Secretary of State Oregon Audits Division

OF



Veterinary Medical Examining Board The Oregon Veterinary Medical Examining Board's Monitoring of Controlled Substances Needs to Be Strengthened

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Executive Summary

Why This Audit is Important

» The Veterinary Medical Examining Board licenses veterinarians, certified veterinary technicians, and veterinary facilities. The board also investigates public complaints and inspects veterinary facilities for compliance with state and federal regulations.

» The board's mission is to protect animal health and welfare, public health, and consumers of veterinary services.

» Monitoring controlled substances in veterinary clinics can help reduce the risk of diversion and protect animals and public health.

» Performing background checks on veterinarians and veterinary technicians is important to uphold the board's mission and prevent diversion or misuse of controlled substances.

Veterinary Medical Examining Board The Oregon Veterinary Medical Examining Board's Monitoring of Controlled Substances Needs to Be Strengthened

What We Found

- 1. The Oregon Veterinary Medical Examining Board's inspections of veterinary facilities do not include verification that the federal Drug Enforcement Agency's requirements for controlled substances are being followed. These medications are known contributors to Oregon's opioid crisis. (pg. 6)
- 2. The board did not conduct background checks on new or renewing licensees, despite a 2014 board resolution to begin doing so. This is in contrast to other health licensing boards in Oregon and other state veterinary boards, which perform background checks. Subsequent to our inquiries, the board adopted rules on October 28, 2019, to conduct background checks. (pg. 10)
- 3. Veterinarians are exempt from participation in Oregon's Prescription Drug Monitoring Program (PDMP). Their inclusion would contribute to a more complete database of opioid prescribers and could provide useful information to the Oregon Health Authority. Our office issued a performance audit in December 2018 examining the state's PDMP in detail. (pg. 12)

What We Recommend

The board should take action to ensure administrative rules allow for inspections of veterinary facilities to monitor the use of controlled substances; complete the implementation of administrative rules and begin conducting background checks; and work with both the Oregon Health Authority and the state Legislature to require that veterinarians participate in the state PDMP.

The board agreed with all of our recommendations and has recently initiated rule changes to implement changes. Their response can be found at the end of the report.

The Oregon Secretary of State Audits Division is an independent, nonpartisan organization that conducts audits based on objective, reliable information to help state government operate more efficiently and effectively. The summary above should be considered in connection with a careful review of the full report.

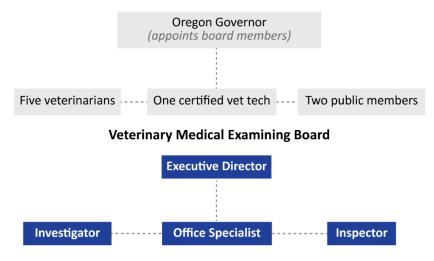
Introduction

The Oregon Veterinary Medical Examining Board is responsible for regulating veterinarians and veterinary facilities. The board's mission is to protect animal health and welfare, public health, and consumers of veterinary services.

Veterinary clinics range from large hospitals to single-veterinarian mobile practices, the majority of which prescribe and dispense drugs that are controlled substances. These drugs are used for surgical procedures, administered during in-clinic treatments, or dispensed for animal patient home use.

Oregon is in the midst of an opioid epidemic and the Governor has indicated that addressing the issue is a high state priority.¹ While much of the focus has been on medical doctors and pharmacists, doctors of veterinary medicine prescribe and dispense many of the same controlled substances used by human practitioners, including opioids.

This audit focused on whether the board is meeting its mission to protect the public health with regard to controlled substances.



The board licenses and regulates veterinary professionals

The board was established in 1903 to test, license, monitor, and regulate practitioners of veterinary medicine in the state. The board consists of eight members, appointed by the Governor and approved by the Senate. Five of the eight board members are licensed veterinarians, one is a certified veterinary technician, and the remaining two are public members.

The board is one of six independent health-related licensing boards. Each board operates in essentially the same manner, issuing and regulating their particular licenses according to their statutory guidelines. The other five boards are the Board of Examiners for Speech Pathology and Audiology, the Board of Naturopathic Medicine, the Mortuary and Cemetery Board, the Occupational Therapy Licensing Board, and the Board of Medical Imaging.²

¹ Office of the Governor, State of Oregon; <u>Executive Order No. 18-01</u>, "Building Oregon's Commitment to Addiction Prevention, Treatment, and Recovery Priorities, and Setting Deadlines for Statutory Requirements, and Declaring a Public Health Crisis"; signed March 27, 2018.

² These boards, because of their size and similar nature, are grouped together in one agency. Other health-related boards, such as the Oregon Medical Board and the Oregon Board of Dentistry, operate as individual agencies.

The board's 2017-19 legislatively adopted budget includes four budgeted positions: an executive director, a facility inspector, an investigator, and a part-time administrative staff. For 2017-19 the board is funded by approximately \$973,220 in annual revenue from veterinarian license, application, and examination fees, and veterinary facility registration fees.

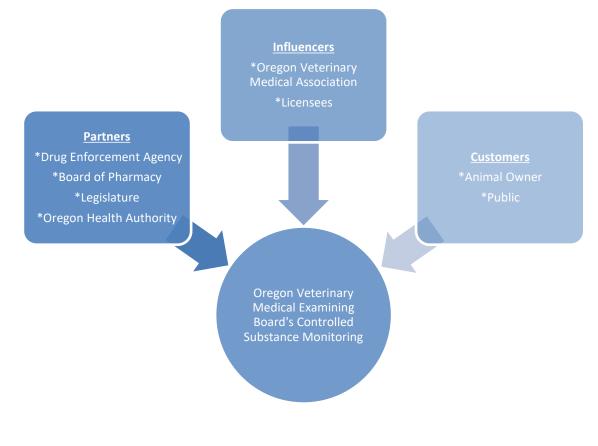
Primary board functions include the licensing of veterinary professionals and facilities, investigating public complaints against licensees, and inspecting veterinary facilities for compliance with state and federal requirements. The board currently licenses more than 650 veterinary facilities and approximately 4,000 veterinarians and certified veterinary technicians.

The board's authority comes from the Veterinary Practice Act.³ The act defines who is required to be licensed, what constitutes the practice of veterinary medicine, qualifications for licensing, and continuing education requirements. The act also defines unprofessional or dishonorable conduct and states that the board may discipline any permit or license holder for such acts. The board develops and maintains rules under which licensees practice, codified under Oregon Administrative Rules chapter 875.

Several stakeholders play a role in board operations

Several entities play a role in the board's mission to protect the public health with regard to controlled substances as shown in Figure 1. Two of the board's main stakeholders include the federal Drug Enforcement Administration (DEA) and the Oregon Veterinary Medical Association (OVMA).





³ <u>ORS 686.210</u> establishes the Oregon State Veterinary Medical Examining Board. Chapter 686 of Oregon law more generally is referred to as the Veterinary Practice Act.

The DEA's primary responsibility is to enforce the Controlled Substances Act.⁴ One of the responsibilities of the DEA Office of Diversion is to investigate complaints of suspected diversion of controlled substances; they receive about eight to ten complaints each month of which two to three pertain to veterinarians and veterinarian practices. Diversion with respect to controlled substances is re-routing these drugs from their intended, legal purpose to other uses. Diversion occurs when a person fakes illness or injury or intentionally injures themselves or others to obtain a prescription. The board has a responsibility to ensure DEA regulations over controlled substances are followed.

As a regulatory entity, the board has a relationship with and is influenced by the OVMA, a professional association that exists to promote and protect the interests of the veterinary profession. The OVMA seeks to influence legislation to benefit their members. According to the OVMA website, 80% of Oregon veterinarians in active practice are members of the organization.

Oregon's opioid crisis has focused attention on medical doctors and pharmacists, but veterinarians also prescribe controlled substances

Opioids are extremely addictive and opioid-related deaths are still rising

Opioids are controlled substances⁵ that act on receptors in the brain and are widely used to control pain; however, they are also highly addictive and pose significant danger when misused. Heroin, morphine, and opium are natural opiates derived from the poppy plant. Synthetic opioids are made in a laboratory and include drugs such as fentanyl and tramadol. Some opioids, such as heroin, have no currently accepted medical use and a high potential for abuse and are therefore illegal. Others, such as oxycodone or fentanyl, can be legally prescribed, but are often sold or obtained illegally.

Widespread misuse and abuse of opioids has led to a public health crisis in the United States. The National Center for Health Statistics reported 341 opioid-related deaths in Oregon from November 2017 to November 2018, which translates to 28 Oregonians dying from opioids every month. According to the Centers for Disease Control and Prevention, drug overdose deaths, including those involving opioids, continue to increase in the United States. The rate of opioid overdose deaths has more than doubled since 2007 (see Figure 2).

Addiction is a public safety issue that continues to plague Oregon. Three out of every five prescriptions written in the state, or 60%, are for schedule II-IV opioids.⁶ In addition, Oregon has some of the highest rates in the country of addiction involving vulnerable populations, including teens, seniors, and those with mental health issues. Addiction has been shown to exacerbate homelessness and crime. Drug addiction is also expensive. In 2015, annual costs related to opioid addiction were \$1,413 per Oregonian, or 2.46% of Oregon's gross domestic product.⁷

Executives, legislators, and state agencies have issued declarations, passed laws, and strengthened guidelines in an attempt to stem the tide of opioid addiction. The Oregon Prescription Drug Monitoring Program (PDMP) is one component of the Oregon Health Authority's "Opioid Initiative," launched in 2015, to address the opioid crisis.

The PDMP facilitates collection of drug prescribing data that can be used by the Oregon Health Authority to develop strategies and policies, allowing the agency to determine whether their

⁴ The Controlled Substances Act of 1970 is codified in Title 21 of the United States Code, Chapter 13. Related regulations are in the Code of Federal Regulations, Title 21, Chapter II, Parts 1300-1399.

⁵ Controlled substances are drugs and other substances, including opioids, identified with potential for abuse or dependence, and as a result their manufacture, distribution, and use is highly restricted or illegal under the Controlled Substances Act.

⁶ Centers for Disease Control and Prevention website, U.S. State Prescribing Rates, 2017.

⁷ Alex Brill, "New State Level Estimates of the Economic Burden of the Opioid Epidemic", AEI, January 16, 2018.

actions are effective. The PDMP is a tool used by pharmacists and other medical professionals to identify unusual prescribing patterns and prevent individuals from obtaining prescriptions for illicit use.

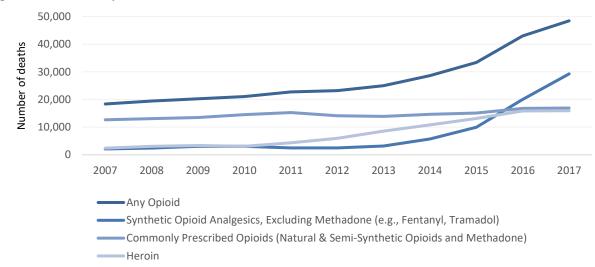


Figure 2: The rate of opioid overdose deaths has more than doubled since 2007

Source: Centers for Disease Control and Prevention, Opioid Data Analysis and Resources

Veterinarians purchase their controlled substances directly from suppliers and manufacturers, much like pharmacists. However, unlike pharmacists, they are not required to independently report this information to the PDMP or query the data in PDMP when dispensing prescription drugs. Our office issued a performance audit in December 2018 examining the state's PDMP system; in that audit, we recommended including veterinarian prescriptions in the information to be collected by the PDMP.⁸

Diversion of controlled substances can occur through veterinary practices

Those who prescribe, dispense, and administer controlled substances are required to register with the DEA and maintain a strict accounting for all distributions. Logs should include the drug type, dosage, patient name, and number of pills dispensed. Controlled substances must be stored in a locked cabinet and a detailed physical inventory should be performed at least every two years. The drug dispensing information should correspond to patient records. For a minimum of two years, practitioners must maintain copies of DEA order forms (used to order controlled substances from distributors), copies of invoices for drug orders, and records of transfers of controlled substances to other DEA registered practitioners.

Those who work in occupations with access to controlled substances can steal drugs, write fake prescriptions, and alter records to hide missing inventory if internal controls are not sufficient to prevent or detect such actions. All of these diversion activities have been known to occur in the veterinary field.

Veterinary practices often function as both doctor and pharmacy. Drugs are stored on site for surgical procedures administered in the clinic, or dispensed for clients to take home for their pet. Veterinary practices, which can range from large hospital settings to single-veterinarian mobile practices, vary in their capacity to meet the DEA requirements. Small practices may only have one person ordering the drugs, entering them into logs, and recording use of the drugs on a

⁸ Report no. <u>2018-40</u>; "Constraints on Oregon's Prescription Drug Monitoring Program Limit the State's Ability to Help Address Opioid Misuse and Abuse," December 2018; recommendation no. 12(c)

pet's medical chart. In some cases, DEA regulation may not be followed at all. There is little hands-on training available on the subject, compliance with regulations is not monitored on a consistent basis, and some practices find the regulations cumbersome and view them as unnecessary.

Controlled substances prescribed in veterinary medicine are identical to those used in human medicine, even though differences exist between animal and human physiology. Tramadol and fentanyl, for example, are used to treat moderate to severe pain in many species of animals. Ketamine is used as an anesthetic agent. Hydrocodone can be used to treat coughing in dogs. Alprazolam (Xanax®) and diazepam (Valium®) are used to treat anxiety, panic disorders, and seizures. These are all drugs used for human medical treatments and favored by drug addicts. According to the Centers for Disease Control and Prevention, overdose deaths from synthetic opioids (e.g., tramadol and fentanyl) have had the sharpest rise in recent years.

Since many dogs, cats, and other animals have lower weights and higher metabolisms, they may require lower drug strengths, or dosages of drugs, than humans. However, smaller dosages can be combined to provide enough strength to get a human high.

We conducted a survey of veterinary facilities that showed that over 23% of respondents have seen an increase in the number of customers exhibiting doctor shopping behaviors in the last three years, including suspicious pet injuries. The survey results mirrored those of a survey conducted by the Colorado School of Public Health.⁹ Just over 15% of respondents suspected a co-worker of having a controlled substance issue or of diverting medications to themselves or others in the last three years. Additional survey results are covered in greater detail later in this report.

According to the president of the National Alliance for Model State Drug Laws: "Those misusing or selling drugs for nonmedical purposes tend to take the path of least resistance. As states close routes to obtaining medications, addicts and sellers will choose others." One such route could be the veterinary industry, where insufficient controls and lax monitoring increase the risk of diversion occurring. Therefore, if a significant veterinary diversion problem does not exist now, the risk is high that one will develop in the current climate, with the advent of the PDMP and other barriers to obtaining opioids.

⁹ Derek S. Mason, Liliana Tenney, Peter W. Hellyer, Lee S. Newman, "Prescription Opioid Epidemic: Do Veterinarians Have a Dog in the Fight?", American Journal of Public Health 108, no. 9 (September 1, 2018): pp. 1162-1163.

Audit Results

We found the Oregon Veterinary Medical Examining Board is not proactively managing the risk of controlled substance diversion in Oregon. We identified three main areas for the board to address. To begin with, the board needs to improve its inspection process. The board developed veterinary facility inspection rules, but neither the rules nor the inspection process includes a review of invoices for drug orders, patient records, or other required DEA documentation. The board only investigates if there are complaints involving diversion, but has few processes in place to identify risks involving inappropriate use of controlled substances. During the course of the audit, the board had not determined what action it would take against a fast approaching deadline pertaining to Board of Pharmacy rules over inspections.

Second, although background check rules were proposed and approved by the board in 2014, rules were not adopted until October 28, 2019. Lastly, the board has not taken a position on whether to include veterinarians in the PDMP.

Without proactive measures, the board's mission is undermined and the possibility of controlled substance diversion is heightened, putting both the public health and the welfare of animals at increased risk.

Incomplete inspections of veterinary facilities increase the risk of diversion

The board established its current facility inspection process as a result of amendments the Legislature made to the Oregon Veterinary Practice Act in 2015. Prior to this, the board only conducted inspections in response to complaints. The board recognized that without inspections, facilities could fall short of minimum cleanliness and safety standards, so the board requested these statutory changes.

Over the years, non-veterinary ownership of facilities has become more prevalent as it allows greater opportunity for veterinarians wishing to expand ownership or sell their practices upon retirement. By requiring all veterinary practices to register as facilities, the board has the authority to regulate all facilities, whether or not they are owned by a veterinarian.

The 2015 amendments enabled the board to conduct regular facility inspections and investigate issues or complaints against facilities that were not owned by veterinarians. Prior to the amendment, the board could enforce rules against veterinarians but had no ability to enforce rules against a facility owned by a non-veterinarian. In 2017, the board hired a facility inspector and began inspections of veterinary facilities.

Inspections of veterinary facilities focus on safety, cleanliness, and sanitation, but do not include review of controlled substance logs

The board used an inspection checklist from the state of Virginia as a model for its own checklist, but did not include Virginia's detailed steps related to controlled substance and patient record review. The board excluded these steps because it believes they are not within its authority. The current checklist focuses primarily on best practices for safety, cleanliness, and sanitation, which includes verifying controlled substances are properly stored in a locking cabinet and that expired drugs are separated and not sold. The board's inspection procedures are not designed to detect diversion, which is known to be a problem with some Oregon veterinarians.

The DEA enforces the Controlled Substance Act, which requires strict accounting for controlled substances. According to the DEA, they do not have the resources to perform regular facility inspections to ensure compliance, so they rely on the states to conduct regular inspections. In relation to veterinary practices, the DEA's role is to investigate only if they have reason to believe a violation has occurred (i.e., a public complaint or report from the board). Only 3% of

our survey respondents indicated they have had a facility inspection by the DEA in the last three years.

Since the board determined it does not have authority to monitor for controlled substances, board inspections do not include compliance with all DEA requirements. The board's inspector must adhere to the limited checklist and is at a distinct disadvantage to discover, note, or address controlled substance violations or irregularities. For example, if during an inspection the inspector suspected the veterinarian was hiding or manipulating the opioid stock, the board contends its inspector would not be able to comment on or note this suspicious behavior for further follow up because of specific instructions to focus only on verifying that controlled substances were locked up. In addition, the inspector would not be allowed to review controlled substance documentation that would have shown if there were any missing pharmaceuticals.

The board has not taken sufficient action to ensure its authority allows for inspection of controlled substances

The board contends its current inspection authority, as spelled out in law and rule, does not allow inspecting veterinary facilities for DEA requirements related to handling of controlled substances. Yet the board has not taken action to amend its administrative rules to permit inspections of controlled substances.

Current law allows the board to adopt certain rules for facility registration and renewal procedures, to establish fees, and to define health and safety standards, which includes rules for monitoring of controlled substances. Current administrative rules for veterinarians and veterinary facilities state "all biological substances shall be stored, maintained, administered, dispensed and prescribed in compliance with federal and state laws and manufacturers' recommendations."¹⁰ The board contends that since this requirement is included in a rule for veterinary practice standards and not specifically stated in the rule for veterinary facilities and licensees,¹¹ the board would assume legal risk if it inspected facilities for controlled substances.

As a result, the board specifically scopes inspections so that the inspector adheres to a checklist that does not allow for monitoring of controlled substances (see Appendix B). Because the board is not seeking amendments to its rules so they align with federal requirements for administering, dispensing, and prescribing controlled substances, it is not meeting its mission to protect the public.

Amending administrative rules to enhance inspections takes time, as it involves writing proposed rules, holding a hearing, obtaining feedback from interested parties, making any necessary revisions, and implementing the rules. However, in this particular instance, the process is even more onerous due to a recent requirement to involve a specially formed rules advisory committee.

When the Legislature was considering granting authority to the board to register and regulate veterinary facilities as part of the 2015 legislative process, the OVMA successfully presented testimony to have the bill amended to require convening a rules advisory committee prior to the board's approval of any addition or change to facility inspection rules. The advisory committee requirement is in place until January 2020 and mandates the committee consist of a diverse group.¹² According to the board's executive director, due to difficulty in meeting this additional

¹⁰ Oregon Administrative Rule <u>875-015-0030(7)(a)</u>

¹¹ Oregon Administrative Rule <u>875-015-0020</u>

¹² Oregon Revised Statutes <u>686.210</u>, Section 7, requires that the advisory committee include representatives of the following: a rural veterinary facility, an urban veterinary facility, a mixed animal practice, a large animal practice, a nonprofit animal shelter, a nonprofit caring for indigent animals, the OSU College of Veterinary Medicine, a certified veterinary technician (or individual who represents a veterinary technology program offered in the state and accredited by the American Veterinary Medical Association), two current members of the board, and one former member of the board.

requirement, the board did not take action to revise its administrative rules to include administering, dispensing, and prescribing controlled substances.

Since 2017, the board has initiated 78 investigations in response to complaints. At least seven of those investigations, or 9%, involved diversion of controlled substances by veterinarians or veterinary staff. When conducting an investigation where the board inspector suspects diversion has occurred, the inspector passes that information to a local DEA agent in Portland to investigate and determine whether diversion did occur. The agent estimates that 20% to 30% of their caseload is veterinary-practice related.

A more robust inspection process would help the board identify diverters so they could be investigated and disciplined. In addition, if record keeping deficiencies are found, the inspection process provides an opportunity to educate veterinary facility personnel on proper practices for maintaining DEA required records.

The board must change its inspection processes by 2021 or become subject to the Board of Pharmacy's inspections

The board's inspection process also falls short of the more rigorous inspections conducted by the Board of Pharmacy for controlled substances. The board has until June 2021 to align its rules and controlled substance inspection process with the Board of Pharmacy or its controlled substance inspection responsibilities could be transferred to the Board of Pharmacy. During the course of the audit, the veterinary board had not determined what action it plans to take.

In 2013, the state Department of Justice issued a final opinion that medical practice sites with dispensing practitioners (such as veterinary clinics) are subject to Oregon Board of Pharmacy dispensing practitioner drug outlet (DPDO) registration requirement.¹³ The Board of Pharmacy began working with other agencies and stakeholders to establish rules to regulate DPDOs. The Notice of Proposed Rule-making, filed in January 2017, provides an explanation for these new rules:

"Prescription drug dispensing has changed significantly in the last 5 years with increased access outside the pharmacy model. The process is also more sophisticated around the access to drugs, compounded drugs, supply and the chain of custody; i.e. how drugs are acquired, stored, labeled, when they expire etc. The Board of Pharmacy is charged with the regulation of the practice of pharmacy, as well as the risks and public safety related to the distribution of prescription drugs. Practitioner Dispensing Drug Outlets are not currently regulated or inspected as all other dispensing locations. The Board wants to facilitate and ensure safe dispensing practices occur for the public."

The rules became effective December 1, 2017, and require DPDOs to register and be inspected on an annual basis.

Based on the Department of Justice opinion, since veterinary facilities dispense controlled substances, they meet the definition of a DPDO and would be subject to these rules and inspections. However, veterinarians expressed concerns to the Board of Pharmacy during the rule-making process that the DPDO rules would constitute an undue burden on their practices, such as additional fees and inspections. The board requested a waiver, and was allowed an exemption from the registration requirements on the condition that the board's controlled substance inspection process mirror the Board of Pharmacy's.

¹³ Oregon Department of Justice Opinion Request <u>OP-2013-1</u>, February 6, 2013.

The board has until June 2021 to comply. At the time of this report, the board's inspection process encompassed only a few limited portions of two of the Board of Pharmacy's 11 specific areas of compliance related to controlled substances, which are documented in Appendix B. The new administrative rules need to be written and approved, and an inspector needs to be trained in DEA controlled substance requirements by the June deadline.

In May 2019, the board's executive director stated they had not determined what action to take and indicated it might be easier if the responsibility for controlled substance inspections was transferred to the Board of Pharmacy, as their inspectors are registered pharmacists trained to monitor DEA documents and review patient records for compliance and signs of diversion. However, the shift would mean veterinary facilities would have to register separately

Non-compliance with controlled substances is a risk at Oregon veterinary facilities

We reviewed examples where two Oregon veterinarians received stipulated final orders in April and May 2019 related to Controlled Substance Act violations. Both voluntarily surrendered their licenses and are now prohibited from practicing veterinary medicine in Oregon.

Details of the investigations are confidential in accordance with ORS 676.175.

with the Board of Pharmacy and have a separate facility inspection on an annual basis — resulting in additional costs and inspections for veterinarians and veterinary facilities. Meanwhile, veterinary practices are not being monitored for compliance with controlled substance requirements by the veterinary board, the DEA, or the Board of Pharmacy.

Many other states inspect for controlled substances as part of their facility monitoring process



California has extensive inspection procedures that apply to veterinarians handling controlled substances. Their inspection process covers 42 areas, including drug security controls and drug logs. In addition, California requires that veterinary assistants who have access to controlled substances hold a Veterinary Assistance Controlled Substance Permit. The permit holder is required to wear a badge displaying the required information.



In addition to keeping controlled substances in a secure location, Arizona inspects the facility's dispensing logs, and requires separate inventory logs of each substance linking purchases to specific invoice numbers. The logs are required to contain the drug name, strength, and amount of each substance; the name of the animal and owner; who dispensed or administered and when; and a running balance of the controlled substance available. The latter requirement in particular makes it very easy to verify the accuracy of the facility's recordkeeping.

We found similar facility inspection processes in Florida, Nevada, New Mexico, North Carolina, Virginia, and West Virginia.

Strengthened inspections are a proactive and effective way for the board to combat diversion

Controlled substance diversion is a problem in the veterinary industry, one that is compounded by a lack of oversight related to diversion. In October 2018, an Oregon veterinarian was arrested on charges of menacing and coercion. The charges stemmed from threatening an employee with a gun and tampering with drug records. The DEA and other authorities also investigated allegations of diverting opioids, falsifying drug records, and being abusive to animals under veterinary care. The board subsequently denied the veterinarian's 2019 license renewal pending resolution of the criminal charges. Had a thorough inspection of drug ordering and dispensing records occurred, the diversion activity may have been detected sooner.

Responses to our survey indicated diversion related to client doctor shopping is likely occurring; however, the larger risk of diversion appears to be through veterinarians and their staff. Almost 9% of the complaints brought to the board in the past three years were related to controlled substance diversion by veterinarian staff.

A thorough and periodic inspection of DEA required documentation would bring a multitude of benefits. It would highlight areas where veterinary practice training is needed in documenting controlled substances. It could uncover current diversion and could deter further diversion by making it more difficult for diversion to continue without being detected.

The board recently initiated action for more thorough inspections

Despite the board's opinion that they could not change the administrative rules related to facility inspections without convening an 11-member rules advisory committee, rules were drafted and proposed on October 29, 2019. On the proposed rules notice, it indicates that input from the OVMA was sufficient to justify not consulting with a rules advisory committee.

The board does not require criminal background checks

Unlike other health licensing boards in Oregon, the Veterinary Board only requires selfreporting of criminal history

Criminal background checks can help protect public safety and animal welfare by alerting the board to applicants that have drug-related arrests and convictions prior to issuing or renewing a veterinary license. Of the six health-related licensing boards, the Veterinary Medical Examining Board is the only board that does not require background checks.

Instead, the board requires licensees to indicate on their license applications and renewals if they have been charged or convicted of a crime. A positive response triggers a review of the applicant's background to determine whether the license should be renewed or other action taken. Those who fail to self-report a conviction are subject to civil penalties or other sanctions.

The American Association of Veterinary State Boards created a Practice Act Model, which recommends boards require veterinary licensee applicants provide a full set of fingerprints for the purpose of obtaining criminal records checks.

To date, 17 states, including Washington and California, require background checks on veterinary licensees. These are primarily states that, like Oregon, have significant issues with opioid addiction.

Despite earlier opposition, the board recently initiated action to conduct background checks

The board voted unanimously to adopt rule amendments for criminal background checks on October 14, 2014, after considering audit recommendations in a report our office released earlier that year.¹⁴ The 2014 rules were never adopted.

According to the board's executive director, the board did not initiate background checks in 2014 because of the negative feedback received from respondents in the public comments stage of rule-making. We examined the public comments and found that out of twelve responses, five

¹⁴ Report no. <u>2014-06</u>: "Health Professional Regulatory Boards: General Review"

respondents opposed the rule change, four were in favor, and three had questions about the proposed rules or unrelated comments.

According to the board's executive director, the OVMA also opposed the rule amendments to adopt criminal background checks. During a July 2014 board meeting, the OVMA stated that online comments it received by OVMA members did not support adoption. During interviews with board members and staff, some indicated that conducting background checks on veterinarians and their staff was either not necessary because veterinarians go through four years of schooling and there are very few problems in the veterinary industry; or, in the case of veterinary technicians, it is the responsibility of the employer.

In contrast, our survey found widespread support among veterinarians and veterinary technicians for background checks. When asked whether they believed that veterinarians should be subject to a criminal background check before beginning practice in Oregon, 72% of respondents said yes. With respect to background checks for veterinary technicians, 70% of respondents said yes. In addition, the majority of respondents (59%) said they believed it was the responsibility of the board to conduct those background checks.

Survey respondents support background checks Our survey found 72% of respondents supported criminal background checks for veterinarians and 70% support for background checks for veterinary technicians. The need for background checks becomes even more important considering the fact that the DEA issues controlled substance registration numbers based on whether the board issued a license to the veterinarian. The DEA assumes that the applicant has been properly vetted by the board and found to have no history of controlled substance diversion. The DEA looks into an applicant's background only if they self-disclose a felony drug charge or conviction.

Not performing due diligence, including background checks,

increases the risk of noncompliant veterinarians and diversion of opioids. Given the board's application process, individuals who engage in these activities could gain a professional license that allows them to apply for DEA registration. That, in turn, would enable them to prescribe, dispense, and directly order controlled substances, thereby increasing the risk of controlled substance diversion to the public.

The board recently took action to address this concern. On July 23, 2019, the board filed proposed administrative rules to implement background checks for veterinarians and veterinary technicians.¹⁵ As proposed, the rules will allow the board to conduct background checks on initial and renewing applicants and require applicants to provide any police and court records for any arrests and convictions. The rules were adopted on October 28, 2019. The new rules state the board may conduct background checks on intern, initial, and renewing license applicants and on initial and renewing CVT license applicants. According to board management, staff were instructed to begin conducting background checks on new applicants in November 2019.

Veterinarians are exempted from participating in Oregon's Prescription Drug Monitoring Program

Oregon's PDMP is designed to promote public health and safety and help improve patient care by providing information to better manage patients' prescriptions. It was also developed to help ensure the appropriate use of prescription drugs. During the course of the audit, the board had

¹⁵ Notice of Proposed Rulemaking, Chapter 875, Veterinary Medical Examining Board, published in the Oregon Bulletin for August 2019. (<u>https://secure.sos.state.or.us/oard/displayBulletins.action</u>)

not taken a position on whether to include veterinarians in the PDMP. Currently, veterinarians are not required to participate or query the data when dispensing prescription drugs.

Prescription monitoring programs are in place in 49 states, Puerto Rico, Guam, and the District of Columbia. While all states with programs require pharmacies to report, as of July 2019, just 19 required dispensing veterinarians to report controlled substances. Oregon is not among them.

Our survey of veterinarians and veterinary technicians found the majority of respondents were in favor of some level of involvement with the PDMP. Slightly more than half of survey respondents said they would be willing to report dispensed controlled substances to the PDMP and 89% said they would be willing to query the PDMP if they suspected a customer may be diverting controlled substances from their animal. Additionally, 74% said they would be willing

to write prescriptions for scheduled drugs in lieu of directly dispensing them, which would result in the filling pharmacy entering the information the PDMP.

Participation in PDMP aids in gathering more complete data on controlled substances

Adding veterinarian prescriptions to the PDMP will improve its usefulness as a complete database of prescribers of controlled substances. Although this requirement may not deter all diversion and may require more effort by veterinarians, it will help determine the prescribed controlled substance volume, identify potential prescribing and dispensing issues, and contribute to the board's mission of protecting public health.

The addition of veterinarians would give the Oregon

OVMA opposition On their website, t

On their website, the OVMA states their position against monitoring of veterinary prescriptions for controlled substances:

"An increasing number of states have adopted an onerous and burdensome reporting program for controlled substances ... Veterinary clinics in Idaho and Washington, among several other states, must comply with similarenacted laws, all of which are cumbersome and costly. The OVMA will continue to monitor this and seek an exemption for veterinary practices if rules are proposed in Oregon."

Health Authority a clearer picture of controlled substances being prescribed and dispensed in the state, and provide a tool for veterinarians to detect and prevent drug diversion through their practices. Our office issued a performance audit examining the state's PDMP system in detail, in which we recommended including veterinarian prescriptions in the information to be collected by the PDMP.¹⁶

When implementing any new process, there may be inefficiencies and challenges. However, when considering public health and the extent of the opioid crisis in Oregon, all reasonable efforts to thwart the epidemic should be seriously considered. The board and its stakeholders need to consider the needs of Oregonians in addition to the impact to their specific responsibilities.

¹⁶ Report no. <u>2018-40</u>; "Constraints on Oregon's Prescription Drug Monitoring Program Limit the State's Ability to Help Address Opioid Misuse and Abuse," December 2018; recommendation no. 12(c)

Recommendations

Strengthened inspections, background checking licensees, and helping to provide more complete PDMP data is the most effective course of action for addressing controlled substance diversion in the veterinary community.

Strengthening inspections would put an emphasis on controlled substance monitoring in the practice setting, allowing veterinarians and managers to identify diversion sooner. This would also allow the inspector to proactively identify diversion, rather than the more reactive method of responding to a complaint.

Background checks in and of themselves may prevent those with arrests or convictions from even applying for a license and would eliminate the risk of someone with a diversion-related felony arrest or conviction being licensed and having access to controlled substances. Adding veterinarian prescriptions to the PDMP would improve its usefulness as a complete database.

We recommend the Oregon Veterinary Medical Examining Board take the following actions to more effectively monitor controlled substances:

- 1. Take action to ensure administrative rules allow the board to inspect veterinary facilities to monitor controlled substances, ensuring inspections comply with required DEA documentation.
- 2. Complete the implementation of proposed administrative rules and begin conducting background checks on all new and renewing veterinary and certified veterinary technician licensees.
- 3. Work with the Oregon Health Authority and the state Legislature to require veterinarians to participate in the state PDMP.

Objective, Scope, and Methodology

Objective

The objective of this audit was to determine whether the Oregon Veterinary Medical Examining board is upholding the tenets of its mission: to protect animal health and welfare, public health, and consumers of veterinary services.

Scope

This audit focused on proper inspection and monitoring of veterinary controlled substance prescribing and dispensing.

Methodology

To address our objective, we interviewed key staff and members of the board, including the executive director, several board members, the investigator, and the inspector. We also interviewed the executive director of the OVMA, a Portland DEA Diversion Agent who works with the board, a practicing veterinarian, and the compliance director from the Oregon Board of Pharmacy. We developed a survey of questions to elicit the opinions of Oregon veterinarians about the board's processes. We also requested their views on whether veterinarians and technicians should be subject to background checks, the extent of the veterinary role in the opioid crisis, and use of the PDMP.

We accompanied the facilities inspector on inspections of a nonprofit practice affiliated with an animal rescue and a small veterinary practice. We obtained information from other states regarding their practices for facility inspections to establish best practices nationwide. We also traced the development and implementation of House Bill 2474 (2015 legislation), which established facility registrations, and reviewed the board's presentation to the legislature and testimony made during that process.

We attended a board meeting, reviewed minutes of board meetings, board policies and procedures, Oregon Revised Statutes, and Oregon Administrative Rules that relate to the board. We traced the history of background check discussions during board meetings, proposed administrative rules, and public comments regarding rule changes.

Our team also reviewed complaint files processed since 2017, documenting the total number of complaints, type of complaint, and how each was resolved. We identified which complaints were specifically related to controlled substance abuse or diversion.

We developed and emailed a survey to 623 licensed veterinarians and veterinary technicians. We received 222 responses to our survey, which is documented in appendix A. We also received numerous written comments that help explain some of the respondents' concerns.

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

We sincerely appreciate the courtesies and cooperation extended by members and employees of the Oregon Veterinary Medical Examining Board during the course of this audit.

Appendix A: Survey Results in Detail

The audit team developed a survey to inquire about the following topics:

- Licensee Type
- New license application process
- Renewal license application process
- Complaint process
- Accessibility and user friendliness of the Board's Website
- Background checks
- Controlled substances and diversion
- Prescription Drug Monitoring Program usage
- Board inspections

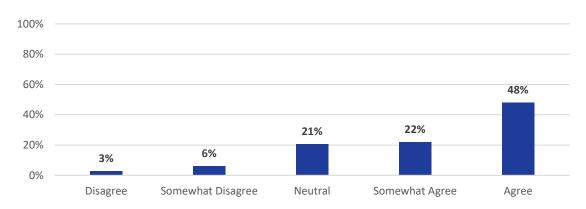
Auditors used SurveyMonkey to develop and complete the survey. Using a list of facility emails provided by the Oregon Veterinary Medical Examining Board, we sent the survey to 623 facilities. We received 222 responses, a 35.6% response rate. Of the total responses, 211 were licensed veterinarians and 11 were certified veterinary technicians. The survey included 38 questions, six of which required open-ended responses. To preserve the anonymity of the respondents, the open-ended responses have not been included.

Question 1: I am a:

Licensed veterinarian: 95% Certified veterinary technician: 5%

Question 2: I have gone through the veterinarian or certified veterinary technician initial licensing process in Oregon.

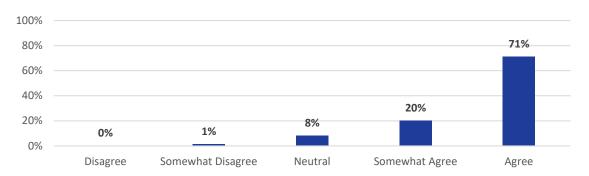
Yes: 88% No: 12%



Question 3: I found the initial licensing process easy to complete.

Question 4: I have renewed my veterinarian or certified veterinary technician license in Oregon.

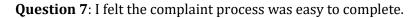
Yes: 99% No: 1%

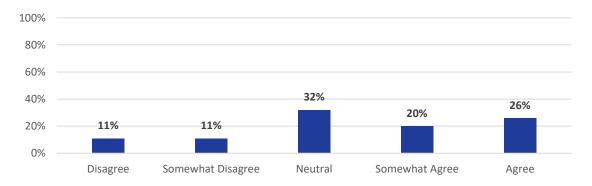


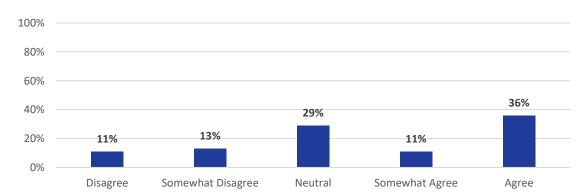
Question 5: I found the renewal process easy to complete.

Question 6: I have been involved in the Oregon Veterinary Medical Examining Board complaint process.

Yes: 30% No: 70%

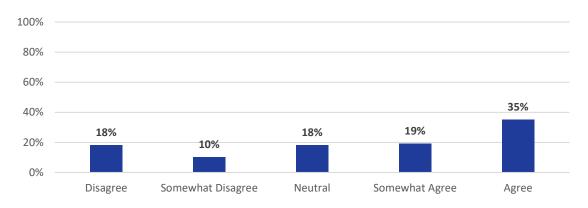






Question 8: I felt the person taking my complaint understood my concerns.

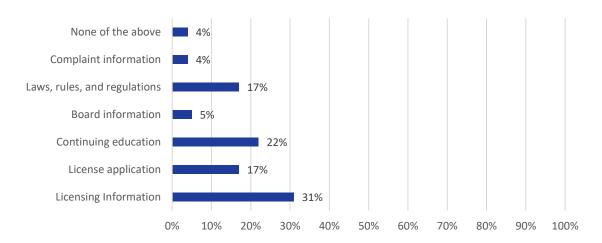
Question 9: I felt that the Oregon Veterinary Medical Examining Board handled my complaint appropriately.

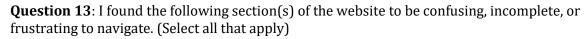


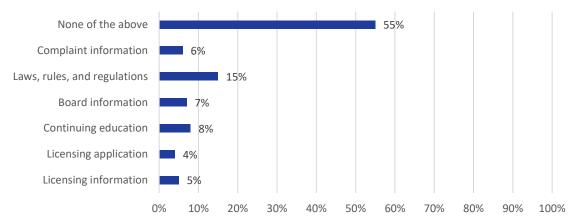
Question 11: I have visited the Oregon Veterinary Medical Examining Board's website within the last year.

Yes: 85% No: 15%

Question 12: I found the following section(s) of the website to be helpful, easy to understand, and easy to navigate. (Select all that apply)







Question 15: I believe that veterinarians should be subject to a criminal background check before beginning to practice in Oregon.

Yes: 72% No: 10% Unsure/No opinion: 18%

Question 16: I believe that certified veterinary technicians should be subject to a criminal background check before beginning to practice in Oregon.

Yes: 70% No: 11% Unsure/No opinion: 19%

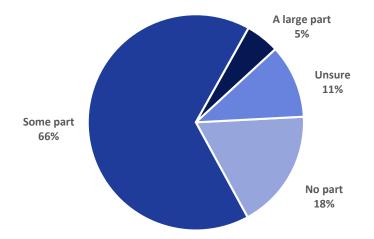
Question 17: I believe that it is the responsibility of the Oregon Veterinary Medical Examining Board to administer criminal background checks on all new license applicants.

Yes: 59% No: 15% Unsure/No opinion: 26%

Question 18: I believe it is the responsibility of the Oregon employer to run criminal background checks on prospective employees.

Yes: 33% No: 35% Unsure/No opinion: 32%

Question 20: Please rate how large of a role you believe veterinarians and certified veterinary technicians play in the opioid crisis.



Question 21: In the last three years, I have seen an increase in the number of customers exhibiting "vet shopping" behaviors (i.e., suspect injuries, asking for medications by name, asking for early refills, etc.).

Yes: 24% No: 76%

Question 22: In the last three years, I have suspected a co-worker of having a controlled substance abuse issue and/or diverting medications to themselves or others.

Yes: 15% **No: 85%**

Question 23: My workplace has an FDA-recommended safety plan in place to handle instances of abuse related to controlled substances.

Yes: 29% No: 31% **Unsure: 40%**

Question 25: I have my own Drug Enforcement Agency (DEA) identification number, which allows me to prescribe and dispense controlled substances.

Yes: 90% No: 10%

Question 26: I think the PDMP could be useful in the detection and prevention of controlled substance abuse and diversion.

Yes: 27% No: 25% **Unsure/No opinion: 48%**

Question 27: I am willing to report dispensed schedule II-IV drugs to Oregon's PDMP.

Yes: 53% No: 47%

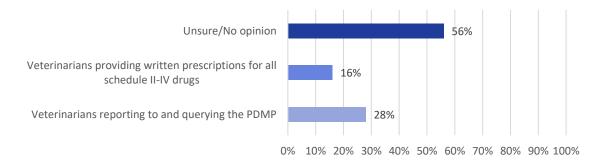
Question 28: I am willing to query the PDMP if I suspect a customer may be diverting schedule II-IV drugs from their animal.

Yes: 89% No: 11%

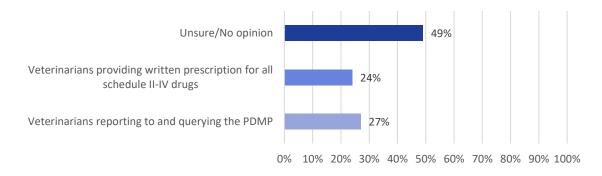
Question 29: I am willing to provide my clients with written prescriptions (as opposed to direct dispensing) for schedule II-IV drugs.

Yes: 74% No: 26%

Question 30: Out of the options below, I believe this option would be the most *effective* in helping control the diversion of schedule II-IV drugs.



Question 31: Of the options below, I believe this option would be the most *efficient* in helping control the diversion of schedule II-IV drugs.



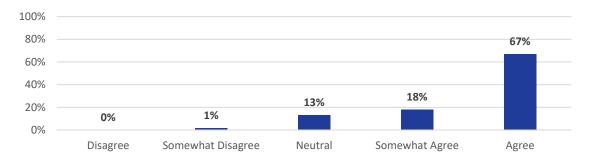
Question 33: Are you the managing veterinarian are your workplace?

Yes: 81% No: 19%

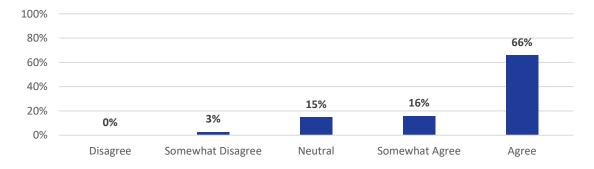
Question 34: My facility has had an Oregon Veterinary Medical Examining Board inspection in the last three years.

Yes: 42% No: 58%

Question 35: I found the inspection to be efficient.



Question 36: I found the inspection to be thorough.



Question 37: My facility has had an inspection by the Federal Drug Enforcement Agency (DEA) in the last three years.

Yes: 3% No: 97%

Appendix B: Comparison of Facility Inspection Checklists for Controlled Substances

The table below compares inspection points related to DEA required controlled substance requirements. The table includes excerpts from the Oregon Veterinary Medical Examining Board's facilities inspection checklist and the Oregon Board of Pharmacy's Dispensing Practitioner Drug Outlet Self-Inspection report, which encompasses steps to comply with DEA regulations.

Oregon Veterinary Medical Examining Board – Veterinary Facility Inspection Report	Oregon Board of Pharmacy – Dispensing Practitioner Drug Outlet Self-Inspection Report
 Guidance: <u>Controlled and legend</u> <u>substances</u> must be purchased, stored, secured, inventoried, logged and dispensed according to DEA, FDA and manufacturers' requirements. Expired drugs must be clearly marked or segregated to ensure no fee is charged. 	1. Does the outlet have policies and procedures for drug management, including security, acquisition, storage, labeling, disposal, record keeping?
	2. Are drugs kept in a locked drug cabinet or drug storage area that sufficiently denies access to unauthorized persons?
In regards to above, the board's current checklist only includes verifying controlled substances are properly stored in a locking cabinet, adequate refrigeration is provided for perishable drugs, and that expired drugs are separated and not sold.	 Have you verified the pharmacy, wholesaler(s), manufacturer(s), that the outlet purchases medication from is registered in Oregon with the Board of Pharmacy? You may verify licenses and registrations on the Board website <u>www.oregon.gov/pharmacy</u>. Where are invoices kept?
	4. Are all drugs stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space?
	 Are recalled, outdated, damaged, deteriorated, misbranded, identified as suspect/illegitimate, or adulterated medications documented and physically separated from other drugs?
	Where are they stored prior to being destroyed or returned to the supplier?
	6. Are prescriptions properly labeled?
	7. Are drugs dispensed in compliance with current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162 (Poison Prevention Act))?
	8. Does the outlet maintain a list of sites in Oregon where drugs may be disposed?

Oregon Veterinary Medical Examining Board – Veterinary Facility Inspection Report	Oregon Board of Pharmacy – Dispensing Practitioner Drug Outlet Self-Inspection Report
	9. Is a unique dispensing record maintained separately from the patient chart and kept for a minimum of 3 years?
	 10. Does the dispensing record contain; Name of patient Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor Directions for use Date of dispensing And Initials of person dispensing the prescription
	11. Is the dispensing record readily retrievable and available for inspection?





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November 12, 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 "The Oregon Veterinary Medical Examining Board's Monitoring of Controlled Substances Needs to be Strengthened."

The Board is in agreement with the Audit Division's recommendations. We note that the recommendations are subject to current statutory limitations. We appreciate that the Audit recognizes that the Board follows the current statutes and rules in the Veterinary Practice Act. Additional oversight authority may require legislative approval. To the greatest extent possible, the Board will consider rules and policies consistent with Audit recommendations.

The Board wishes to acknowledge the Auditors for their diligence and professional courtesies. We appreciate the work that went into this Audit and are grateful for its fresh perspectives and policy recommendations. Thank you for the opportunity to respond.

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

RECOMMENDATION 1 We recommend the board take action to ensure administrative rules allow the board to inspect veterinary facilities to monitor the use of controlled substances, ensuring inspections comply with required Drug Enforcement Agency documentation.		
Agree or Disagree with Recommendation	Target date to complete implementation activities	Name and phone number of specific point of contact for implementation
Agree	Already in progress, implementation upon adoption of final rules.	Lori Makinen 971-673-0223

Narrative for Recommendation 1

The Board has proposed new administrative rules for veterinary drugs and biologicals that incorporate monitoring requirements of the Board of Pharmacy Drug Practitioner Dispensing Outlet (DPDO) program. The proposed rules have been published for public comment. Inspections would include monitoring for compliance with both Board of Pharmacy and DEA requirements.

The Board has inspected for compliance with basic DEA regulations for securing drugs and maintaining drug logs. In 388 inspections completed since December 2018, nine facilities appeared to have one of the following minor DEA noncompliance issues:

- Controlled substances at location other than DEA registrant.
- Expired controlled substances not separated from non-expired drugs.
- Controlled substance logs missing required information.
- No controlled substance logs available for review.
- Facility needs to add additional information to the drug logs.
- Expired controlled substances not separated from other expired meds, not locked.

During each inspection, the Managing Veterinarian is informed that the facility must maintain controlled substances in compliance with all federal and state laws, and should obtain exact requirements directly from the controlling authority. The inspector reviews basic DEA requirements and suggests further resources, such as manufacturers' guidelines. Managing Veterinarians are provided with the DEA 'hotline' for follow-up.

Should the inspector encounter what appears to be a violation of the Veterinary Practice Act, or significant noncompliance with DEA regulations, they would immediately contact the Board investigator or executive director for instructions. Should the inspector encounter an immediate, potential criminal activity taking place, law enforcement would be contacted.

The Board will make a policy decision as to whether and to what extent other agencies' regulations should be monitored and enforced by the Veterinary Board.

	complete the implementation nd checks on all new and rene	
verennary technician licens		

Agree or Disagree with Recommendation	Target date to complete implementation activities	of specific point of contact for implementation
Agree	Completed	Lori Makinen
		971-673-0227

Narrative for Recommendation 2

The Board has adopted rules authorizing, and has begun performing, background checks for new and renewing license applicants.

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It should be noted that a background check is a snapshot in time and will only provide the Board grounds to deny an application for cause if the conduct has a direct nexus to the practice of veterinary medicine.

Available data from six other health related licensing boards shows that since 2012, two license applications were denied based on actionable information obtained through background checks.

RECOMMENDATION 3 We recommend the board work with the Oregon Health Authority and the state legislature to require veterinarians to participate in the state PDMP.		
Agree or Disagree with Recommendation	Target date to complete implementation activities	Name and phone number of specific point of contact for implementation
Agree	Unknown	Lori Makinen 971-673-0223

Narrative for Recommendation 3

Consistent with the best interests of animal health care and public protection, the Board will actively support efforts by the Legislature and/or Oregon Health Authority to include veterinarians in state PDMP reporting requirements.

Please contact me at 971-673-0223 with any questions.

On behalf of the Board,

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Lori Makinen Executive Director



Audit Team

Mary Wenger, CPA, Deputy Director Julianne Kennedy, CPA, Audit Manager Tracey Gates, CPA, Principal Auditor Bentley Walker, MSFA, Staff Auditor

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