

November 30, 2022

Maine State Board of Pharmacy  
35 State House Station  
Augusta, ME 04333-0035

**RE: Proposed Rules - Chapter 42, Compounding Drugs for Veterinary Office Use**

Dear Members of the Maine State Board of Pharmacy:

The Alliance for Pharmacy Compounding (“APC”) is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as educators, prescribers, researchers, and suppliers. Compounding exists for patients and animals whose needs cannot be met by traditional pharmaceutical manufacturers. Every day, APC and NCPA members play a critical, often life-or-death role in patients’ lives, creating essential medications unavailable elsewhere for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women’s health, animal health, and others.

APC appreciates the opportunity to comment on the proposed rules in Chapter 42 concerning Compounding Drugs for Veterinarian office Use (the “Proposed Rules”). While we would like to note that the Proposed Rules are a significant step in the right direction, there are several provisions that cause concern. Accordingly, we offer the following comments to the Proposed Rules:

**The Collection of a Signed Acknowledgment from the Veterinarian with Each Order for Veterinarian Office Use is Impractical and Burdensome.**

Section 3(2)(B) of the proposed regulations includes a requirement that a pharmacy obtain an acknowledgement from an ordering veterinarian that, among other things, the veterinarian is aware that the order is for office use, that the medications will only be administered or dispensed to patients under an established VCPR and that the medications will not be dispensed in a greater than 5-day supply. This acknowledgement must be signed by the veterinarian placing the order and, apparently, collected every time an order for office use compounded medication is placed. We are aware of no other state that requires a signed acknowledgement each time an office order is placed.

In a majority of cases, the prescribing veterinarian or their authorized agent when permissible will phone in an order for compounded office use medications. It is even more likely that the order will be placed by the office manager or a veterinary technician. In some cases, the order may be placed through an on-line portal. In all of these cases, there will not be a written order, nor will there be any exchange of paper in-person or via mail, fax or email. Does the MBOP anticipate that the veterinarian’s office will maintain a supply of pre-printed acknowledgements to be signed by the veterinarian and hand delivered or mailed to the pharmacy? What if the veterinarian is not available to sign the acknowledgement at the time the order is placed? If the acknowledgement is pre-signed, is it valid? Or is it the pharmacy’s responsibility to print the acknowledgement and mail, fax or email it to the veterinarian for signature? What happens if there is a delay in receiving the signed acknowledgement? Do patients suffer?

The proposed regulation allows for either an original or an electronic signature. Since veterinarians do not have NPI numbers, they do not have access to any of the e-Prescribe platforms currently authorized by the

NCPDP, meaning that they do not have the ability to provide an electronic signature. Does this mean that a faxed or scanned and emailed signature is acceptable? If the veterinarian places an order through an online portal, could there be an electronic copy of the acknowledgement and a checkbox “signature?”

We seriously question the need for this type of written correspondence between the veterinarian and the pharmacy. As you can see from the questions posed, the burden placed upon both the veterinarian and the pharmacy are unclear, impractical, and unnecessary.

### **Conclusion**

In summary, we very much appreciate the opportunity to comment on the Proposed Rules and we applaud the MBOP’s decision to promulgate regulations for compounded office stock for veterinary use. Nevertheless, we believe that the Proposed Rules require further consideration and clarity to ensure that compounding pharmacies and veterinarians dispensing medication for animal health can provide optimal care for their patients while ensuring the safety of the general public.

We’re grateful for your attention to these important requests. If I may be helpful, please contact me at [Savannah@a4pc.org](mailto:Savannah@a4pc.org).

Sincerely,

Savannah Cunningham, PharmD  
Director of Public Policy