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January 25, 2019

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

Dear Mr. Memmott:

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

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

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

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

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

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

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

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

Narrative for Recommendation 5

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

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

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

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

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

Narrative for Recommendation 6

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

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

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

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

RECOMMENDATION 7

(OHA-OMMP) Under the guidance of the Governor’s office and the Legislature, review the level of authority OMMP needs to improve its regulatory framework for security, product tracking, and bolster resources for inspections, or consider placing the medical marijuana compliance program within the existing OLCC authority and control framework.

Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree, but not allowed under current statute	TBD, pending provision of statutory authority	Holly Heiberg, OHA Government Relations 971-207-7767

Narrative for Recommendation 7

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

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

RECOMMENDATION 8

(OHA-OMMP) Evaluate the reasons behind high inspection staff turnover and implement management strategies to reduce turnover.

Agree or Disagree with Recommendation	Target date to complete implementation activities (Generally expected within 6 months)	Name and phone number of specific point of contact for implementation
Agree	July 25, 2019 or TBD, pending position authority	Carole Yann Section Manager 971-673-2507

Narrative for Recommendation 8

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

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

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

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

Narrative for Recommendation 9

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

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

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

Narrative for Recommendation 10

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

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

Narrative for Recommendation 11

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

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

Narrative for Recommendation 12

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

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

Narrative for Recommendation 13

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

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

Narrative for Recommendation 18

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

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

Narrative for Recommendation 19

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

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

Narrative for Recommendation 20

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

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

Narrative for Recommendation 21

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

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

Narrative for Recommendation 22

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

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

Narrative for Recommendation 23

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

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

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

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

Sincerely,



Patrick M. Allen
Director

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