• Veterinary Wellbeing

• Compounding Bill Passes

• CVMA Convention 2016
CVMA Legislative Efforts Expand Options for Veterinary Access to Compounded Drugs

After months of preparation and constant presence at the Capitol, CVMA is pleased to announce that House Bill 16-1324 (titled Veterinary Access Compounded Pharmaceutical Drugs) has passed both houses of the Colorado General Assembly. Representative Joann Ginal (D-Fort Collins/House District 52) and Senator Jerry Sonnenberg (R-Sterling/Senate District 1) were the prime sponsors of the bill, and CVMA is immensely grateful for their willingness to address this critical issue. Governor John Hickenlooper signed the bill into law on June 10, and it will take effect on August 10, 2016.

Why CVMA Undertook This Action

A 2014 survey of CVMA members underscored the importance of veterinary access to compounded drugs (see VOICE 2014:4 or “Drug Compounding” on the Issues section of the CVMA website at colovma.org). Recognizing that patient care was being compromised because of the barriers surrounding compounding medications, CVMA leadership made it a high priority to find a legislative solution that clarifies office use, allows office stock with dispensing in certain situations, and addresses access to compounded controlled drugs.

There are important distinctions between current law and the revised law that results from the passage of HB16-1324, as follows:

- **Office use**—Under current law, a compounding pharmacy may provide up to 10% of its volume of a compounded drug for office use (i.e., in-office administration). CVMA members have reported that some pharmacies are unaware of this allowance, or aware of it but unsure that it applies to veterinary compounded drugs. HB16-1324 makes it clear that the 10% allowance for office use DOES apply to veterinary compounded drugs.

- **Office stock**—Under current law, there is no provision for a veterinarian to maintain stock of a compounded drug for subsequent dispensing. HB16-1324 allows and defines office stock as “the storage of a compounded drug that was distributed or sold by a registered prescription drug outlet to a veterinarian, without a specific patient indicated to receive the compounded drug, and that the veterinarian may subsequently administer to a patient or dispense to a client.”

A veterinarian may dispense a compounded drug from office stock only if (a) the compounded drug is necessary for the treatment of a patient’s emergency condition AND (b) as determined by the veterinarian, the veterinarian cannot access in a timely manner the compounded drug through a registered prescription drug outlet. Further, a veterinarian may not dispense a compounded drug in an amount greater than the amount required to treat a patient’s emergency condition for five days.

The bill requires that a veterinarian shall not administer or dispense a compounded drug from office stock without a valid veterinarian-client-patient relationship in place at the time of administering the compounded drug to an animal patient or dispensing the compounded drug to a client.

- **Resident vs. non-resident pharmacies**—Under current law, only prescription drug outlets in Colorado (i.e., in-state pharmacies) are allowed to provide compounded drugs for casual sale (that is, on a non-patient specific basis). Because no compounding pharmacy in Colorado currently holds a DEA manufacturing license, which allows a compounded controlled drug to be provided to a veterinarian rather than the end user, it has been impossible for Colorado veterinarians to obtain compounded controlled drugs. HB16-1324 allows any registered prescription drug outlet, whether in-state or non-resident, to provide compounded medications—whether controlled or non-scheduled—to a Colorado licensed veterinarian for office use or office stock. To compound and distribute a controlled substance, the bill requires that a registered prescription drug outlet possess a valid manufacturing registration from the federal Drug Enforcement Agency.

In short, HB16-1324 significantly changes the landscape for veterinary compounded medications in Colorado. Licensed veterinarians can now access compounded medications, both controlled and non-scheduled, from in-state or non-resident compounding pharmacies—and maintain those medications for office use or office stock, with an allowance for dispensing up to a five-day dosage of the drug.

“Dr. Curtis Crawford, CVMA President

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medications. There is not a compounding pharmacy in our area, so I can’t run down to the corner store with a prescription for a specific patient when an emergency situation arises. We have to call in a prescription and trust the mail system to get it to us, hopefully within a couple of days. If your luck is like mine though, that emergency situation arises on the Friday evening of a three-day weekend and it isn’t until Tuesday that you can even get the prescription filled and shipped. That means a full five days of suffering and additional illness for that patient. I needed the ability to have a compounded medication on my shelf, ready to go for that emergency situation, when time is of the essence. The CVMA recognized the need, and through careful crafting with the Task Force on Pharmaceuticals, Dr. Pete Hellyer and Ralph Johnson came up with a straightforward bill that would address the issue.

It looked like a no-brainer to have legislation introduced that would allow veterinarians to carry a limited stock of compounded medications for in-office use and dispensing. I couldn’t have foreseen all the obstacles and objections that could be raised over this bill. I have never heard the phrase “You have got to be kidding” and all its various permutations used so often by the Executive Committee as we tackled all the roadblocks that came up—and there were many. It took the diligent vision and experience of Leo Boyle, our CVMA lobbyist, watching for problems; the tenacity of Ralph Johnson and the Executive Committee in reaching out to and discussing the conflicts with each possible stakeholder; and the competent testimony of Drs. Will French, Randa McMillian, and Bill Fredrigill before the legislature to finally get this bill passed. And of course, a big tip of the hat to Rep. Ginal and Sen. Sonneberg for listening to the need and sponsoring the bill.

This was a project that could not have been accomplished by one person. It took the resources and commitment of the whole CVMA community to bring it about. This bill benefits the entire veterinary community in Colorado and serves to underline another reason that organized veterinary medicine is essential to the well-being of veterinarians and their patients.

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of veterinarians to do their job. The task force evaluated how other states were handling the issues of compounded drugs for office use and office stock and modified legislation from those states to fit with the regulatory environment in Colorado. The proposal that started with the task force went through several iterations that ultimately led to the framework for legislation that other members of CVMA moved through the legislative process.

Dr. William French, CVMA Secretary/Treasurer

The 2016 legislative session marked my introduction to the legislative process in Colorado, and it was certainly eye opening. What started as a request from Ralph Johnson to discuss compounding issues in front of the CLAW Caucus at the start of the session, turned into being involved in stakeholder meetings, lobbying legislators, and presenting formal testimony in front of two House and one Senate committees. Seeing the journey of this very important bill from its infancy to being signed by the governor drove home to me the absolutely critical importance of organized veterinary medicine being involved in the conversation of policy at all levels. “Advocacy” sounds like a feel-good thing that CVMA does, but in this case it is so much more. The passage of this bill will make a tangible difference in my daily practice of medicine, and improve patient outcomes by providing easier access to critical medications.

One of my mentors, and past CVMA president Dr. Terry Swanson, has told me numerous times that the reason organized veterinary medicine is so important is because no one is assigned to be the gate keeper of our profession besides ourselves. In other words, if we don’t ensure as professionals that veterinary medicine is headed in a direction that we decide to collectively pursue, that direction will be decided for us. Regulators and legislators have shown they are more than willing to tell us what they think is best for our profession and patients. Having a seat at the table, a voice in the conversation and to advocate for veterinary medicine, is a crucial role of the CVMA that was underscored time and time again during this process.

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The other aspect that was striking to me was how fluid the legislative process is. There were numerous times when the future of the bill hung in seeming perilous balance over unrelated political wrangling, or was threatened as other groups were unsure of how the bill would change their professional landscape. During these times, it was extremely important that CVMA be able to respond immediately and artfully to “put out fires.” Having our lobbyist Leo Boyle present was invaluable to help navigate the minefield that is the political process. And having
CVMA past and present leaders and our executive director present to continually reinforce the importance of the bill allowed guidance for legislators, and nudging where appropriate, to ensure a desirable outcome.

"Advocacy is one of the most important and vital endeavors of the CVMA."

I was encouraged with how well veterinarians are received and respected at the capitol, and this speaks to hours and years of building relationships that Ralph Johnson, Leo Boyle, and past leaders of the CVMA have put in place. Being involved in the process of HB 1324 has left me optimistic about future endeavors under the Golden Dome, but also has solidified my belief that Advocacy is one of the most important and vital endeavors of the CVMA.

Dr. Ashley S. Morgan, Assistant Director, AVMA Governmental Relations Division

Veterinary medicine is unique in that we treat a multitude of species with an even greater number of unique diseases and conditions. Compounding is a necessary practice for veterinarians because there are, and always will be, a limited number of FDA-approved drug products for the many species and conditions that we treat. Veterinarians must also be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations; without access, animals would die before the medication could be delivered. Many of these preparations are not only needed for immediate in-house administration by the veterinarian, but also for dispensing to the patient’s owner or caretaker for treatment at home.

There has been an enormous amount of activity at the state and federal level on compounding for both humans and animals over the past few years. Much confusion still exists, but veterinarians voicing their needs will ensure access to needed compounded preparations. Passing HB16-1324 is a victory for Colorado veterinarians, proving once again how critical advocacy at the state level can be and how profoundly it can affect the ability of veterinary professionals to do what’s best for their patients.

Leo Boyle, CVMA lobbyist

HB16-1324 is the most challenging and ambitious piece of legislation that the CVMA has promoted since I have been working with the profession over the course of more than 20 years. The most difficult part of this effort was the drafting of the bill. Countless versions were written and rewritten (and rewritten again) before the final product was concurred by the House of Representatives, just days before the legislature adjourned for the year. Great credit must be given to Representative Joann Ginal who, due to her education in animal science at CSU, had the background to understand the complexity of all the issues involved with compounding. She convened multiple stakeholder meetings with different pharmacies to iron out all nuances of the intersecting DEA, FDA, and Colorado statutory rules and regulations. Without her leadership, I doubt this bill could have passed.

Senator Jerry Sonnenberg was masterful in shepherding the bill through the Senate Agriculture Committee and the floor action in the full Senate.

Ralph Johnson requires enormous credit for his mastery of the intricate detail needed to write a comprehensive statute for compounding veterinary drugs. Drs. Will French, Randa MacMillan, Sam Romano, and Bill Fredregill deserve accolades for their clear and persuasive testimony before the House and Senate Committees for the bill.

Representative Joann Ginal

I am always honored when I can help my friends in the veterinary community to deliver the highest quality of animal care. HB16-1324 will significantly improve Colorado veterinarians’ ability to treat animals in a timely manner with the kinds of pharmaceuticals most appropriate for their patients. As a legislator from Larimer County with a PhD from CSU’s College of Veterinary Medicine and Biomedical Sciences in reproductive endocrinology, I consider it my responsibility to look out for animal health and welfare and for the integrity of the veterinary profession.

Senator Jerry Sonnenberg

I was happy that I could carry this bill that will help rural veterinarians to treat sick and injured animals in a timely manner. Living in rural Colorado, we know that access to vital medicines and pharmaceuticals is not always available, making our animals vulnerable to needless suffering and even death because of our inability to obtain these medicines quickly. Now, the quality of animal life and health in Colorado has been measurably improved.