

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Veterinary Medical Licensing Board

Regulation/Package Title: New rules: Vaccination Clinic, Home Visit and Livestock Ambulatory Rules

Rule Number(s): 4741-1-16, 4741-1-17 and 4741-1-20

Date: _____

Rule Type:

New 5-Year Review

Amended Rescinded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) has drafted three new rules to address concerns submitted to the Board regarding the practice of veterinary medicine in Vaccination Clinics (usually off-site clinics) and home visits and Livestock rules.

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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 has received multiple inquiries from veterinarians related to the requirements for vaccination clinics that are operating outside of a designated veterinary hospital setting. Additionally, the Board has received inquiries related to home visit veterinary practices, including veterinarians who perform veterinary medicine for livestock. Since these practices are “non-traditional” 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.

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

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In October, 2012 at the Ohio Association of Veterinary Technician conference, attendees were informed of the upcoming development of rules to address vaccination clinics and home visits by veterinary practitioners.

In December, 2012, the OVMLB newsletter was sent out to the listserv informing the licensees that the Board was in the process of soliciting ideas for the development of rules to address vaccination clinics and home visits by veterinary practitioners. The newsletter was also placed on the Board's web site. The listserv consists of veterinarians, RVTs and interested parties who have submitted their emails for alerts and the newsletter.

In February, 2013, at the Ohio Veterinary Medical Association's Midwest Conference, attendees were informed of the upcoming development of rules to address vaccination clinics and home visits by veterinary practitioners.

In May, 2013, the proposed draft of the rules was sent to the Director of the OVMA, the state veterinarian, and a link was sent via email to the veterinarian listserv. Additionally, the proposed draft of the rules was posted on the Board's web site for 30 days for input by interested parties.

The new Rules were not discussed again until the September board meeting, due to review of the rules for five year review. At the September, 2013 board meeting, John Izzo, attorney at law, asked for time on the Agenda to discuss the new vaccination clinic rule. Mr. Izzo, representing VIP Pet Care, and Dr. Katryna Fleer, DVM, Medical Director were in attendance to discuss the proposed new rule regulating vaccination clinics. Mr. Izzo expressed their support for the new vaccination clinic rule (B) through (O), but had concerns with Paragraph (A) regarding the limitation of hours. Mr. Izzo expressed that (B) through (O) addressed specific medical concerns. However, there was no medical basis for limiting the number of hours that a vaccination clinic can operate as defined in Paragraph (A). Mr. Izzo and Dr. Fleer did not believe that the proposed OVMA language was acceptable either. The Board members did not modify the proposed rule at this time but will consider again before filing with JCARR.

At the October, 2013 board meeting, discussion was held regarding the proposed vaccination clinic and the "time parameters" established in paragraph (A). The Board by general consensus made a proposed modification to delete that "time parameter" sentence. The rule will be on the Agenda for the November board meeting. Jack Advent, Executive Director of OVMA, indicated that there have been a lot of questions regarding livestock medicine through his organization and the Board members indicated the same. It was agreed to develop language to address the concerns in a proposed rule.

At the November, 2013 board meeting, Mr. Izzo, Dr. Daniella Ranstetter, DVM and Will Santana, President of VIP Pet Care provided supportive comments with the vaccination rule

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without the time parameters. Jack Advent, Executive Director of OVMA voiced concern about not having any time parameters in the rule. Discussion of the vaccination rule was tabled until the December meeting at which time proposed recommended language from Mr. Izzo and the OVMA will be provided and considered. The Board also considered the proposed new rule related to livestock veterinary management and believed it adequately addressed the inquiries raised.

At the December board meeting, suggested modifications to the vaccination clinic rule were provided by Jack Advent of OVMA, John Izzo, Esq, and board member, Dr. Salinger. After much discussion, the Board revised the rule to include compromised language of each. The rule, as modified, will be reviewed at the January board meeting

At the January, 2014 board meeting, further revisions were made to the Vaccination Clinic rule to include prevention and treatment of parasitic diseases.

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

The Board received e-mails from interested individuals which were provided to the Board members for their discussion in drafting of the rules. Meetings and discussions were held with the Ohio Veterinary Medical Association during the drafting of the rules. Additionally, communication regarding the proposed rules and opportunity for input was provided at the OAVT Conference (October, 2012), the OVMA Conference (February 2013) and an article was placed in the Board newsletter which was emailed to licensees as well as placed on the Board's web site in December, 2012.

At the July 10, 2013 board meeting, the Director of OVMA attended the meeting to discuss the feedback regarding the proposed rules. Additionally, any comments that were received by the Board staff was taken to the board members for consideration. (There was no additional feedback via email, phone or fax). The Board modified the proposed rules based on recommendations from the OVMA, however did not change the vaccination rule Paragraph (A) as suggested by OVMA related to the number of hours that a vaccination clinic can take place.

At the August 14, 2013 Board meeting, the Board President received a request from a private attorney representing an interested party to discuss the vaccination rule at the September board meeting. The Board President approved the request.

At the September 11, 2013 board meeting, John Izzo, Esquire representing VIP Pet Services, which operates mobile vaccination clinics and Dr. Katryna Fleeer, DVM, Medical Director for VIP Pet Services, expressed their support for the new vaccination clinic rule (B) through (O), but had concerns with Paragraph (A) regarding the limitation of hours. Mr. Izzo expressed

that (B) through (O) addressed specific medical concerns. However, there was no medical basis for limiting the number of hours that a vaccination clinic can operate as defined in Paragraph (A). Mr. Izzo and Dr. Fleer did not believe that the OVMA language was acceptable either. The Board members did not modify the proposed rule at this time.

At the October 9, 2013 meeting, the Board discussed the vaccination rule and determined that language in the rule could be considered merely for “economic purposes” and asked to remove the sentence that had caused concern to interested parties at the previous meeting.

All of the rules were reviewed at the November 13, 2013. (See above for result)

Proposals for revision to the vaccination rule were provided by interested parties, discussed, and included into the proposed vaccination rule at the December 11, 2013 board meeting.

At the January 2014 board meeting, the Board voted to submit the rules as revised. John Izzo, Esq and Jack Advent, Director of OVMA were in attendance and permitted to provide input.

The rules will be posted on the Board’s web site with the BIA for at least fifteen (15) business days with feedback to be provided to the Board and CSI.

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 and/or home visits. The research developed the proposed rules 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 AVMA and 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?

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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 and/or home visits. 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 drafting of these rules 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, the 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 listserv, post on the Board web site, through the associations (and their publications and web sites) and speaking engagements throughout the State. (These rules will be presented at the MidWest Veterinary Medical Conference in February, 2014 as well as highlighted in the 2014 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. These three new rules will impact primarily the licensed Veterinarian as only a veterinarian can direct these independent practices (Vaccination Clinics, Home Visits and

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Livestock visits.) An RVT 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 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 Store, while the home visit and livestock visit would be considerably less as the veterinarian would not need to have as many drugs available, staff, records, etc.

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. Additionally, while an RVT can make a home visit or livestock visit at the direction of the Veterinarian, it is the veterinarian who must have established a previous Veterinary-Client-Patient relationship and direct the care provided. The veterinarian must always be available by telecommunication in such a situation.

There is the potential for penalties if the Board finds a violation of the Veterinary Medical Practice Act, including these proposed rules. 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 these rules 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?

These rules provide 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, home setting and livestock setting are meeting at least minimum standards. Having emergency drugs/supplies are necessary in the event of

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an adverse reaction to a vaccination as well as mandating that the veterinarian remain on the premises until the last patient has been discharged. Requiring the maintenance of medical records in a central location 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.

Regulatory Flexibility

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

The new rules do 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 new rules are to provide guidance to veterinarians practicing in a remote vaccination clinics and making home or livestock visits.

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 these rules.

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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