*
- *The CRC will coordinate and support original research projects on the health effects of cannabis in the areas of public health policy and public safety policy, agricultural and horticultural best practices, and medical and pharmaceutical best practices, and will establish a competitive grant process with a rigorous external peer review.*
- *The CRC will provide a report of expenditures and grants awarded and a summary of any original research findings at the end of year two and year four to the legislative assembly.*

We recommend that the state of Oregon establish a Cannabis Research Center (CRC) devoted to advancing science related to the health effects of cannabis consumption. According to the Senate Bill 844 (20) Task Force report, (21) such a body "will be capable of driving forward critical research at a much faster pace than other similar attempts have been able to … No other single initiative could do as much to strengthen the Oregon cannabis industry and to support the needs of Oregon medical marijuana patients."

A CRC would develop lines of inquiry within three general priority areas defined by the state (in HB 2198):

1. Cannabis-related public health policy and public safety policy
2. Agricultural and horticultural best practices, and
3. Medical and pharmaceutical best practices.

Within those areas, priority topics may include (as outlined within SB 844):

- Basic plant and agricultural research. Studies on the cannabis plant to fully understand the medicinal properties of the plant, define means of ensuring product safety, and determining the health impact of product integrity and safety efforts.
- Public health research. Research projects designed to assess impacts of policies (such as those relating to time, place and manner of sale) on use, attitudes, and health effects critical to developing policies and procedures for cannabis retail and medical distribution systems, as well as to inform interventions to mitigate potential negative impacts of cannabis legalization; public health questions around cannabis involving toxicology and contamination issues relating to cannabis grown in Oregon.
- Medical observational research. Observational studies related to the medical benefits of cannabis, which will provide evidence of the likely medical and public health benefits of cannabis and preliminary information for the development of clinical research studies.
- Pre-clinical research. Research establishing the safety and efficacy of cannabis and its components necessary to obtain FDA approval to conduct clinical (human) research.
- Clinical research (meeting FDA standards). Rigorous clinical trials meeting FDA standards necessary to develop the evidence base for use of cannabis use in Oregon and lead to products FDA approved for medical use.

The CRC is conceived as a collaboration across academic institutions, the Oregon Health Authority, and any new centralized body governing the Oregon Medical Marijuana Program. The CRC would likely be housed within Oregon Health & Science University (OHSU), given its focus on health effects and medical treatments and its existing infrastructure and funding portfolio focused on human subjects and public health research, and with potential co-leadership by other universities. Member investigators will have established experience in cannabis research relevant to public health and medical care.

Oregon legislature should allocate a minimum of $10 to $12 million over four years to support the CRC. A potential source of funding is suggested by other states, which use cannabis tax receipts to fund their cannabis research programs. A portion of the funds will provide administrative support for the center. The remainder of the funds would establish a grants program. Although center investigators will pursue federal and other sources of support, a foundation of sustained support from the state will ensure the long-term success and effectiveness of such a program.

The CRC grants program could support both internal grants, which would be awarded to center investigators, and external grants, which would be awarded to investigators from public and private entities outside the center. Both programs would be administered through a competitive process with a rigorous external peer review process, similar to a National Institutes of Health (NIH) grant program, and with input from the Oregon Health Authority. This process will be designed to:

- Maximize support for research that will be of the highest possible impact in the scientific community
- Answer critical questions necessary to promote the health and safety of Oregonians, and
- Support best practices and policies for OMMP.

Grants provided by a CRC could focus on innovative early stage research that will generate the data necessary to obtain external federal grant funding. The funds could also be used to support critical areas of cannabis research that are not likely to be funded by NIH or other federal agencies. Grants could be

awarded to investigators outside the state but should include at least one in-state team member to ensure the focus on addressing the needs of Oregon citizens.

A rigorous peer review process will guard against funding research that is biased in favor of or against particular outcomes, or that brings up potential conflicts of interest, including commercial, personal, and political interests.

With sustained funding, the center has great potential to develop innovative, dynamic, state-of-the-art cannabis-related research focused on the health of Oregonians. Resources and activities may include:

- A centralized, secure, web-based research participant registry for OMMP members or other citizens who want to learn about getting involved in IRB approved research studies involving medical cannabis.
- Creation of partnerships and data-sharing arrangements with other institutions and relevant state agencies in order to assemble, organize, and make available as much collected data as possible on the use of cannabis in the state of Oregon.
- Standardized administrative, educational, training, and structural support for university-based researchers in Oregon working on cannabis-related issues in order to expedite the process of obtaining institutional and federal approvals for research using cannabinoids
- In-depth understanding of policy and other barriers to cannabis research, establishment of appropriate recommendations to state agencies in addressing those barriers, and creation of internal or collaborative routes toward completing research that is hindered by such barriers
- Partnerships, collaborations, or contractual relationships with public or private entities within the U.S. and other countries in furtherance of the Institute's objectives
- A repository of current literature related to medical cannabis for clinicians and scientists
- Expertise in medical cannabis-related policy and a resource for state and local policymakers
- A potential future site for production of FDA-approved cannabis preparations
- Supporting and examining the impact of education and training efforts

Clinical practice and training

The focus of the training subcommittee is to examine, standardize and advance the clinical practice of medical providers who recommend the use of cannabis. The subcommittee members are:

- Rachel Knox, attending physician
- Michael Rochlin
- Kim Jones
- Kevin Wilson
- Janice Knox
- Ruben Halperin

The training subcommittee met Apr. 20, 2018, May 18, 2018, Jun. 22, 2018 and Sept. 17, 2018.

The Oregon Medical Marijuana Program (OMMP) should oversee the provision of effective, evidence-based patient care by medical providers who recommend the use of cannabis.

Presently, Attending Physicians (defined by ORS 475B.791 as Medical Doctors [MDs] and Osteopathic Physicians [DOs]) act in the capacity of gatekeepers, assigned with the right to approve or deny patients' access to medical cannabis and other allowances that OMMP registration provides. This Report will refer to Attending Physicians as Attending Providers under the assumption that Recommendation 7 expanding medical professionals who may recommend cannabis is accepted.

While Attending Providers (APs) are required to abide by established standards of care and other expectations as outlined in HB 4014, the *Clinical Guidelines Work Group's "Guidelines for Attending Physicians When Recommending the Medical Use of Marijuana*," (22) there remains a need for minimum training requirements to advance the clinical preparedness and clinical management skills that APs are expected to have when evaluating and managing the patients they approve.

Barrier 6: Inconsistent assessment, consultation, and management of patients by Attending Providers.

Mandatory AP training will help ensure uniformity in the assessment, consultation and management of patients considering OMMP enrollment or renewal across all AP encounters. Training will reaffirm the basis for ORS 475B.916, prohibiting the Oregon Medical Board (OMB) from imposing civil penalties or taking other disciplinary action against an AP who is abiding by the standard of care established by HB 4014 and expanded through the minimal training requirements set forth by the commission.

Recommendations 6:

- *Develop or license existing materials to provide rigorous training in cannabis use in patient care in the state of Oregon.*
- *Require that all APs who wish to evaluate patients for OMMP-approval first complete this training.*

Minimal training requirements should be fulfilled through a novel training program prepared and overseen by OMMP or any centralized body governing OMMP or licensed through an existing education platform. Several continuing education platforms in cannabis medicine exist and have been similarly licensed for mandatory training requirements in New York and Pennsylvania.

The expectation of any AP training program developed or licensed is that it will be kept current and in compliance with the established standards of medical continuing education. As a reference, we recommend that the standards should reflect those of the American Medical Association and Accreditation Council for Continuing Education, a standard recognized by the OMB. AP training will offer continuing education credits, award certifications for completion and require recurrent renewal to ensure that OMMP APs remain up-to-date with respect to scientific and clinical research, and the advancing clinical principles in cannabis medicine.

AP Training Structure: The ideal AP training platform will be disseminated through a web-based portal, consisting of modular training and examination on the following:

- Plant Science (Taxonomy and botany)
- Endocannabinoid System (Function and dysfunction)
- Pharmacology (Pharmacodynamics and pharmacokinetics)
- Cultivation, Processing, & Distribution (Familiarizing the clinician with the industry, from seed to sale, as well as the dispensary model through which patients procure their medicine)

- Clinical Application (i.e. evaluating the patient, determining appropriateness of cannabis as a suitable treatment option, formulating a treatment plan, filling out the APS, follow up and ongoing management expectations)
- Legal Considerations (i.e. rules, regulations, protections, privileges, etc.)

The benefit of modular training is the ability to amend module content as often as necessary to keep up with scientific and clinical trends, and as standards of care advance in cannabis medicine.

The benefit of examination is the ability to assess passing rates as a key performance indicator (KPI) as it relates to provider preparedness and proficiency, as well as patient behaviors, outcomes, and satisfaction.

The benefit of a required training program is the ability to better monitor AP practice.

Funding: Funding is required to cover the cost of development or licensing fees, program administration. It is estimated that two full time employees (a Research Analyst and an Administrative Specialist) would be necessary to administer the AP training program. Of note, once established, fees paid by training participants would quickly offset the cost of administering the program.

Statute Revisions Related to AP Training & Clinical Practice

In addition to establishing an AP training program, the commission believes that the following changes will assist with modernizing OMMP policies and aligning them with the broader standards of current medical care.

Barrier 7: Currently the only medical providers who may recommend cannabis to patients in Oregon are Medical Doctors (MDs) and Doctors of Osteopathy (DOs). This restricts patient access to cannabis as an individual's primary medical care provider may not be a MD or DO.

Many individuals receive primary care from a medical provider other than a MD or DO. Other states, such as Washington state allow for a broader range of medical professionals to recommend the use of cannabis to those under their care. (23) Expanding the definition constituting which licensed medical providers in Oregon (24) may recommend medical cannabis will modernize statute to reflect common and current medical practices and broaden OMMP access.

Recommendation 7:

- *Revise ORS 475B.791(1):*

  "Attending ~~physician~~ **provider**" means a physician **(MD or DO) or a physician assistant (PA)** licensed under ORS chapter 677**, an advanced registered nurse practitioner (ARNP) licensed under ORS chapter 678, or a naturopath (ND) licensed under ORS chapter 685,** who has primary responsibility for the care and treatment of a person diagnosed with a debilitating medical condition.

Barrier 8: Current statute limits an AP's ability to recommend medicinal cannabis to patients with debilitating conditions not on the current list, but who can likewise benefit from medical cannabis use, and requires a petitioning process to expand the debilitating medical condition list that in practice is onerous.

As is established in scientific and clinical research, medical cannabis may provide relief for patients with conditions other than the specific debilitating conditions outlined in statute. Statute should be changed to grant the *certified* AP the autonomy to determine the proper medical care for the patient, as is the case in broader medical practice.

Recommendations 8:

- *Revise ORS 475B.791(6):*
  "Debilitating medical condition" means:
  (a) Cancer, glaucoma, a degenerative or pervasive neurological condition, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, or a side effect related to the treatment of those medical conditions
  (b) A medical condition or treatment for a medical condition that produces, for a specific patient, one or more of the following:
  (A) Cachexia
  (B) Severe pain
  (C) Severe nausea
  (D) Seizures, including seizures caused by epilepsy, or
  (E) Persistent muscle spasms, including spasms caused by multiple sclerosis.
  (c) Post-traumatic stress disorder, or
  (d) Other medical conditions or side effects related to the treatment of a medical condition ~~adopted by the Oregon Health Authority by rule or approved by the authority pursuant to a petition filed under ORS 475B.946~~ **that a certified AP determines in accordance with evidence-based practice and professional judgement, may be mitigated with cannabis**.

- *Remove ORS 475B.946:*
  ~~Petitioning for disease or condition to be included as debilitating medical condition; rules. Any person may petition the Oregon Health Authority to request that a disease or condition be included among the diseases and conditions that qualify as debilitating medical conditions under ORS 475B.785 to 475B.949. The authority shall adopt rules establishing the procedure for filing a petition under this section and the manner by which the authority evaluates a request made under this section. Rules adopted under this section must require the authority to approve or deny a petition within 180 days of receiving the petition. Denial of a petition is a final agency action subject to judicial review.~~

Patient access

The focus of the patient access subcommittee is to ensure OMMP patients have access to all cannabis and cannabis-derived products which mitigate their debilitating medical conditions. The subcommittee members are:

- Anthony Taylor, OMMP registry identification cardholder
- André Ourso, Oregon Health Authority representative
- Esther Choo, research faculty, OHSU
- Cedar Grey, OMMP Grower
- John Sajo
- Todd Dalotto
- Clifford Spencer

- Kris McAlister
- Sarah Bennett, and
- Anthony Johnson

The Patient Access Subcommittee met on Apr. 16, 2018, May 14, 2018, Jun. 22, 2018, Jul. 16, 2018, Aug. 20, 2018 and Sept. 17, 2018.

Patient Access Summary

The key to the success of OMMP has always been facilitation and preservation of the patient and grower relationship. This relationship provides a way for Oregonians unable to grow cannabis themselves to designate someone else to do it for them. Without this compassionate aspect many patients would not have access to affordable medical cannabis. Low-income patients and patients in residential care or hospice often face additional challenges in identifying a grower and may default to prescription medications with higher health risk profiles.

The ability for a patient to designate a grower is essential for the survival of the program and has provided tens of thousands of patients cannabis at little or no cost, often delivered to their home or care facility. While there is little quantitative data to document the scope of care or health system effects of this program function, OMMP patients anecdotally report that access to the program in this way has allowed them to avoid costly traditional healthcare utilization.

Oregon needs to re-evaluate how patients gain access to medical cannabis products in the new landscape of legal cannabis. The commission is committed to determining how to maintain access to cannabis to those least able to obtain it and preserve that access in all its forms into the future. Revitalizing OMMP and returning it to serving the needs of medically fragile Oregonians that benefit from using medical cannabis can be accomplished by facilitating and revitalizing the patient and grower relationship.

Patient Participation Barriers

Barrier 9: OMMP patient fees are prohibitive to patient access; patients on reduced or fixed income are unable to access medical cannabis.

Annual Patient Fees

Patient costs to participate in OMMP have become prohibitive for many Oregonians, especially those who are extremely ill, in care facilities and on low or fixed incomes.

The non-reduced application fee remains the highest in the program's history at $200 a year and is at the highest tier of medical marijuana card application fees in the United States.

Costs for the non-reduced annual patient medical card application fees range from $0 to $200 for the 34 states with medical marijuana programs.

Five states have a fee of $0:

1. Louisiana
2. Maine
3. Maryland
4. New Mexico, and
5. Washington.

Two states are still developing processes and currently do not have fees available; both are included in the $0 fee group:

1. Utah, and
2. West Virginia.

Three states have a $25 fee:

1. Alaska
2. Colorado, and
3. Missouri.

Montana has a $30 fee.

Hawaii has a $35 fee.

Ten states have a $50 fee:

1. Arkansas
2. Massachusetts
3. Nevada
4. New Hampshire
5. New York
6. North Dakota
7. Ohio
8. Pennsylvania
9. Rhode Island, and
10. Vermont.

Michigan has a $60 fee.

Florida has a $75 fee.

Five states and Washington, D.C., have a $100 fee:

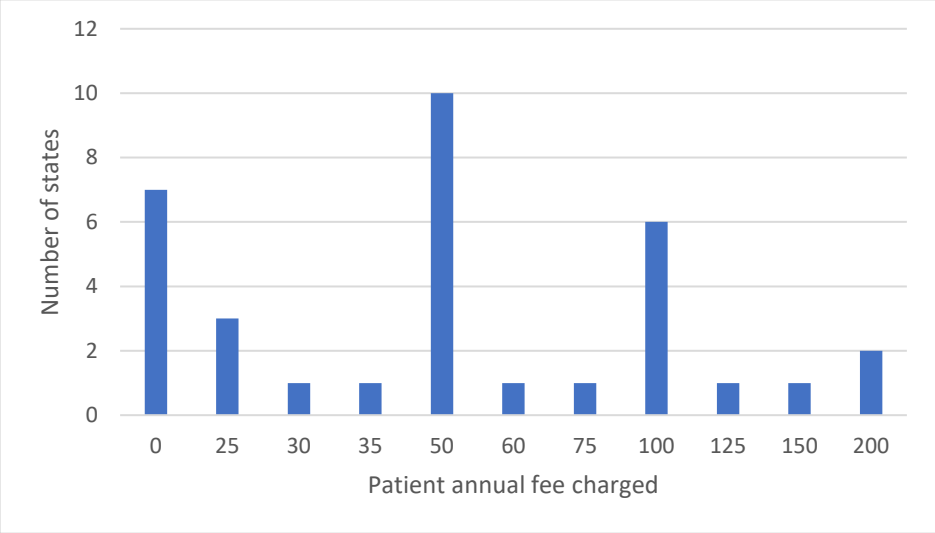
1. California
2. Connecticut
3. Illinois
4. New Jersey, and
5. Oklahoma.

Delaware has a $125 fee.

Arizona has a $150 fee.

Minnesota and Oregon have the highest full price registration fee at $200.

Graph 6. Annual patient card application fee amount charged by state



Along with the annual application fee, there are associated costs which are a deterrent to Oregonians that qualify for the medical cannabis program from participating at all. Current patient annual fee ranges and a sample of other associated costs can be found in Graph 6. While approximately 53 percent of medical marijuana patients qualify for a reduced application fee (25), additional significant out-of-pocket expenses to see an attending provider or pay a grow site registration fee can push annual costs for one patient to participate in OMMP to $500 or more.

Table 7. Sample annual cost of OMMP patient application fee and out-of-pocket medical care

Annual OMMP patient application fees	
Base application fee, or	$200
Supplemental Nutrition Assistance Program (SNAP), or	$60
Oregon Health Plan (OHP), or	$50
Supplemental Security Income (SSI) or U.S. Veteran, and	$20
Estimated annual medical appointment	$150
Grow site registration fee (if growing for self and not exempt)	**$200**
Total patient annual cost range	**$170 to $550**

Need for a supplemental patient care program

There is a need for additional support for those OMMP patients who have little or no resources to facilitate access to medical cannabis. Many in these populations do not already qualify for a reduced OMMP application fee but are below the federal poverty line and cannot afford even the initial costs of becoming a patient let alone out-of-pocket expenses they encounter on their way to becoming a patient. These populations will require subsidized access to the application process, help in working out policy issues that restrict access based solely on the use of cannabis and assistance in meeting the costs of obtaining products.

As with all programs assisting low and fixed income populations, this program will need to be subsidized in some manner so that it will meet the needs of those in outlying areas where access is otherwise unavailable. It needs to address the residential and hospice care populations as more and more of them

find relief from cannabis products that are readily available outside a facility, but statute and policy make access harder to achieve.

Funding could stem from Recommendation 2 or other means such as inventory assessment fees.

Currently, 53 percent of all OMMP patients qualify for a reduced OMMP application fee because they are SNAP, OHP, SSI, or Veteran qualified. These individuals may qualify for any supplemental patient care program with a simple annotation to their cards and can be folded into a supplemental patient access program almost overnight once one is available. The state already uses the federal poverty level to qualify enrollees in other low-income programs and should use the same model for qualifying other cannabis patient populations.

Recommendations 9:

- *Establish an alternative and stable funding source so OMMP may reduce annual application fees for patients, and not require medical patients to wholly fund OMMP. As suggested in Recommendation 2, this source could be from the retail tax receipts.*
- *Explore a Supplemental Patient Care Program that serves low income OMMP patients who do not already qualify for an OMMP reduced application fee but are below the federal poverty line.*

Patient access barriers: Access to affordable medical product from growers

Barrier 10: OMMP patients do not have easy access to medical cannabis growers; grower fees are prohibitive; and growers do not have an avenue to transfer excess product.

- *Grow Site and tracking costs are too high to sustain a robust grower population.*
- *Complex and changing rules make compliance difficult.*
- *Restricted entry into the market for overproduction.*
- *Growers restricted from sharing with general patient population and are only allowed to transfer to patients registered at specific grow sites.*

Annual grower fees

OMMP growers must pay an annual grow site registration fee of $200 per patient to OMMP if they are growing for a patient other than themselves, growing for themselves at a grow site which is not the patient's residence, growing more than 12 plants at the grow site or are transferring product to medical processors or medical dispensaries. If a grower is growing for the maximum of eight patients, this cost $1,600 per year. In addition to this, each grow site with more than two patients must also pay the annual Cannabis Tracking System (CTS) fee of $480, which OMMP collects and transfers to OLCC. Current grower annual fee ranges for a grower growing for the maximum of eight patients can be found in Table 8.

Table 8. Sample annual cost of OMMP grow site registration fee for eight patient grow sites

Annual grow site registration fee, and	$1,600 ($200 x 8 Patients)
Annual CTS system user fee	$480 per Grow Site
Total initial cost to grower	**$2,080**
*Patient maximum is eight. Growers growing for a patient other than themselves, not at patient's residence or transferring must pay $200 grow site registration fee per patient per year. Additional potential costs to a grow site: CTS growers must have a state certified scale on the premises which must be calibrated on a yearly basis. The CTS system requires a grower to weigh harvested plants immediately. Growers that harvest whole plants must purchase two scales, one platform and one hanging. The platform scales range in cost from $300-$1300 and certified hanging scales are in the $500 range.	

A significant factor in fostering patient access to medicinal cannabis is ensuring a robust population of OMMP growers are able and willing to provide for patients. As described previously, there has been a significant decline in OMMP in growers which means patients have lost access to low-cost medicinal cannabis.

The advent of the recreational market severely limited the ability for OMMP growers to transfer authorized excess product to a medical dispensary due to the decline in registered medical dispensaries. Currently, there are only five registered medical dispensaries in Oregon. Many OMMP growers also made a business decision and moved to the recreational market. This reportedly reduced access to specialized product for medical patients. The number of OMMP growers dropped 66 percent from October 2015 to October 2018 (26) leaving many patients without a grower to produce affordable medical cannabis for them. Many patients are unable to locate or afford appropriate medical cannabis products in retail markets.

The costs and regulatory requirements incurred by legislative changes over the last several sessions have been particularly challenging to navigate for the growers. These changes are often expensive and take time to understand and respond to and add to the cost of compliance.

In 2017 multiple patient grow sites were given limited access to OLCC market and allowed to transfer up to 20 pounds per year per grow site into that market. However, this did not provide the relief it was expected to provide, as only a handful of grow sites applied to make these transfers. In addition, OLCC adopted rules requiring an OMMP grow site to provide proof of legal water usage in producing medical cannabis, preventing many of these grow sites from transferring product into the retail system.

Recommendations 10:

- *Establish an alternative and stable funding source so OMMP may reduce annual application fees for growers. As suggested in Recommendation 2, this source could be from the retail tax receipts.*
- *Allow registered growers that are currently required to track in CTS to transfer to any OMMP patient or caregiver cardholder.*
- *Develop and maintain an opt-in for growers to waive their confidentiality protections under current statute and appear on an online list with name, contact information, and product experience.*

Patient Access Barriers to Affordable Medical Product from the Retail Market

Barrier 11: OMMP patients have limited access to affordable medical product in the current retail market system.

- *Lack of participation by OLCC licensees.*
- *Lack of clear direction from the state.*
- *Focus on diversion over adequate patient access.*

There are currently five medical marijuana dispensaries and 591 retail market dispensaries in the state of Oregon. The needs of medical patients can be very different from recreational users, including higher potency or quantity needs. While medical products may be sold in OLCC licensed retail shops, specialized medical products may not be affordable or even available. Retail shops often cater to the popular consumer rather than the specialized needs of medical patients.

In addition to lack of affordable medical cannabis product in retail shops, there is no state-wide program providing access to affordable (or no-cost) medical cannabis products for vulnerable, low-income or rural OMMP patients.

This may be addressed in a number of ways, such as by revising ORS 475B.873 (27) so that it is utilized as discussed below, or by creating a new Supplemental Patient Care Program as discussed under Recommendation 9.

The following revisions would need to be made to ORS 475B.873 in order to make it functional:

- Expand to include OLCC licensed retail stores
- Include either incentives to participate or mandatory participation, and
- Change the qualification from patients whose income is at or below the federal poverty guidelines to patients who qualified for a reduced OMMP application fee.

Recommendation 11:

- *Revise ORS 475B.873 to facilitate OLCC retail store participation in a non-profit patient access program, or*
- *Create incentives for OLCC licensees to participate.*

Ongoing discussion and action plan

Commission next steps

The commission and subcommittees discussed many issues, ideas and suggestions that were not developed enough to be included into this report. Additionally, the commission would need additional time to consider specifics and detail of the Governance recommendations in this report.

Over the next year the commission has the following goals:

- Define the role of a medical marijuana program in a legalized market.
- Work with OMMP to develop and analyze a comprehensive survey of current and past OMMP patient participants to determine:

    - Reasons patients do not renew registration
    - Patients' ability to access medical cannabis product
    - How patients use medical cannabis to mitigate conditions, and
    - Patients' vision for the commission, OMMP and overall cannabis regulation in Oregon.
- Continue with listening tours throughout the state to open dialogue with stakeholders.
- Revisit the priority areas to add, revise, or eliminate priority areas as needed.
- Further explore and refine the vision of one body being responsible for cannabis in Recommendation 1.
- Highlight the commission's work in creating a path for how Oregon can continue to serve cannabis patients and create and fund cannabis programs, training, regulation, and research into the future.

Other commission discussions included:

- Patient issues with employment, drug screening, lease or rental agreements, health care treatment options, professional licensing restrictions, denial of public resources, research of existing poverty guidelines in other states to qualify more patients for reduced application fees, and promote the knowledge of benefits of being a patient to the general public.
- Grower issues with inability to transfer to any patient and have a verification mechanism, per-patient grow site registration fee, removing grow site registration fee and reporting requirements.

Endnotes

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