

2011 SENATE AGRICULTURE

SB 2080

2011 SENATE STANDING COMMITTEE MINUTES

Senate Agriculture Committee
Roosevelt Park Room, State Capitol

SB 2080
January 14, 2011
12915

☐ Conference Committee

Committee Clerk Signature

Greta Nelson

Explanation or reason for introduction of bill/resolution:

Relating to the practice of pharmacy and dispensing veterinary prescription drugs and to provide a penalty.

Minutes:

Attachment #1, #2, #3, #4, #5

Senator Klein: Called meeting to order on the 14th day of January 2011

Senator Klein: Senate Bill 2080

Howard Anderson, Jr: Executive Director of the Board of Pharmacy (Attachment #1)

Senator Klein: Could our opportunity to go down to Farmers Union and buy something, assuming we are not buying legend drugs at the FU, could we be tying the hands of the producers who have become accustomed to going up town to get what they need in case of an emergency what they need for their cattle or even non emergency as things happen on their ranches/farms?

Howard Anderson: Two things: I haven't heard that Farmers Union is selling legend drugs, they sell OTT drugs (perhaps that doesn't mean that a few wouldn't like to be licensed under this) they can get a license under this now. If you have legend drugs, you have to have security and lock your placenot a big issue as is a retail store. However, not have legend drug sitting on the shelf to be picked up by anyone. They would fall under same group as these stockmen's supplies. It is not our intention to tell these people to quit; we would have done that in Jan 2010.

Senator Klein: If we don't pass this, some folks are used to having gone to a particular place may not have that opportunity anymore, because what you guys have discerned that there are some things happening in the industry that aren't up to pharmacy rules and law of ND.

Howard Anderson: Correct. We just had a case of an unlicensed seller from Nebraska who sold legend drugs to a pet store. Those legend drugs that were dispensed (companion animals) Veterinarians saw this and discovered the puppies antibiotics

needed things for parasites. Those are the kind of things the laws are intended to prevent. So the licensed whole seller shouldn't have sold to the pet store.....keep the proper records. Nobody is checking up on them ...as we inspect our pharmacies every year for record keeping. We have these complaints about persons using these drugs when he shouldn't have even had them. In those cases, the regulation would let us track that back.

Senator Murphy: How is this going to affect the availability of the drugs of what our people need around the state. Is it going to be more limiting or is it going to be more liberal?

Howard Anderson: This is intended to facilitate what is going on outside the law. This bill will make it more availableWhen we find someone doing something outside the law, we need to tell them to quit. That is why we brought this decision to you. Do you want us to tell them to quit or want us to license them? We can change the other laws and say that everyone can sell anything they want to.....unlikely, but the decision up to you this would make what they are doing legal. Once the person sees he is doing it, he may want to get into the business and make it legal.

Senator Miller: Setting up this veterinary technician (dispensing technician) you have someone Grandfathered in going to dispensing these drugs, can that person have on the job training or have absolute requirement for some schooling?

Howard Anderson: Usually a technician cannot train another technician, but veterinarian can. Or could go through our program. Probably be some kind of testing or verification...they might have to come in for one day...as the people whose sell virus vaccines do now. The board of animal health has a couple hour sessions where they have to come in to take the training to get their certificate if they are going to sell live virus vaccines. Perhaps some could be online and some could be experience.....we have to set something up for both the new and old.. Ask ones involved to sit down and decide exactly what these people need to know and then design a training program that works. Our board has insisted we have on the job training programs; we don't want someone to have to go away for a week.....something that works for the people.

Senator Luick: Idea for the cost of training?

Howard Anderson: Training onsite training would run about \$100-\$140 for a module. Not a promise if it would be farmed out to Wahpeton ...credit and non credit programs for certificates.

Senator Luick: Typically is it an annual renewal for this certificate?

Howard Anderson: Annual renewal. \$35 annual fee for registrationthere would be many free technician trainings. Maybe a fee for registering for a seminar if attending.

Senator Heckaman: On page 4 of bill, subsection 7, talks about labeling prescription drugswhat is the current practice on that? And how will this vary?

Howard Anderson: We don't know what the labeling practices are because they are all unregulated. What we have seen, they use the mfg labeling with the product. Put the label

with the product....who the veterinary was and who owns the animals. Now referring to standard directions in the package insert. If veterinary directions vary, they would need to put that on there. Not clearly defined yet so that won't change....what we are going to require is this outfit that licenses under this have a prescription from a veterinary, but doesn't change how they get that prescription from current requirements.

Senator Heckaman: Do currently administer any kinds of the parts of veterinary dispensing of the medication? Does the Board of Pharmacy do that?

Howard Anderson: Now all legend drugs are treated the same in ND. Yes, we regulate all of that through whole sellers and pharmacies. Biggest area of veterinary business is compounding pharmacies that compound specifically for veterinary.

Senator Heckaman: Do you see this as a financial benefit to young veterinary starting a business where they may see an increase in their sales of prescription legend drugs vs. going to a store and getting them?

Howard Anderson: We haven't evaluated if that would make a difference. No intention here to take out of business and give it to someone else.

Senator Klein: Question of clarification: What we are doing here is making legal what they are doing now?

Howard Anderson: Correct

Senator Klein: Any other discussion? Any other individual for testimony?

Jim Clement: Veterinary from Mandan and Business Partner in Stockmen's Supply West (ATTACHMENT #2)

Senator Miller: Clarification for 5 -11 page 6, you are asking to make that more specific, assuming you would like to omit the bottom portion of that paragraph?

Jim Clement: Just build some simplicity in The rules that will govern the initial training and continuing education really haven't been pursued, so seems logical to do that and have a committee of people who are true stake holders in this essentially define what that initial education and continuing education would be.

Senator Miller: Veterinary board or Pharmacy (whomever) would create a language as have some sort of minimum of 5 hours and max of 10 hours.

Jim Clement: The regulatory agency would be the board of pharmacy and I would leave it up to the Board of Pharmacy to essentially create a rule for that after if and when it passes.

Senator Klein: Have you been in the loop of this for quite some time? This doesn't come as a surprise....have you had an opportunity to put input in?

Jim Clement: My partners and I (Stockmen's Supply West) essentially initiated the push to get the Board of Pharmacy to look at these issues, so I have been involved with input.

Senator Klein: Discussion? Continue to hear testimony for SB 2080

Nancy Kopp: Executive Director for ND Veterinary Medical Association. I appear before you in support of SB 2080. ND Veterinary Medical Association does support this bill as the veterinarians, staff, and clinic and practice as a whole is exempt from these registration and licensing requirements. If there are any amendments to be made and conversing with some of our members, the most confusing part of the bill is on page 6, lines 1-2-3. That has to do with support of personnel whether the veterinary dispensing technician is neither required nor prohibited, we wondered what the supportive personnel what they are allowed to do. I interpret it as record keeping and/or answering the phone. We thought that was very confusing. So if you do go through any amendments of this bill, we ask you to take a look at this and explain the intent.

Dr Del Rae Martin: President of ND Veterinary Medical Association and owner of small animal practice in Mandan. (Attachment #3)

Senator Larsen: Is this a somewhat to mirror as the medical practice where you have a CNA, LPN, RN etc? So now we have a veterinary technician/dispenser; is this to set up a tiering system as you want to proceed or continue in that field?

Dr. Martin: Do not know intent; just want to make certain the veterinary client/patient relationship is maintained. Dr Johnson can answer questions.

Senator Miller: Confusion page 6 lines 1-2-3can we just omit thatdoes that have to be in the bill?

Dr Martin: It would be left up to the Board of Pharmacy; we felt it was very confusing. It would not bother us if it would be omitted from the bill.

Senator Klein: Further discussion? Anyone else in favor of SB 2080?

Kirk Johnson: Veterinarian west of Mandan. My input as utilize Stockmen's Supply West as a whole seller/retailer. Our current arrangement we will write prescription if there is a product that I have unavailable. We do part of it as a convenience to my clients....I am 12 miles west of town. And it will save my clients time and energy if they can fill that prescription through Stockmen's S West. Until 8 months ago, I wasn't aware that I was doing anything illegal. We thought we were within the lines of practicing in a legal fashion with established client veterinary patient relationship and writing a script for that. I would have some clients that wouldn't be very happy if we change this.....95% of my prescription products go out my door. I am a one man practice. I don't have \$300,000 in inventory.....when somebody needs something in large volume or in medical emergency; it is nice to have that ability to fill those demands. I would hate to see that go away.

Senator Klein: Any discussion? Anyone else in favor of SB 2080?

Julie Ellingson: Represent North Dakota Stockmen's Association. (Attachment #4)

Senator Klein: We heard that earlier on and I keep asking that without this, we are making legal what we are currently doing. If we don't pass this, we certainly could have more issues as it relates to some of our animal producers, wouldn't we?

Julie Ellingson: That was when we first read that we were confused about what all the implications might be, this actually would afford the opportunity for just people to be able to dispense those drugs and keep our producers have that flexibility again and support veterinarians that want to market those products. They have a good system that is working out and good relationship and hopefully will benefit all parties involved.

Senator Larsen: Any other discussion?

Senator Klein: You want to work with the Board of Pharmacy and try to iron out the differences that you see and come up with a product everybody feels much better with?

Julie Ellingson: If that would be the case.

Senator Larsen: Discussion? Now we will hear any testimony against SB 2080.

Barry Steffan: Full time rancher. Working for Walco Animal Health in Dickinson. (Attachment #5)

Senator Klein: We don't usually take neutral testimony. You understand that we need to do something to make legal what folks are doing out there. We can appreciate this if we get some amendments, as we heard among the number of speakers, that we need to "tweak" somewhat.

Barry Steffan: I would agree

Senator Klein: Do you see the cost analysis that would be to be getting people up on board and getting certified? What will that cost an individual to come into the company?

Barry Steffan: The individual/new technician/dispenser?I don't know with the requirements and bill. If you look at the schooling requirements, education requirements, and permits, there is no clear definition as to how much is going to cost. If the requirements of the bill just to become a technician, don't allow a grandfather clause for the people that have already been doing this, then if there is an additional hiring necessary obviously that is huge.

Senator Larsen: If a person from another state with comparable background transferred in (into your company), would they have to be certified and have to go through this process or would they be grandfathered in?

Barry Steffan: My opinion – any new hires I would consider, if a new set of regulations were in place, they would have to go through the proper channels to get licensed.

Senator Heckaman: Have you, your store, or veterinarian in your facility been notified that you're out of compliance of state or federal law?

Barry Steffan: No ...we try to keep in constant contact with regulatory dept. to make sure what we are doing is in complianceif we are out of compliance, we are unaware of it.

Senator Heckaman: Do you have a number of forms that you need to complete to show that you are in compliance or is that just taken an assumption when you get your permit or license?

Barry Steffan: When our regulatory dept reviews the statutes that are in place, they come to us to make sure we have done prescription right.... We have it within our computer system to document everything from the vet's information, client's information, refills are all in place. As far as we know, that has all been in compliance.

Senator Klein: Obviously you have a regulatory office in your group. Please explain who Walco is and what you do?

Barry Steffan: Yes, we are a national distributor.....much like Stockmen's Supply. We have divisions all over the US. Our regulatory dept has a challenge to be in compliance with each individual division and each state regulation. We were servicing veterinarians, producers, dealers, for many years. That is basically what we do.

Senator Klein: Just as we go through this process, to let you know your input is valuable not only to the committee, but the group that is working on this. It would be great if you could get involved with the group as we go through this to see if we can come to some resolution. I hope you will get involved with the final product.

Barry Steffan: Absolutely, we would invite that and certainly appreciate the opportunity to share some of our input as far as what we see and make sure can be compliant with all of this.

Senator Larsen: Is there a prescription that is a cross from a buffalo to a cow to a chicken to an alligator? Can you use the same prescription for each critter?

Barry Steffan: Prescription should be specific.

Senator Larsen; Putting penicillin in my horse, I can sure put penicillin in a pig?

Barry Steffan: Correct

Senator Larsen: Is there a prescription pain reliever for my dog? Can I use the same pain reliever on my horse?

Barry Steffan: May be used on multiple species, if the prescription is given for a dog, they would have to consult with the veterinarian before administration to another specie.

Senator Larsen: Why are we excluding when that prescription would be the same?

Barry Steffan: I am not qualified to answer the question. Dr Row would be a better person to ask.

Senator Larsen: Please submit a paper copy of testimony to committee as there were many important points.

Senator Larsen: Any other discussion? Anyone else in opposition of SB 2080?

Doug Row: Veterinarian for 35 years, practice Dickinson area. I have an office at Walco and I am a consulting veterinarian. Years ago, drugs were taken out of the veterinary profession by legislators and latest one, 15-20 years, ago modified live vaccines were taken away from us.....the legislature did that. The root of the problem, is we have lost control over a lot of these medications, especially vaccination protocols, etc. The other problem, we have live in Dickinson, radius and I have this client/patient veterinarian relationship to me is over 100,000 patients minimum. When a client calls, I am a one man operation....I operate the auction market, teach at college, so when we talk about veterinary client/patient relationship. I will not be able to see all my patients....the other thing is most of my client are well educated in prevention in disease, vaccination protocols, they know what products to use and what not to use or they would not be in business. There are not poor producers anymore. They know how to use these drugs.....when I am on the road and my client calls, I will prescribe over the phone what for them to use. This will cut down the availability of medications and control of disease in cattle. I feel the problem is coming from companion animals....if we are not doing things right, why don't you come here to become a bovine practitioner? They don't like the work and the money is not there. Problem there are so few of us, we have to do the best we can. Barry knows more about preventative medicine and how to treat animals than the new vets coming out of vet's school. We already have dispensing techs. If this bill passes (I am opposed to it.) what we should do is what they do with vaccine, do it online and be done with it. I have to diagnose over the phone with all the clients due to the mileage distance of my patients.

Senator Miller: What you are reading in this bill....you are going to have to go out to look at all sick animals?

Doug Row; It depends upon how you interpret and how they interpret it.....taking the test in South Dakota it was interpreted as being familiar with the herd. I am not familiar with all the ranchers....they are excellent ranchers. I have set them up on herd health programs and know their operations.

Senator Klein: When you heard the comment that the question was asked, "Does it change the client/patient relationship that currently exists?" That was the question do we have to bring the cow with you when going to the prescribing vet? Certainly does need to be worked out, but does not change the current client/patient relationship.

Doug Row: I won't fill some people's prescriptions because I don't know them, but do know they are poor producers. The one I am referring to are my excellent clients that are making money in the livestock industry.

Senator Klein: You hit it on the head, you have a client/patient relationship with the producers out there that you know because if one calls that you don't know or not a good producer, and you won't give me that. I will not be able to go to Walco and pick it up. What we are saying, I am hoping we are not ruining or hurting the relationship you have developed with your clients.

Doug Row: It is a step that I don't care for. I think it will hinder the practice of all our vets and medication in my area. Just another hurdle for me. Blame going to the legislators.

Jim Clement: What Barry and Dr Row are saying, they are in regulatory compliance. We also thought we are not the pharmacy rules and regulation govern who has the right to dispense script drugs, the only available source would be a licensed veterinarian. Dr Row being a consultant doesn't qualify him the licensed veterinary as receiving the product from Waco. A veterinary cannot fill a script written by another veterinary that has the valid client relationship. The intent of this legislation is to create an entity that can legally do this. Stock and supply is in the same arena that Walcocurrent rules and regulations should not allow us to do Dr. Row is essentially describing. Legally we can't because of the restrictions. So this is to everyone's benefit as we do business.

Senator Heckaman: Question for Barry Steffan....when we look at the generic dispensing technician, educational requirement. To me it would seem someone like Barry would be ok in doing what he is doing right now.

Barry Steffan: the initial training and continuing education...the imposition is very minimal. We have 4 individuals that are counter people and we would put them all through the training. The expenses there is a limit to how much the permit and license would cost and imposition would be minimal.

Senator Heckaman: My question is more if this has to be approved by the State Board of Pharmacy, what are they going to use for criteria for a person like Barry? If Barry understands what he is asked to do and understands his roleit sounds like he does it well. When is says the State Board must approve that what will they say when they say Barry has had no schooling on this specific thing. What concern for a veterinarian and a technician met criteria #4 as I understand there is some cohesiveness and blending here, Barry is convincing there is a definite difference.

Jim Clement: Suggested we need to re-visit these educational and continue educational and requirements for the technician in working with Howard and the Board of Pharmacy. They don't represent the typical attitude.....I have faith they would not impose burdensome requirements on individuals.

Senator Klein: We laid this out line by line to avoid much of the rule process so it is specific to the legislature....to take a hard look at it rather than the rules committee. Also, we haven't determined the rules are to the dispensing technician. There will most likely be some grandfathering, but make sure that if this should pass, there is a rule making process doesn't mean we're done yet. We have to continue working on this to get the rules that industry can see that it works in their setting.

Jim Clement: Both groups vocal about this, sit down and hash issues out, we will come up with something that is very workable and simple.

Senator Miller: Substantial content of this bill, nice to know if examples from other states that we can look at. Need more information over all ... this is a lot to digest.

Joe Hochhalter: Veterinarian at Steele Clinic for 2 years. On the ledger, states I am against this bill....clarification, I am neutral, but against it as it is written. Specifically, concerns with the enforcement of these rules....nothing outlined as to how they will be enforced. Specifically will the record keeping preformed by the technician or will the facility be audit....if so, by whom and how often? The other concerns, continuing education or licensing requirement for the technician to be reduced....my opinion, like to see something more than just as it states. I did not have enough pharmacy training to be able to perform the tasks of dispensing technician should perform. I don't believe it adequately describes the roles or tasks that should be performed by the veterinarian dispensing technician. If the intent of this bill is the technician job is to take the medication, apply the label with veterinarian prescribing instructions, then this is an adequate piece of legislation. Worked in places where people working behind the counter will always be addressed with questions....gray area ...if that technician should be allowed to offer advice to the customer. My opinion, that role should be of the veterinarian, to insure that prescription drugs are used appropriately. We are looking out for animal health and welfare, responsible for
Providing insuring food safety for consumers.

Senator Klein: The section on support of personnel, many commented on today. That section is very confusing.... No one has been able to give me a good answer. There needs to be some changes to that and there's no mention of a license exam for the dispensing technician. I am sure Pharmacy dispensing technician is handling prescription products is required to take an exam. Those are the concerns.

Senator Klein: My daughter in pharmacy required to attend college for 6 years. If we don't do anything, it could hurt us in the country. We want to make sure it doesn't cheat our producers We have to do something; don't you agree otherwise, we are putting ourselves behind the eight ball?

Doug Row: I agree there are some needs for these facilities to be in operation in ND...especially in areas where they may not have an easy access to a veterinarian as in our area. I do support the bill, but with amendments. There needs to be some changes made so we regulate to the benefit of everyone.

Senator Klein: Could you hammer these out at home. We are not going to do this, as in a couple weeks, there will be a lot of discussion on this...Send them to the board or me.

Shirley Myers: State Representative from District 36, Livestock Producer. Are you taking neutral testimony? Concerns ...I understand the intent of this legislation, however in the form that is drafted; I am in disagreement with this. My opinion, it would take so many amendments.....could look at study resolution, if we are going to put language in the code;

it needs to be done correctly. Page 2, veterinarian, client, patient relationshipI have issues with calling cows patients. We cannot keep referring to animals under people terms. Line 21, this relationship exist only when the veterinarian has recently seen and personally in care of the animal by examination of the animal. We need to look at the language in this. There is nothing in there to grandfather in anyone. More time to look at this if someone is going to be doing the amendments to this bill, should be input from all areas of the animal world, working on the bill.

Senator Larsen: Not anything new coming to the table. Anything to add? Any more opposition of SB 2080 with new information?

Senator Heckaman: Ask Mr. Anderson question...My concern that it has not come in the finest shape that we would like to see it come out. How many other states have similar legislation or how many do not have. Is this patterned after specific states?

Howard Anderson: When we drafted this bill, had a legal intern who worked with me. (Consultant who works for Walco was earliest consultant) CA and ID had some legislation along this line. Have to review the file....basically put this together as to what other states did and what we do relative to technician. I apologize for the confusion on the technician among some of the group. It is clear to us; we use pharmacy technicians all the time. We didn't put enough detailed information, which we can easily fix. The language referred to by Representative Myers, Dr. Boyce can explain...directly from their code. It was copied directly from the rules and laws of the Veterinary Board.

Senator Heckaman: CA and ID...does every state have this?

Howard Anderson: I think only 4 or 5 states. Most states do not allow their whole seller to sell directly to the consumer.

Senator Heckaman: Technician language question in here, is that pharmacy technician language in code....how specific is this?

Howard Anderson: Most of our technician language is in the rules. All it says in the law, the Board of Pharmacy can regulate and control pharmacy technicians....the rest are in the rules. Yes, it is in the rule but not in the code.

Senator Klein: Most are more restrictive than we are...did I hear that?

Howard Anderson: Correct

Senator Klein: So we're making it a little more restrictive, but we're not more flexible than other states?

Howard Anderson: Correct

Howard Anderson: Difference: two ways business is done. Sometimes the whole seller will take a call from a veterinarian and say someone is coming in to pick up something

....bill it to me. That is a sale to the veterinarian. The sale is to the client where the client pays the bill directlythose are the things that are not according to law.

Senator Heckaman: Wouldn't there be a much simpler way to say that?

Howard Anderson: I agree.

Senator Heckaman: Isn't that what we are supposed to be doing? Is there a breakdown somewhere if these laws aren't followed?

Howard Anderson: You are exactly right. When this was discovered, he was asked what can be done about this? We'll use enforcement discretion until you get a chance to look at it. You decide whether you want us to enforce the laws, it makes much more sense to bring this to you first, before we started stirring up the pot.

Senator Heckaman: If there is enforcement out there and if not being done, why would we write more laws that aren't being enforced by the boards?

Howard Anderson: We do enforce the laws. We just started to write this in May and it went out to most of the interested people in August. Just receiving more input in the last few days.

Senator Larsen: Closing SB 2080 because of no further discussion.

2011 SENATE STANDING COMMITTEE MINUTES

Senate Agriculture Committee
Roosevelt Park Room, State Capitol

SB 2080
January 21, 2011
13238 Timer at .00

SB 2194 continues after this bill recording.

☐ Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

Relating to the practice of pharmacy and dispensing veterinary prescription drugs and to provide a penalty.

Minutes:

You may make reference to "attached testimony."

Senator Flakoll: Discussion. We have amendments that are acceptable by everyone.

Senator Klein: Move the amendments 11.8011.01001

Senator Heckaman: Second

Senator Flakoll: Discussion?

Senator Klein: Briefly, the issues that came up were pharmacies and producers, vets, cattle people all issues were addressed and feel it is a good "buy in". Discussion is continuing on dogs and cats, but is not part of this....left out. We have something here that is quite workable, even the gentleman from Dickinson will be ok.

Senator Flakoll: Any inclination this would change the fiscal note?

Senator Klein: I don't believe it will.

Senator Flakoll: If so, we could request a new fiscal note from Howard Anderson.

Senator Klein: They are still going to have to go through the process as an original fiscal note indicated.....I don't know why it would change...because I believe just as many folks would be interested in licensed as there currently are.

Senator Flakoll: Discussion on 1001 amendment?

Senator Flakoll: Clerk take roll

Clerk: Roll vote 7 yes/ 0 no/ 0 absent

Senator Flakoll: Motion carries

Senator Heckaman: I move the Do Pass amendment for SB 2080

Senator Klein: Second

Senator Flakoll: Discussion?

Senator Flakoll: Clerk take roll

Clerk: Take roll 7 yes/ 0 no/ 0 absent

Senator Flakoll: Motion carries

Senator Flakoll: Senator Murphy will carry bill

Senator Flakoll: Committee will stand at ease.

FISCAL NOTE
Requested by Legislative Council
02/03/2011

Amendment to: SB 2080

1A. State fiscal effect: *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2009-2011 Biennium		2011-2013 Biennium		2013-2015 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	\$0	\$10,100	\$0	\$10,100	\$0	\$10,100
Expenditures	\$0	\$10,100	\$0	\$10,100	\$0	\$10,100
Appropriations	\$0	\$0	\$0	\$0	\$0	\$0

1B. County, city, and school district fiscal effect: *Identify the fiscal effect on the appropriate political subdivision.*

2009-2011 Biennium			2011-2013 Biennium			2013-2015 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

2A. Bill and fiscal impact summary: *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

This Bill licenses veterinary dispensing outlets and registers veterinary dispensing technicians, to make legal what appears to be going on in the industry at present. The amendments do not change the fiscal note information.

B. Fiscal impact sections: *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

NDCC 43-15.4-03 is the licensing provision that accounts for the revenue on the licensees and 43-15.4-06 accounts for the registration fees on the technicians.

The amendments do not change the fiscal note information.

3. State fiscal effect detail: *For information shown under state fiscal effect in 1A, please:*

A. Revenues: *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

We estimate 20 licensees at \$200 per year accounting for \$8,000 in revenue for the biennium.

We estimate 30 Veterinary technicians at \$35 each accounting for \$2,100 per biennium.

The amendments do not change the fiscal note information.

B. Expenditures: *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

We estimate that the license and registration fees totaling \$10,000 will be used in maintaining our database, executing the licensing process, inspecting the facilities and auditing the continuing education of the technicians.

The amendments do not change the fiscal note information.

C. Appropriations: *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

NONE

Name:	Howard C. Anderson Jr.	Agency:	Board of Pharmacy
Phone Number:	701-328-9535	Date Prepared:	02/03/2011

FISCAL NOTE

Requested by Legislative Council
12/30/2010

Bill/Resolution No.: SB 2080

1A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2009-2011 Biennium		2011-2013 Biennium		2013-2015 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	\$0	\$10,100	\$0	\$10,100	\$0	\$10,100
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Appropriations	\$0	\$0	\$0	\$0	\$0	\$0

1B. **County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2009-2011 Biennium			2011-2013 Biennium			2013-2015 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

2A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

This Bill licenses veterinary dispensing outlets and registers veterinary dispensing technicians, to make legal what appears to be going on in the industry at present. The license and registration fees will cover the inspections and continuing education audit requirements.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

NDCC 43-15.4-03 is the licensing provision that accounts for the revenue on the licensees and 43-15.4-06 accounts for the registration fees on the technicians.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

We estimate 20 licensees at \$200 per year accounting for \$8,000 in revenue for the biennium.

We estimate 30 Veterinary technicians at \$35 each accounting for \$2,100 per biennium.

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

We estimate that the license and registration fees totaling \$10,000 will be used in maintaining our database, executing the licensing process, inspecting the facilities and auditing the continuing education of the technicians.

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

NONE

Name:	Howard C Anderson, Jr, RPh	Agency:	ND State Board of Pharmacy
Phone Number:	701-328-9535	Date Prepared:	01/07/2011

January 20, 2011

PROPOSED AMENDMENTS TO SENATE BILL NO. 2080

Page 1, line 14, after the underscored comma insert "to provide for suspension or revocation of a veterinary retail facility's license, to regulate and control veterinary retail facilities,"

Page 3, line 1, after "pharmacist" insert "or a pharmacy"

Page 3, line 2, remove "supplying the veterinarian's own patients with such remedies"

Page 3, line 3, replace "as the veterinarian may desire" with "or a veterinarian's practice"

Page 3, line 16, after "on" insert "Equidae,"

Page 3, line 16, after "food-animals" insert an underscored comma

Page 3, line 31, after the first "on" insert "Equidae,"

Page 3, line 31, after "food-animals" insert an underscored comma

Page 4, line 12, after "7." insert "Records of receipt and dispensing of legend drugs must be kept for three years and may be audited by the board of pharmacy."

8."

Page 4, line 26, replace "8." with "9."

Page 5, line 3, remove "Be engaged in on-the-job training program directed by a pharmacist, a veterinarian, or"

Page 5, line 4, replace "a licensed veterinary technician and" with "Successful completion of a certification program"

Page 5, line 4, after the underscored semicolon insert "or"

Page 5, line 6, replace the underscored semicolon with an underscored period

Page 5, remove lines 7 and 8

Page 5, line 30, replace "ten" with "eight"

Page 6, remove lines 1 through 3

Page 6, line 4, replace "43-15.4-08" with "43-15.4-07"

Page 6, line 5, replace "ten" with "eight"

Page 6, line 7, replace "ten" with "eight"

Page 6, line 8, replace "six" with "four"

Page 7, line 1, replace "43-15.4-09" with "43-15.4-08"

Page 7, after line 2, insert:

"1."

Page 7, after line 5, insert:

"2. The license of a veterinary retail facility violating drug laws or rules may be revoked by the state board of pharmacy and the veterinary retail facility may be subject to the penalties of section 43-15-42.1."

Renumber accordingly

Date: 1-21-11
Roll Call Vote #: 7-0-0

#1

2011 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2080

Senate Senate Agriculture Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken

Amendment

Motion Made By

Senator Heckaman

Seconded By

Senator Klein

Representatives	Yes	No	Representatives	Yes	No
Senator Tim Flakoll	✓		Senator Joan Heckaman	✓	
Senator Oley Larsen	✓				
Senator Jerry Klein	✓				
Senator Larry Luick	✓				
Senator Joe Miller	✓				
Senator Bill Murphy	✓				

Total (Yes) 7 No 0

Absent 0

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 1-21-11
Roll Call Vote #: 7-0-0

#2

2011 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2080

Senate Senate Agriculture Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken

Do pass

Motion Made By

Senator Heckaman

Seconded By

Senator Klein

Representatives	Yes	No	Representatives	Yes	No
Senator Tim Flakoll	✓		Senator Joan Heckaman	✓	
Senator Oley Larsen	✓				
Senator Jerry Klein	✓				
Senator Larry Luick	✓				
Senator Joe Miller	✓				
Senator Bill Murphy	✓				

Total (Yes) 7 No 0

Absent 0

Floor Assignment

Senator Murphy

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2080: Agriculture Committee (Sen. Flakoll, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2080 was placed on the Sixth order on the calendar.

Page 1, line 14, after the underscored comma insert "to provide for suspension or revocation of a veterinary retail facility's license, to regulate and control veterinary retail facilities."

Page 3, line 1, after "pharmacis" insert "or a pharmacy"

Page 3, line 2, remove "supplying the veterinarian's own patients with such remedies"

Page 3, line 3, replace "as the veterinarian may desire" with "or a veterinarian's practice"

Page 3, line 16, after "on" insert "equidae."

Page 3, line 16, after "food-animals" insert an underscored comma

Page 3, line 31, after the first "on" insert "equidae."

Page 3, line 31, after "food-animals" insert an underscored comma

Page 4, line 12, after "7." insert "Records of receipt and dispensing of legend drugs must be kept for three years and may be audited by the state board of pharmacy."

8."

Page 4, line 26, replace "8." with "9."

Page 5, line 3, remove "Be engaged in on-the-job training program directed by a pharmacist, a veterinarian, or"

Page 5, line 4, replace "a licensed veterinary technician and" with "Successful completion of a certification program"

Page 5, line 4, after the underscored semicolon insert "or"

Page 5, line 6, replace the underscored semicolon with an underscored period

Page 5, remove lines 7 and 8

Page 5, line 30, replace "ten" with "eight"

Page 6, remove lines 1 through 3

Page 6, line 4, replace "43-15.4-08" with "43-15.4-07"

Page 6, line 5, replace "ten" with "eight"

Page 6, line 7, replace "ten" with "eight"

Page 6, line 8, replace "six" with "four"

Page 7, line 1, replace "43-15.4-09" with "43-15.4-08"

Page 7, after line 2, insert:

"1."

Page 7, after line 5, insert:

- "2. The license of a veterinary retail facility violating drug laws or rules may be revoked by the state board of pharmacy and the veterinary retail facility may be subject to the penalties of section 43-15-42.1."

Renumber accordingly

2011 HOUSE AGRICULTURE

SB 2080

2011 HOUSE STANDING COMMITTEE MINUTES

House Agriculture Committee
Peace Garden Room, State Capitol

SB 2080
March 11, 2011
Job #15298

☐ Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

(Fiscal Note)

Relating to the practice of pharmacy and dispensing veterinary prescription drugs; and to provide a penalty.

Minutes:

Howard Anderson, Executive Director, ND Board of Pharmacy: (See attached #1)

We introduced this bill. It is new legislation and a new class of licensees which are these veterinary dispensing outlets. We have technicians which we have authorized in this legislation and their educational requirements on page 5. In this case we want someone who knows what they are doing, how to keep the records, and smart enough to know when they can sell the drug and when they shouldn't. They have to verify the prescription with the veterinarian. We've talked with the program at Wahpeton that trains our pharmacy technicians and they are interested in developing a module. They are not interested in spending money on it until this bill is passed. Page 6, line 16, we forgot to change "10" to "8" hours of continuing education. That could be done as an amendment in this committee.

Representative Rust: Would you explain a legend drug?

Howard Anderson: It has a legend on there that says, "This drug requires the prescription of a practitioner." Lots of veterinary drugs are sold in Cenex etc. that are not legend—they are over the counter. We are just talking about a smaller number of drugs that require the prescription of the veterinary.

Representative Boe: Where does Pet Meds heart worm fit into?

Howard Anderson: Those are licensed out-of-state pharmacies. You need to send them a prescription from your veterinarian. We do have some problems with them. Some internet operations are not licensed and they sell without prescription. We just had a case with one of them. They had a form that they sent the veterinarian and they had the refills preauthorized on there so the veterinarian would sign it and send it back. Then they say he didn't cross it out so now they can refill. We had a settlement with them.

Jim Clement, Veterinarian from Mandan: (See attached #2)

We support the effort of the ND Board of Pharmacy.

Nancy Kopp, ND Veterinary Medical Assn.: We have been in communication with the State Board of Pharmacy, the State Board of Veterinary Medical Examiners in the draft of this bill. We do not believe there is a fiscal impact on the development of this new licensing body because there is a registration fee.

Dr. Del Rae Martin, President ND Veterinary Medical Assn.: (See attached #3)

Vice Chair Kingsbury: What is a Zoonotic disease?

Del Rae Martin: It is diseases that are communicable between animals and people.

Sheyna Strommen, ND Stockmen's Assn.: (See attached #4)

Opposition: None

Vice Chair Kingsbury: Closed the hearing

Representative Boe: Moved to amend by changing "10" to "8" hours on page 6, line 16.

Representative Holman: Seconded the motion.

Voice Vote taken. Motion passed.

Representative Boe: Moved Do Pass as amended.

Representative Schatz: Seconded the motion.

A Roll Call vote was taken. **Yes: 10, No: 0, Absent: 4,**
Representatives Johnson, Headland, Trottier, Mueller)

DO PASS carries.

Representative Schmidt will carry the bill.

11.8011.02001
Title.03000

Adopted by the Agriculture Committee

March 11, 2011

VR
3/11/11

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2080

Page 6, line 16, replace "ten" with "eight"

Renumber accordingly

Date: 3/11/11

Roll Call Vote # 1

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. SB 2080

House **Agriculture** Committee

Legislative Council Amendment Number _____

Action Taken: ☐ Do Pass ☐ Do Not Pass ☒ Amended

☐ Rerefer to Appropriations

Motion Made By Representative Boe Seconded By Representative Holman

Representatives	Yes	No	Representatives	Yes	No
Dennis Johnson, Chair			Tracy Boe		
Joyce Kingsbury, Vice Chair			Tom Conklin		
Wesley Belter			Richard Holman		
Craig Headland			Phillip Mueller		
David Rust					
Mike Schatz					
Jim Schmidt					
Wayne Trottier					
John Wall					
Dwight Wrangham					

Total Yes _____ No _____

Absent _____

Bill Carrier _____

If the vote is on an amendment, briefly indicate intent:

Page 6, line 16 change "10" to "8"

Date: 3/11/11

Roll Call Vote # 2

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. SB 2080

House **Agriculture** Committee

Legislative Council Amendment Number _____

Action Taken: ☒ Do Pass ☐ Do Not Pass ☒ Amended

☐ Rerefer to Appropriations

Motion Made By Representative Boe Seconded By Representative Schatz

Representatives	Yes	No	Representatives	Yes	No
Dennis Johnson, Chair	AB		Tracy Boe	X	
Joyce Kingsbury, Vice Chair	X		Tom Conklin	X	
Wesley Belter	X		Richard Holman	X	
Craig Headland	AB		Phillip Mueller	AB	
David Rust	X				
Mike Schatz	X				
Jim Schmidt	X				
Wayne Trotter	AB				
John Wall	X				
Dwight Wrangham	X				

Total **Yes** 10 **No** 0

Absent 4

Bill Carrier Representative Schmidt

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2080, as engrossed: Agriculture Committee (Rep. D. Johnson, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (10 YEAS, 0 NAYS, 4 ABSENT AND NOT VOTING). Engrossed SB 2080 was placed on the Sixth order on the calendar.

Page 6, line 16, replace "ten" with "eight"

Renumber accordingly

2011 TESTIMONY

SB 2080



BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

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Rick L. Detwiller, R.Ph.
Bismarck, President
Gary W. Dewhirst, R.Ph.
Hettinger
Laurel Haroldson, R.Ph.
Jamestown
Bonnie J. Thom, R.Ph.
Granville
Gayle D. Ziegler, R.Ph.
Fargo
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

#1

Senate Bill No 2080
Senate Agriculture Committee
Roosevelt Room – State Capitol Bldg
9:00 AM – Friday - January 14th, 2011

Chairman Flakoll and members of the Senate Agriculture Committee, thank you for the opportunity to speak with you today.

This Bill creates new legislation. It attempts to make legal what we have discovered is happening in North Dakota. As a regulator, once we discover something is contrary to current laws we are generally obligated to take action. In this case we have told some of our businesses that we will use enforcement discretion until such time as you, the North Dakota Legislature, have an opportunity to way in on the issue.

Step back a bit to 2008 when Dr. John Boyce at the Board of Veterinary Medical Examiners and I receive some information from Dr. King in Minnesota and Pharmacist Candace Fleming, an Inspector for the Minnesota Board of Pharmacy, that one of our Fargo businesses was selling legend drugs as a pharmacy, when in fact they did not have a Pharmacy Permit. At that time Dr. Boyce left the issue to me, and I left it to Dr. Boyce.

In the fall of 2009 we began to get a few complaints from patients and veterinarians that legend drugs were being sold by pet shops and in some cases, the veterinarians wanted to service some clients whose animals they had not seen personally. Part of the solution for that is in Senate Bill 2088 heard yesterday.

The North Dakota Wholesale Licensing Law clearly says that wholesalers can sell to other wholesalers, pharmacies, practitioners such as veterinarians and other licensed entities. The Wholesale Statute also clearly states that a wholesaler cannot sell directly to the consumer, or in the case of veterinary products, the consumer's owner. Several of our licensed operations, such as Stockmen's Supply in Fargo and in Mandan, or Lextron Animal Health in Dickinson are licensed as wholesalers. In the fall of 2009 the Veterinary Board asked Dr. Boyce to prepare an advisory for veterinarians about what is legal or not legal relative to the selling of prescription drugs. Dr. Boyce asked me to collaborate on that article and it was written by us, in collaboration and then published in the Newsletter for the Veterinarians. As a result of that article, several individuals contacted us saying "we did not realize that this was illegal, but this is how we do business".

Once we met with those individuals, some of whom had wholesale licenses, we promised them that we would work on writing legislation to try and make legal what was going on or to give you a clear opportunity to say, No, if you do not wish to change the law. Then, of course they would have to cease what they were doing that was outside the current law. I had a legal intern who was also a NDSU College of Pharmacy PharmD graduate from New Town, ND working with me over the past summer. Dr Stubstad researched what other states were doing and wrote the piece of legislation you see before you.

Let's look at the Legislation.

43-15-02. Exemptions. The provisions of this chapter shall not apply to the following:

1. A duly licensed practitioner of medicine supplying the practitioner's own patients with such remedies as the practitioner may desire.
2. The exclusive wholesale business of any dealer.
3. The keeping for sale and sale by general dealers of proprietary medicines in original packages and such simple household remedies as from time to time may be approved for such sale by the board.
4. Registered or copyrighted proprietary medicines.
5. The manufacture of proprietary remedies or the sale of the same in original packages by other than pharmacists.
6. A veterinary dispensing technician operating within a veterinary retail facility.

43-15-10 (22) Powers of the Board give the Board of Pharmacy the power to do what this legislation says.

43-15.4 is the new Legislation.

I will answer questions about it, line by line or section by section.

Thank you very much.

Howard C. Anderson, Jr. R.Ph.
Executive Director

Howard Anderson

From: John R. Boyce [boyce@ndbvme.org]
Sent: Monday, October 19, 2009 8:16 AM
Subject: article on veterinary drugs

Attachments: veterinary drugs.rtf



veterinary drugs.rtf
(5 KB)

Howard, at the ND veterinary board meeting last week, the board recommended that we prepare an article on prescription drugs and compounding for the ND Veterinary Medical Association newsletter. The idea came as a result of recent correspondence and the ongoing complaint involving Dr. Dan Schuler, and the realization that some veterinarians probably do not have a good understanding of what the laws are. I have prepared the attached rough draft, and welcome your input. I'm pretty confident in the parts that refer to our practice act and rules, but seek your comments on the parts that deal with the pharmacy board.

Thank you in advance for your help with this.

John.

--
John R. Boyce, DVM, PhD
Executive Secretary
North Dakota Board of Veterinary Medical Examiners P.O. Box 5001 Bismarck, ND 58502
Phone: 701-328-9540
Fax: 701-224-0435
Email: <mailto:ndbvme@nd.gov>
Website: <http://www.ndbvme.org>

Veterinary Prescription Drugs, Dispensing, and Compounding

John R. Boyce, DVM, PhD
Executive Secretary
North Dakota Board of Veterinary Medical Examiners

Howard C. Anderson, Jr. R.Ph.
Executive Director
North Dakota Board of Pharmacy

Veterinary prescription drugs are to be used or prescribed only within the context of a valid veterinarian-client-patient relationship (VCPR) (87-04-01). The definition of the VCPR in the North Dakota veterinary medical practice act (43-29-01.1) was taken directly from the US Code of Federal Regulations, and includes three provisions:

A veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client, who is the owner or other caretaker, has agreed to follow the instructions of the veterinarian.

There is sufficient knowledge of the animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal.

The practicing veterinarian is readily available for followup in the case of adverse reactions or failure of the regimen of therapy. This relationship exists only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal and by medically appropriate and timely visits to the premises where the animal is kept.

The use, prescription, or sale of any veterinary prescription drug, or the prescription or an extra-label use of any over-the-counter drug in the absence of a valid VCPR constitutes grounds for discipline (43-29-14).

According to the board rules, in order for a veterinarian to exercise properly the rights granted by the veterinary license, a VCPR must exist (87-05-02-02).

Veterinarians may prescribe drugs for their patients, and they may fill their own prescriptions and dispense drugs to their own clients. Prescriptions may also be filled by licensed pharmacists. Veterinarians may not fill prescriptions written by other veterinarians.

Pharmacies must be licensed to do business in North Dakota in order to fill prescriptions for clients living in North Dakota. Mail-order or internet pharmacies are subject to the same provisions. The National Association of Boards of Pharmacy maintains an accreditation process for internet pharmacies called the Veterinary-Verified Internet Pharmacy Sites (Vet-VIPPS™), and clients seeking to fill prescriptions on the internet should be directed to a Vet-VIPPS-accredited pharmacy (see www.nabp.net).

Veterinarians may compound drugs for use on specific animals owned by their own clients, as long as there is a valid VCPR, and there is no approved animal drug available for use. In such cases, the veterinarian must diagnose the condition requiring treatment, must establish an appropriate withdrawal time, and must ensure the identity of the treated animal(s) to avoid illegal drug residues. Pharmacies may also compound drugs for use by a veterinarian. Those compounded drugs should not be sold to other pharmacies or veterinarians, or directly to animal owners. The US Food and Drug Administration is concerned when veterinarians and pharmacies engage in compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards.

The rules of the Board of Veterinary Medical Examiners require veterinarians to maintain adequate treatment records for at least three years, to show that the drugs were supplied to clients with whom a valid VCPR existed. The rules also contain specific provisions regarding drug records, prescriptions, and prescription labels (87-04-01-02 and 87-04-01-03).

Veterinarians who have questions about these topics should consult the applicable practice act and rules, which are available on the board web sites (www.ndbvme.org and www.nodakpharmacy.com) or the veterinary or pharmacy board offices.

Howard Anderson

From: Jim Clement [jclement@bis.midco.net]
Sent: Saturday, February 13, 2010 12:54 PM
To: Dr. John Boyce
Cc: Howard Anderson; 'Rob Jameson'; Guy Halvorson; 'Vollmer, Jesse L.'; Arlyn Scherbenske
Subject: Vet script article NDVMA Jan 2010 newsletter

Dr Boyce,

I have concerns regarding the article authored by you and Howard Anderson that appeared in the January 2010 NDVMA newsletter. Paragraph 7 states, "Veterinarians may prescribe drugs for their patients, and they may fill their own prescriptions and dispense drugs to their own clients. Prescriptions may also be filled by licensed pharmacists. Veterinarians may not fill prescriptions written by other veterinarians." This statement implies that ND animal owners have the following options for procuring prescription veterinary drugs:

1. The animal or herd veterinarian with a valid veterinarian-client-patient relationship (VCPR) provided this veterinarian inventories the drug being prescribed.
2. Licensed pharmacists.

I am a partner in Stockmen's Supply West (SSW) an animal health product business located in Mandan ND. "Paragraph 7" has the potential to impact our business and the availability of veterinary script products to ND producers. Today's veterinary pharmaceutical distribution industry that focuses on legitimate dispensing of veterinary prescription drugs to animal agriculture in general would not involve option 2. Licensed pharmacists do not play a significant role nationally or in North Dakota.

However, there are businesses that provide producers with veterinary prescription drugs, e.g. Stockmen's Supply West (SSW). Procurement of veterinary script drugs through SSW requires a valid prescription from the producer's veterinarian. Accurate records are maintained and script drugs are labeled properly. SSW has developed script drug services that are well received by ND veterinarians and their clients.

Steele Veterinary Clinic and their clients provide an example. On Thursday 2/11/10, a Steele Veterinary Clinic client stopped by SSW to purchase a script drug. In accordance with SSW policy Dr. Scherbenske was called to provide a script however the script was denied and therefore the product. I spoke with Dr. Scherbenske asking why the script was denied. He said that it was because of the implied rule associated with "paragraph 7" but added that Steele Veterinary Clinic appreciates the services SSW provides (Steele client requests product ... SSW secures script, dispenses product and invoices Steele Veterinary Clinic (SVC) ... SVC bills their client).

In summary I believe SSW is compliant regarding ND law and the administrative rules governing veterinary prescriptive practices. Could you please provide comment and references that support the context of "Paragraph 7".

Regards
 Jim

James C. Clement, DVM
 Cow-Calf Research & Consulting
 2248 Sunny Rd South
 Mandan, ND 58554
 701-663-6800 (Office and Fax)
 701-663-6806 (Home)
 701-220-0375 (Mobile)
 Email jclement@bis.midco.net

1/13/2011

Howard Anderson

John Boyce [boyce@nbvme.org]

Wednesday, February 17, 2010 11:39 AM

To: Howard Anderson

Subject: response to Dr. Clement

Howard, I have drafted the following response to Dr. Clement. Please let me know what you think. Feel free to modify it any way you want to.

Thank you for your help.

John.

John R. Boyce, DVM, PhD
Executive Secretary
North Dakota Board of Veterinary Medical Examiners
P.O. Box 5001
Bismarck, ND 58502
701-328-9540
ndbvme@nd.gov

17 February 2010

Dr. James Clement
248 Sunny Rd. South
Mandan, ND 58554

Dear Jim:

I am responding to your e-mail message to me dated February 13 concerning the article that Mr. Howard Anderson and I wrote for the NDVMA newsletter regarding veterinary prescription drugs. You copied your e-mail message to Mr. Anderson, two people at Stockmen's Supply (Rob Jameson and Guy Halvorson), and Drs. Jesse Vollmer and Arlyn Scherbenske. I am copying Mr. Anderson and Drs. Vollmer and Scherbenske on this letter, and would appreciate it if you would give copies to Mr. Jameson and Mr. Halvorson.

The article was written at the request of the Board of Veterinary Medical Examiners, because of several cases involving veterinary prescription drugs that the board has dealt with in the past year or so. The intent was to remind veterinarians what the law and rules are governing the distribution and use of veterinary prescription drugs in North Dakota.

As noted in the article, the use, prescription, and sale of veterinary prescription drugs requires a valid veterinarian-client-patient relationship. Doing so in the absence of a VCPR is listed in the veterinary practice act as one of the grounds for discipline (43-29-14). The VCPR is defined in the practice act, and that definition was taken from the US Code of Federal Regulations.

Your specific question had to do with the statement in the article that veterinarians may not fill prescriptions written by other veterinarians. North Dakota licenses veterinarians to practice veterinary medicine, as defined in the practice act. Because a valid VCPR must exist to support the use, prescription, or sale of veterinary prescription drugs, a veterinarian who sells prescription drugs to someone who is not their client, for use on animals her or she has not examined, would appear to be in violation of the veterinary medical practice act.

North Dakota licenses pharmacists and pharmacies, and requires pharmacists and pharmacies to comply with various laws and rules regarding the practice of pharmacy. Individuals who are not licensed pharmacists who sell prescription drugs to the public may be practicing pharmacy without a license.

Neither the board of veterinary medical examiners nor the pharmacy board wishes to impose unreasonable barriers to people who need access to veterinary prescription drugs for use on their animals. The key here is accountability. Our only interest is in following state law and administrative rules, and protecting the public by

ensuring that people who sell veterinary prescription drugs are qualified to do so, maintain adequate records, and are accountable to the public if something goes wrong.

In Minnesota, veterinarians are allowed to fill a prescription written by another veterinarian. The dispensing veterinarian must create a medical record with the client/patient. The North Dakota practice act does not contain this provision.

My understanding is that there are several large businesses in Minnesota that sell veterinary prescription drugs, and in those cases, the business employs a pharmacist or is licensed as a pharmacy, so that the practice is in compliance with the pharmacy practice act and rules. That is certainly something that Stockmen's Supply could consider.

Mr. Anderson and I discussed this case yesterday, and we agreed that our two boards should consider it at their next meeting. The pharmacy board meets in May and the veterinary board meets in June. If you have any additional comments or recommendations for the boards to consider, please send them to us. We would like to be able to resolve this situation to the satisfaction of all parties.

Thank you again for sharing your concerns with us.

Sincerely,

John R. Boyce, DVM, PhD
Executive Secretary

c: Mr. Howard Anderson, ND Board of Pharmacy
Dr. Jesse Vollmer, ND Board of Animal Health
Dr. Arlyn Scherbenske, Steele Veterinary Clinic

#2

Testimony in Support of Senate Bill 2080

Senate Ag Committee

James C. Clement, DVM

January 14, 2011

Chairman Flakoll, and members of the Senate Agriculture Committee, I am Jim Clement a veterinarian from Mandan and a business partner in Stockmen's Supply West. I also established Mandan Veterinary Clinic in 1975. For the record I stand in support of Senate Bill 2080.

Today ND animal owners have only two options for procuring veterinary prescription drugs:

1. The animal or herd veterinarian with a valid veterinarian-client-patient relationship (VCPR) provided this veterinarian inventories the drug being prescribed. The law does not allow a neighboring veterinarian to fill a script unless they also have a VCPR with the animal owner.
2. A North Dakota Licensed pharmacist.

The current reality associated with veterinary prescription drugs has the potential to impact our business and the availability of veterinary script products to ND producers. Licensed pharmacists do not play a significant role as sources for veterinary prescription drugs used in animal agriculture. This is true for North Dakota and also true nationally.

Senate Bill 2080 provides initiative to resolve issues relating to the limited availability of veterinary script drugs, especially those drugs used in animal agriculture. I appreciate the cooperation and efforts extended by Howard Anderson and the ND Board of Pharmacy towards understanding and resolving these issues. This first draft addresses nearly all issues adequately and demonstrates a real understanding of the issues. The following would be my recommendations for change:

- Page 3 line 16: substitute **traditional livestock** for food animals.
- Page 4 line 22: insert ***and or on accompanying sales documents*** after manufacturers label.
- Page 5 line 30: reconsider the 10 hour continuing education requirement in that it seems excessive.
- Page 6 lines 2 and 3: Rewrite in order to clarify the intent regarding support personnel.
- Page 6 lines 5-11: Reduce the number of hours required and eliminate the veterinary technician component. Make the continuing education specific to veterinary dispensing technicians working in an environment defined by SB2080 and focused on dispensing veterinary script drugs specific to animal agriculture.

I urge the committee to support the basics associated SB2080 and to clarify and simplify where needed.

Nancy Kopp

From: "Dr. Del Rae Martin" <drmartin.hrah@midconetwork.com>
To: "Nancy Kopp" <nkopp@btinet.net>
Sent: Thursday, January 13, 2011 4:32 PM
Subject: SENATE BILL 2080.doc

#3

SENATE BILL NO 2080

Chairman Flakoll and members of the Senate Agriculture Committee, my name is Dr. Del Rae Martin. I currently serve as President of the North Dakota Veterinary Medical Association and own a small animal practice in Mandan, ND. The North Dakota Veterinary Medical Association membership was informed of the legislative proposal by the North Dakota Board of Pharmacy in our fall newsletter. At our Executive Board meeting in November we had not received any comments from our membership on the pending legislation proposed by the Board of Pharmacy. The Executive Board voted to support Senate Bill 2080. Our Executive Board is composed of 6 members from large animal/mixed practices, 2 from academic practices, 1 from government practice and 1 from small animal practice. Veterinarians are the first line of defense in the diagnosis, prevention and treatment of communicable and zoonotic disease. We are committed to ensuring a healthy food supply. We would request businesses licensed as veterinary retail pharmacies respect and acknowledge the education and expertise of our veterinarians to maintain the health and well being of the livestock industry. Subsequent to the Executive Board decision to support Senate Bill 2080, we have received concerns from 2 veterinarians about maintaining the integrity of the veterinary-client patient relationship.

Thank you for your time and I will answer any questions.

1/13/2011

Good morning, Vice Chairman Larsen and members of the Senate Agriculture Committee. For the record, my name is Julie Ellingson and I represent the North Dakota Stockmen's Association.

#4

Over the last several days, our association has been working to gather more information about SB 2080 and to understand its implications for our beef cattle industry in North Dakota. We've engaged in discussions with our producers, as well as many veterinarians and retail veterinary businesspeople – industry segments we consider as vital partners in maintaining the health of our herds and, ultimately, providing a safe, wholesome food supply – in order to get a better handle on the pros and cons of this proposed legislation.

In our research, it appears that all sectors accept that some level of regulation for those dispensing veterinary prescription drugs is appropriate. Retail vet facilities want to comply with state law; many veterinarians want to be able to utilize these facilities to support their clients' pharmaceutical needs, particularly if they are unable to keep a substantial inventory of these prescription medicines on hand; and livestock producers want flexibility in obtaining them so they can readily respond to their animals' needs. So, for these reasons, we agree with the bill's intent.

However; some of language seems overly burdensome and bureaucratic and leaves many questions about what is actually required.

One significant question, for instance, is if these requirements apply to vet clinics if lay people are dispensing prescription drugs in the physical absence of a veterinarian. What is required of those businesses in order to be in compliance?

Also, dispensing technicians would be required to have a certain educational background. What kind of academic programs would be approved by the board?

Further, the continuing education component seems intense, yet it is unclear as to where this education is obtained.

Also, is there a reason this language applies only to prescription medicine for food animals and non-traditional livestock only? What are the requirements for those dispensing prescription medicine for companion animals?

Is there a reason that a lay person other than a dispensing veterinary technician cannot receive an orally transmitted new or refill prescription if the dispensing technician is actually doing the work?

And, finally, does the nametag requirement have any significance in ensuring that prescription medicines are handled appropriately and that animals get the best care?

From our perspective, the legislation needs some additional work in order to clarify these uncertainties and to simplify some of the requirements to be more applicable to the real world of animal agriculture before it moves forward. We'd suggest that the industry be engaged in helping draft the appropriate amendments, either now or through the interim process, so the legislation can be clarified and strengthened.

With that, I would stand for any questions you may have.

Jan 14, 2011

5

Re: Senate Bill 2080

Ladies and gentlemen of the Senate Ag Committee. I appreciate the opportunity to speak to you today. My name is Barry Steffan. I am a third generation rancher. My Dad and I have a cow/calf operation north of Dickinson. I also have a full time job working for Walco Animal Health in Dickinson, where I am the assistant manager, purchasing agent and lead inside salesman. I have been with Walco going on 14 years now. I started right out of college. I graduated first from DSU with a degree in farm and ranch management and then transferred to NDSU where I completed a Bachelors degree in Animal and Range Science with a minor in Business.

I mention this because I have felt throughout my years at Walco, I have been able to use my firsthand experience as a rancher and my education to serve the animal health industry in many capacities. For those of you not familiar with Walco, we are an animal health distributor, servicing veterinarians, dealers, feed yards and producers, throughout the U.S. Our Dickinson division has filled this role of a wholesale distribution site for the state of ND and into surrounding states for 17 years. Our division also offers a large retail point of purchase business for local producers in our area. In 2002, with the approval of the board of pharmacy, we expanded our retail business by bringing Dr. J.D. Rowe on board, giving his clients access to both over the counter and the prescription drugs that they would need.

With that said, Senate Bill 2080 that you have before you today, has a very direct affect on how we offer product to our clients and could possibly hinder our producers access to the veterinary medications that they need. This bill calls for an additional permit and more so additional manpower and/or education to what we have already been doing following regulations in place. I would initially question the agenda of this bill, as it states no specific reason for the additional permits, personnel and other requirements. There are federal and state regulations already in place. The FDA places specific guidelines on every pharmaceutical product that we buy and sell. We have always made it a priority to be compliant with all regulations, state and federal. We have a regulatory department whose sole purpose is to make sure that we are following all guidelines set before us. In fact, the head of our regulatory department, Angus DeWalt was solicited for insight back in June of 2010 by Howard Anderson, Executive Director of the ND board of Pharmacy, regarding the issue of this bill. However, after we agreed to participate and offer our input, no further contact was made, and our regulatory dept. was not included at all.

It should be made very clear that there is an extreme distinction between human medicine and animal medicine. It would be a huge mistake to compare the two as the same. If this bill was simply a bill calling for additional oversight by the board of animal health, we would be all for it. If the board of pharmacy feels that the regulations that are currently in place are not being adhered to, then perhaps we need to start by follow that avenue first, without adding additional constraints that I fear will ultimately inhibit the producer from getting the veterinary service they deserve. In addition, who will police these regulations and at what cost to the state? The extreme shortage of veterinarians is a topic that most everyone in production agriculture has realized. This bill does not come close to addressing that issue, instead it looks to exacerbate the issue further. The veterinarians of this state, who know very well the dynamics of the livestock industry and the needs of the producers in North Dakota, know very well this situation.

I would like to point out some bothersome aspects of this bill. First off, this bill as it is written, does not make any reference whatsoever to companion animal and equine prescription drugs. Section 43-15.4-04, mentions food-animals and nontraditional livestock only. There is no clarity and no reason why companion animal and equine drugs are left undefined. This leaves a huge question as to how these products are handled. Also, I find nothing in the bill that explains whether or not a veterinary retail facility and specifically and VDTech would be able to ship to the client on behalf of the veterinarian. Perhaps this is part of "dispensing" as a definition, but it is not clear. I also find concern with the requirements for becoming a said VDTech under section 43-15.4-05. The set of requirements should be expanded to include those individuals that have in excess of 1500 hours of documented practical knowledge. This would include personnel from existing facilities with several years of experience and show some means of understanding of administrative laws and regulations. This bill lists as a fourth requirement, for example,

that if one holds a license as a ND pharmacy intern, it would qualify them to dispense veterinary prescriptions, when they have no knowledge about veterinary prescription drugs. Unless veterinary medicine becomes part of their curriculum, I fail to see how this individual is qualified. As I mentioned earlier, since we operate at the wholesale and retail level, my job requires me to know about these prescription drugs so that when a veterinarian calls me I can help answer questions and supply them with information and the eventual sale of the product to them. This bill tells me that although I am qualified to sell these drugs directly to a veterinarian, if they call in a prescription or when I take a prescription from Dr. Rowe, I cannot dispense this product to the end user on their behalf. This bill claims that we know nothing of the prescription drugs we handle everyday and it completely disregards the veterinarian's wishes as to how product is dispensed and who is facilitating that job.

Therefore, It is clear that this bills largest weakness is its oversight of "practical knowledge" of the livestock industry and the efforts that already exist to stay above compliance all while making the transfer of prescription drugs from the hands of the veterinarian to the hands of the producer as safe as possible.

Walco has always been open to necessary oversight and to date we have always been compliant. The concept of this bill is not as much the problem as is its lack of clarity and practicality. Bottom line.....our commitment remains to always respect and serve the veterinarians of ND, while striving to meet the needs of our producers.

Thank You.



BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

#/
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Senate Bill No 2080
House Agriculture Committee
Peace Garden Room – State Capitol Bldg
9:30 AM – Friday - March 11th, 2011

Chairman Johnson and members of the House Agriculture Committee, thank you for the opportunity to speak with you today.

This Bill creates new legislation. It attempts to make legal what we have discovered is happening in North Dakota. As a regulator, once we discover something is contrary to current laws we are generally obligated to take action. In this case we have told some of our businesses that we will use enforcement discretion until such time as you, the North Dakota Legislature, have an opportunity to way in on the issue.

Step back a bit to 2008 when Dr. John Boyce at the Board of Veterinary Medical Examiners and I receive some information from Dr. King in Minnesota and Pharmact Candace Fleming, an Inspector for the Minnesota Board of Pharmacy, that one of our Fargo businesses was selling legend drugs as a pharmacy, when in fact they did not have a Pharmacy Permit. At that time Dr. Boyce left the issue to me, and I left it to Dr. Boyce.

In the fall of 2009 we began to get a few complaints from patients and veterinarians that legend drugs were being sold by pet shops and in some cases, the veterinarians wanted to service some clients whose animals they had not seen personally. Part of the solution for that is in Senate Bill 2088 heard earlier.

The North Dakota Wholesale Licensing Law clearly says that wholesalers can sell to other wholesalers, pharmacies, practitioners such as veterinarians and other licensed entities. The Wholesale Statute also clearly states that a wholesaler cannot sell directly to the consumer, or in the case of veterinary products, the consumer's owner. Several of our licensed operations, such as Stockmen's Supply in Fargo and in Mandan, or Lextron Animal Health in Dickinson are licensed as wholesalers. A large part of their business is at wholesale, as they sell to licensed veterinarians. In the fall of 2009 the Veterinary Board asked Dr. Boyce to prepare an advisory for veterinarians about what is legal or not legal relative to the selling of prescription drugs. Dr. Boyce asked me to collaborate on that article and it was written by us and then published in the Newsletter for the Veterinarians. As a result of that article, several individuals contacted us saying "we did not realize that this was illegal, but this is how we do business".

Once we met with those individuals, some of whom had wholesale licenses, we promised them that we would work on writing legislation to try and make legal what was going on or to give you a clear opportunity to say No, if you do not wish to change the law. Then, of course they would have to cease what they were doing that was outside the current law. I had a legal intern who was also a NDSU College of Pharmacy PharmD graduate from New Town, ND working with me over the past summer. Dr Stubstad researched what other states were doing and wrote the peace of legislation you see before you.

Let's look at the Legislation.

43-15-02. Exemptions. The provisions of this chapter shall not apply to the following:

1. A duly licensed practitioner of medicine supplying the practitioner's own patients with such remedies as the practitioner may desire.
2. The exclusive wholesale business of any dealer.
3. The keeping for sale and sale by general dealers of proprietary medicines in original packages and such simple household remedies as from time to time may be approved for such sale by the board.
4. Registered or copyrighted proprietary medicines.
5. The manufacture of proprietary remedies or the sale of the same in original packages by other than pharmacists.
6. A veterinary dispensing technician operating within a veterinary retail facility.

43-15-10 (22) Powers of the Board give the Board of Pharmacy the power to do what this legislation says.

43-15.4 is the new Legislation.

I will answer questions about it, line by line or section by section.

Thank you very much.

Howard C. Anderson, Jr. R.Ph.
Executive Director

Testimony in Support of Senate Bill 2080
Senate Ag Committee
James C. Clement, DVM
March 11, 2011

Chairman Johnson, and members of the House Agriculture Committee, I am Jim Clement a veterinarian from Mandan and a business partner in Stockmen's Supply West. I also established Mandan Veterinary Clinic in 1975. For the record I stand in support of Senate Bill 2080.

Today ND animal owners have only two options for procuring veterinary prescription drugs:

1. The animal or herd veterinarian with a valid veterinarian-client-patient relationship (VCPR) provided this veterinarian inventories the drug being prescribed. The law does not allow a neighboring veterinarian to fill a script unless they also have a VCPR with the animal owner.
2. A North Dakota Licensed pharmacist.

The current reality associated with veterinary prescription drugs has the potential to impact our business and the availability of veterinary script products to ND producers. Licensed pharmacists do not play a significant role as sources for veterinary prescription drugs used in animal agriculture. This is true for North Dakota and also true nationally.

Senate Bill 2080 provides initiative to resolve issues relating to the limited availability of veterinary script drugs, especially those drugs used in animal agriculture. I appreciate the cooperation and efforts extended by Howard Anderson and the ND Board of Pharmacy towards understanding and resolving these issues. I urge the committee to support SB2080 as amended and approved by the ND State Senate on 2/4/11.

#3

SENATE BILL NO 2080

Chairman Johnson and members of the House Agriculture Committee, my name is Dr. Del Rae Martin. I currently serve as President of the North Dakota Veterinary Medical Association and own a small animal practice in Mandan, ND. The North Dakota Veterinary Medical Association membership was informed of the legislative proposal by the North Dakota Board of Pharmacy in our fall newsletter. At our Executive Board meeting in November we had not received any comments from our membership on the pending legislation proposed by the Board of Pharmacy. Our Executive Board is composed of 6 members from large animal/mixed practices, 2 from academic practices, 1 from government practice and I from small animal practice. The Executive Board voted to support Senate Bill 2080. Subsequently, a few members have expressed concerns about maintaining valid veterinary –client –patient relationships, inappropriate distribution and use or abuse of prescription pharmaceuticals. Veterinarians are the first line of defense in the diagnosis, prevention and treatment of communicable and zoonotic disease. We are committed to ensuring a healthy food supply. It is vital for animal agriculture and public safety that the veterinary retail facilities acknowledge the critical need of the veterinary-client-patient relationship and its role in the dispensing of prescription pharmaceuticals. We would request businesses licensed as veterinary retail pharmacies respect and acknowledge the education and expertise of veterinarians in maintaining the health and well being of the animal agriculture.

Thank you for your time and I will answer any questions.

#4

SB 2080

Good morning, Vice Chairman Kingsbury and House Agriculture Committee members. For the record, my name is Julie Ellingson and I represent the North Dakota Stockmen's Association.

We support Engrossed SB 2080, which establishes a veterinary dispensing technician designation and standards in order to bring vet retail facilities, which are relied upon by many producers and veterinarians, into compliance with existing law. The bill before you is the result of a cooperative effort by the State Board of Pharmacy, the North Dakota Veterinary Medical Association, vet retail facility representatives, our organization and other stakeholders.

In drafting amendments for the Senate, our groups agreed that some level of regulation for those dispensing veterinary prescription drugs was appropriate and that we achieved that without overly burdening these businesses or their veterinary dispensing technicians.

Livestock producers consider vets and vet retail businesspeople as vital partners in maintaining the health of our herds and, ultimately, providing a safe, wholesome food supply. Engrossed SB 2080 offers producers flexibility in obtaining prescription medicine so they can readily respond to their animals' needs and supports veterinarians who want to utilize these facilities to support their clients' pharmaceutical needs, particularly if they are unable to keep a substantial inventory of certain prescription drugs on hand.

For these reasons, we support this bill and ask for your favorable consideration of it.

37-8-2916
Proposed Amendments to Senate Bill No 2080
Senate Agriculture Committee

On page 1 line 14, insert "to provide for suspension or revocation of a veterinary retail facility's license," after registration,

On page 1 line 14 insert "and to regulate and control veterinary retail facility's." at the end of line 14

On page 3 line 1, insert "and pharmacy" after pharmacist

On page 3 line 2, insert "and their practice." after veterinarian

On page 3 lines 2 & 3, strikeout "supplying the veterinarian's own practice with such remedies as the veterinarian may desire."

On page 3 line 16, insert "Equidae," before "food-animals"

On page 3 line 31, insert "Equidae," before "food-animals"

On page 4 line 11, add

7. Records of receipt and dispensing of legend drugs must be kept for 3 years and may be audited by the Board of Pharmacy.

On page 5 lines 3 & 4, strike out "Be engaged in on-the-job training program directed by a pharmacist, a veterinarian, or a licensed veterinary technician and" and insert "Successful completion of a certification program"

On page 5, strikeout lines 7 & 8

On page 5 line 30, replace "ten" with "eight"

On page 6 strikeout lines 1,2, & 3

On page 6 line 5, replace "ten" with "eight"

On page 6 line 7, replace "ten" with "eight"

On page 6 line 8, replace "six" with "four"

On page 7 line 3, insert "1." before the start of the statement

On page 7 line 6, add:

2. "The license of a veterinary retail facility violating drug laws or rules may be revoked by the state board of pharmacy, and the veterinary retail facility may be subject to the penalties of section 43-15-42.1

And renumber accordingly