

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Veterinary Medical Licensing Board

Regulation/Package Title: Amended Vaccination Clinic Rule

Rule Number(s): 4741-1-16

Date: October 15, 2015

Rule Type:

- | | |
|---|--|
| <input type="checkbox"/> New | <input type="checkbox"/> 5-Year Review |
| <input checked="" type="checkbox"/> Amended | <input type="checkbox"/> Rescinded |

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

The Ohio Veterinary Medical Licensing Board (Board) implemented the new Vaccination Rule (4741-1-16 OAC) in 2013. The Rule provides guidance for vaccination clinics for companion animals. The rule impacts those vaccination clinics that are in transient locations

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such as a Pet Store or agriculture supply retail location. Since the implementation of the rule, there have been repeated questions regarding what needs to be documented in the veterinary medical record. The proposed amendment to the rule will address the recordkeeping requirement.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

ORC 4741.03(C)(9) authorizes the Board to adopt rules necessary for the administration and enforcement of Chapter 4741.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

No

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The Board had received multiple inquiries from veterinarians related to the requirements for vaccination clinics that are operating outside of a designated veterinary hospital setting. Since this practice is “non-traditional” or does not fall under the category of a “stationary” or a “mobile” veterinary facility, the current rules related to stationary veterinary practices and mobile unit practices do not address all of the concerns raised by the inquiries received.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The Board will measure the success of these regulations as being written clearly and concisely so that the licensees and the public understand the rules, and therefore, there will be compliance with the rules. The Board staff will monitor the compliance through inspections and further inquiries or complaints received.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

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If applicable, please include the date and medium by which the stakeholders were initially contacted.

At the August 12, 2015 Board meeting, there was discussion regarding Rule 4741-1-16 OAC and that the rule does not provide guidance on what needs to be documented in the medical record. The Board suggested bringing the rule forward at the next Board meeting for review and possible revision. On August 17, 2015, an email alerting the Ohio Veterinary Medical Association (OVMA) and John Izzo, Esq, representing a Veterinary Immunization and Wellness Clinic corporation (VIP Pet Care) were notified of the review and intention to amend with the possible incorporation of the recordkeeping rule (Rule 4741-1-21 OAC) into Rule 4741-1-16 OAC.

At the September 9, 2015 Board meeting, the Board members, by consent, approved the amended version of the rule by incorporating Rule 4741-1-21 OAC into Rule 4741-1-16 OAC. Jack Advent, Executive Director of OVMA, John Izzo, Esq and Dr. Katryna Fleeer, DVM, Medical Director representing VIP Pet Care were in attendance. The proposed amended rule was sent to the OVMA, the Ohio Department of Health legal division, and other interested stakeholders who had previously expressed interest in the vaccination clinic rules. The proposed amended rule was placed on the Board web site comment for consideration by the Board members at their October board meeting.

At the October 14, 2015 board meeting, board members reviewed the Letters of Support from VIP Pet Care and Dr. Charles A Curie, DVM for the amended rule. Also considered was a letter of concern regarding the requirement of vaccinations for companion animals from Dr. Paul Clemens, DVM. The Board members did not make any changes to the proposed rule.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

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9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The Board members retrieved and reviewed other state veterinary practice acts that regulated vaccination clinics. The research developed the initial rule and revision based on the research and input from OVMA constituents and other interested parties.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

The primary laws and regulations that the Board considered were the Veterinary Practice Acts of the States of Florida, California, Virginia, Louisiana, as well as the Model Veterinary Practice Act of the American Veterinary Medical Association (AVMA) and the American Association of Veterinary State Boards (AAVSB).

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

No. The purpose of the rule is to provide guidance to the licensee and what documentation, etc. might be required to comply with the statute.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board researched if there was any law or rules by the Department of Health or Ohio Department of Agriculture to address the veterinary vaccination clinics. There is no duplication of an existing Ohio regulation.

13. Please describe the Agency’s plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Any issues that might arise as a result of the proposed rules will come before the Board members at one of their monthly meetings for discussion. For example, inquiries such as the ones that resulted in the revision of this rule are placed on the Board Agenda for consideration at their monthly board meeting. Additionally, interested parties are able to request time on the Board Agenda to discuss issues that might arise as a result of how a rule is written or its impact. The discussion will then be reflected in the Board minutes which are posted monthly on the Board web site at www.ovmlb.ohio.gov. Additionally, any pertinent issues related to the rules are done in consultation with the appropriate representatives from the OVMA, Ohio Association of Veterinary Technicians (OAVT), the Ohio Department of Agriculture, and/or The Ohio State University College of Veterinary Medicine. The Board will notify the licensees through its newsletter and listserve, post on the Board web site, through the associations (and their publications and web sites) and speaking engagements throughout the State. (This rule will be presented at the OVMA MidWest Veterinary Medical Conference in February, 2016 as well as highlighted in the 2015-16 Board newsletter edition). To regulate compliance, the Board has the ability to perform compliance inspections/investigations should there be a concern of non-compliance with the regulation.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

- a. Identify the scope of the impacted business community;**
- b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
- c. Quantify the expected adverse impact from the regulation.**

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

- a. This Rule will impact primarily the licensed Veterinarian as only a veterinarian can direct the Vaccination Clinic and support staff. An RVT (registered veterinary technician) or animal aide can assist, but it is the Veterinarian who directs their practice.
- b. The veterinarian must be licensed in the State of Ohio and there is a cost for licensure and renewal as set in ORC 4741.17. In order for the veterinarian to perform veterinary

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services, there are certain equipment and supplies that the veterinarian will need, including, but not limited to, the vaccinations and syringes, medications that may be needed, ability to store and or transport the drugs, the ability to maintain medical records, communication devices, insurance, and first aid/emergency supplies. The cost for supplies will vary depending upon the type of veterinary practice and the number of anticipated clients and/or vaccination clinics held. The estimated cost of operating a vaccination clinic could be approximately \$500 per clinic as the clinics are typically held in another business such as a Pet or farm supply store. Since the veterinarian is the one who directs the veterinary practice, the veterinarian must be the overseer of the vaccination clinic and therefore must be in attendance for the duration of the vaccination clinic.

There is the potential for penalties if the Board finds a violation of the Veterinary Medical Practice Act, including this proposed rule. The Board members would issue a Notice of Opportunity for a Hearing in accordance with ORC 119.01 to 119.13.

c. The financial impact of compliance with this rule will be decreased for the veterinarian. These rules benefit the veterinary practitioner as the requirements for operation are less than the requirements established in OAC Rule 4741-1-03 (regulating a stationary practice) or OAC Rue 4741-1-08 (regulating a mobile veterinary clinic). Therefore, these rules provide a more cost effective means of providing vaccinations and medical care to the public and meeting a much needed service.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

This rule provides guidance to the veterinarian operating outside of a traditional veterinary hospital setting. The Board reviewed other states' regulations, national standards, and current operations in determining what guidelines would ensure to the public that the practice of veterinary medicine in the veterinary clinic setting is meeting at least minimum standards. Requiring that there be documentation in the medical record of the administration of the vaccination and that the client be informed of where the medical records are maintained enables the client to obtain necessary information in the event of an adverse reaction to a vaccine provided or if further treatment is needed for continuity of care in any of the settings described in this set of rules. The rule also requires having emergency drugs/supplies immediately available in the event of an adverse reaction to a vaccination as well as mandating that the veterinarian remain on the premises until the last patient has been discharged. These requirements are for protection of the public served—the patients and their owners.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The amended rule does not apply to a veterinarian employed by or running a stationary veterinary facility or a mobile veterinary practice which would be the alternative to operating an off-site vaccination clinic. There are already rules in place for guidance for stationary and mobile veterinary units. The amended rule is to provide guidance to veterinarians practicing in a remote/temporary vaccination clinic, which will now provide guidance as to the recordkeeping of medical records for companion animals receiving vaccinations at the temporary vaccination clinic.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

There are no fines or paperwork violations associated with this rule.

18. What resources are available to assist small businesses with compliance of the regulation?

The Board has a working relationship with the associations representing veterinarians and registered veterinary technicians. There is time placed on each monthly Board Agenda for the representatives of these associations to speak regarding any issue of concern or to make members aware of current practices. The Board has a web site that is updated frequently with important issues and resources, in addition to having the annual newsletter posted on the web site. The Board's contact information is as follows:

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