From: <u>Sunset Advisory Commission</u>

To: <u>Trisha Linebarger</u>

Subject: FW: Public Input Form for Agencies Under Review (Public/After Publication)

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----Original Message-----

From: sundrupal@capitol.local [mailto:sundrupal@capitol.local]

Sent: Sunday, October 30, 2016 2:55 PM To: Sunset Advisory Commission

Subject: Public Input Form for Agencies Under Review (Public/After Publication)

Agency: STATE BOARD VETERINARY MEDICAL EXAMINERS

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Your Comments About the Staff Report, Including Recommendations Supported or Opposed:

Please support the TVMA response to the TX Sunset Advisory Commission regarding Monitoring potential diversion of controlled substances by Veterinarians.

TVMA'S RESPONSE TO THE SUNSET COMMISSION ISSUE 3: The State Has an Ineffective and Inconsistent Approach to Monitoring Potential Diversion of Controlled Substances by Veterinarians.

- 3.1 Clarify statute and provide direction for the agency to monitor veterinarians' dispensing and prescribing of controlled substances.
- 3.2 Require Texas veterinarians with a DEA registration to report dispensing data to the Texas Prescription Monitoring Program.
- 3.3 Require the agency to collect and track relevant data to establish a risk-based approach to on-site inspections.
- 3.4 The agency should create and implement inspection guidelines with aggravating and mitigating factors to evaluate controlled substances deficiencies recorded during on-site inspections.
- 3.5 Direct the agency to develop a robust educational process to regularly educate licensees about controlled substances laws, rules and inspection standards.

TVMA agrees and takes very seriously the fact that there is a prescription opioid abuse epidemic in this state and across the nation. Veterinarians as prescribers and dispensers of these dangerous controlled drugs are resolutely committed to their role in preventing diversion and guarding against misuse by employees or clients. Chemical dependency is an equal opportunity disease that touches every profession, including veterinary medicine. TVMA welcomes a discussion about best practices for preventing diversion and the ways in which the profession might institute change to further guard against drug abuse. We also welcome an opportunity to further educate our members in this regard.

TVMA does believe that any new regulations should only be implemented once the legislature possesses a full understanding of how veterinary medical practice differs from human medical practice. Therefore, any regulations may need to be tailored specifically to veterinary medical practice in order to achieve the desired goal. Veterinary Drug Reporting Numbers in the Staff Report Veterinarians do administer, dispense and prescribe what

may seem like a large quantity of controlled drugs to the untrained eye. However, that in and of itself does not necessarily indicate a diversion problem. Veterinarians simply have different needs for their animal patients, and when usage numbers in veterinary medicine, particularly in large animal practice, are compared to human practice, the numbers can be skewed. This is because veterinarians care for a myriad of animals that require many different doses of different medications that cannot be rightly compared to any prescribing or dispensing patterns in human medicine. There is a high degree of variation within different types of veterinary practice, and the use of barbiturates alone will distort any individual administering, dispensing and prescribing activity numbers sought by the state. While human medical practitioners may be moving away from the use of barbiturates, they are an absolute necessity in animal practice. For example, it's likely that the needs of large animal medical practitioners alone would be skewed. This is because in large animal medicine barbiturates are often used for euthanasia purposes and doses are highly dependent on the weight of the animal. For example, it may take three milliliters (mLs) of commercially available pentobarbital for euthanasia to euthanize a small dog while it may take over 100 mLs of the same drug to euthanize a horse. Therefore, it makes sense that veterinarians, and particularly large animal veterinarians, would be at the top of any statewide list that includes human medical practitioners. Barbiturates are also the most widely used drugs to treat epilepsy in dogs. For example, if a veterinarian is treating an epileptic Labrador, they would be prescribing or dispensing what, to a human medical professional, may look like a large amount of phenobarbital. Next, the use of other controlled substances, such as ketamine, in equine practice is also likely to be much higher than in human medicine or small animal practice because a much larger quantity is needed to provide appropriate anesthesia to a horse in order to perform adequate aftercare or surgeries such as castration. To further complicate matters on small animals, ketamine usage for "full" (versus induction for gas) anesthesia is actually ten times higher per pound body weight than for short anesthesia on horses. In addition, like in human medicine, some veterinary practices may specialize in pain management, which leads to much higher usage numbers.

Consequently, because veterinary use of controlled drugs can appear to be high when compared to human medicine and due to the fact that veterinarians actually maintain inventories of controlled drugs when other practitioners do not, it logically follows that veterinarians would report higher instances of theft or loss of controlled drugs. However, this is not necessarily indicative of a significant diversion problem in veterinary practice. Indeed, the Code of Federal Regulations, §1301.76 (b) requires practitioners to report "significant" losses to the DEA but does not provide a definition of "significant." Anecdotally, TVMA is aware of and actually assists conscientious veterinarians in reporting any losses to the DEA whether they are considered significant or not. This is because Texas veterinarians treat their responsibility for reporting so seriously.

The responsibility for maintaining accurate accountability over the use of controlled drugs in order to mitigate the potential risk of diversion is so important that the current Texas Administrative Code, Rule RULE §573.50 Controlled Substances Records Keeping for Drugs on Hand, requires veterinarians to keep a count of the total balance of the drug on hand, which creates a nearly perpetual inventory, whereas the federal law only requires a balance every two years. Veterinarians not only have a legal and moral obligation to prevent diversion but also a financial one as it is a serious financial loss to a small business when inventory is stolen from a veterinary practice. Veterinarians Participation in the PMP

TVMA agrees that something needs to be done in order to improve controlled drug monitoring in Texas. However, much more study and discussion is needed to determine which type of monitoring could best apply to veterinary practice. For example, the sunset staff report proposes to mandate reporting by veterinarians into the PMP. However, more discussion is needed to determine how to apply a PMP program specifically created for use by human medical practitioners to veterinarians because veterinary practice differs in so many key ways that simply do not translate to modern veterinary practice.

For instance, the system contains no ability to determine whether an instance of dispensing or prescribing a controlled drug is for a person or an animal.

The staff report notes that the name, address and birthdate of the "person for whom the controlled substance is dispensed" should be included.

However, the veterinarian is not dispensing to a person but to an animal, and often animals are brought in by different animal caretakers who are not the owners of the animal. For example, adult children may bring in a pet for a parent or a trainer may be charged with the medical care of a horse. The birthdates of animals are generally unknown, and veterinarians do not routinely collect birthdates of humans as such humans are often reluctant to provide personal information to a veterinarian. However, the PMP requires the entry of a birthdate in order to function.

Mandated veterinary participation in the PMP may unintentionally skew the data relating to human prescriptions and addiction issues. If information about animal patient dispensing is mixed in with human patient data, it will be harder to interpret the data accurately. It's also possible that the owners or caretakers of animals may be unable to

obtain an appropriate medication for themselves due to having a pet's or multiple household pets' prescriptions entered into the program that may or may not be properly designated as pet prescriptions.

Of course, our members are extremely concerned about the serious workflow issues that the recommendation presents. We hope that any mandated reporting takes into account the workflow issues that such a system would present for veterinarians, who would undoubtedly be required to report at a rate that far exceeds human medical practitioners.

Alternatives to Full Mandated Reporting

Texas is not the first state to consider including veterinarians in PMP programs. Of the 49 states with a PMP program, only 17 states mandate veterinary reporting, and a number of these states have less frequent and/or less strenuous reporting requirements that better suit veterinary practice than a blanket mandate. The state of Kansas initially mandated veterinary reporting but eventually eliminated the requirement after finding it ineffective at addressing the problem at hand.

The legislature might want to consider other alternatives that can be accomplished in a judicious manner and are less disruptive to a small business. The agency could require the licensing agency or the practitioners themselves to register for the program so they have the option to look up specific human clients if they have a suspicion. However, even this access must be carefully considered because veterinarians are not subject to HIPPA laws or protections and must not be placed in the untenable position of making a determination as to whether a prescription is appropriate for a human as they are prohibited by law from practicing on humans.

Any mandated use of the PMP system for the veterinary profession should only be after fundamental changes are made to the system to specially tailor it for veterinary use. We also hope that any mandate would be phased in to give practitioners time to deal with the economic consequences of potentially needing to hire new staff members or shift existing resources to comply with a one business day reporting requirement.

The stated problem that the Sunset Commission and other agencies are trying to mitigate is the opioid addiction epidemic. In light of this, if a mandate for the veterinary profession is unavoidable, the mandate could be tailored to only apply to veterinary dispensing of Schedule 2 controlled substances and not Schedules 3, 4 or 5. Reporting the dispensing of Schedule 2 drugs would serve the state's need for data on the most dangerous of all drugs, and and while the reporting would be difficult, it would not be as disruptive to veterinary practice. Other less disruptive means of reporting that would provide the state with data could potentially include requirements for less frequent reporting or exemptions from reporting when dispensing only a single week's worth of dispensing of a controlled substance.

Any Alternative or New Recommendations on This Agency: None at this time

My Comment Will Be Made Public: I agree