Virginia Department of Health Professions
Board of Veterinary Medicine

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October 21, 2024
Board Room 4
9:00 a.m.

Agenda
Virginia Board of Veterinary Medicine
Full Board Meeting

Call to Order – Thomas Massie, Jr., DVM, Board President — **Page 1**
- Welcome
- Emergency Egress Procedures
- Mission Statement

Ordering of Agenda – Dr. Massie

Public Comment – Dr. Massie — **Pages 2-31**
The Board will receive all public comment related to agenda items at this time. The Board will not receive comment on any regulatory process for which a public comment period has closed or any pending or closed complaint or disciplinary matter.

Approval of Minutes – Dr. Massie — **Pages 32-37**
June 3, 2024 – Full Board Meeting (**pp 32-35**)
July 3, 2024 – Conference Call (**pp 36-37**)

Legislative/Regulatory Report – Erin Barrett — **Pages 38-58**
- Regulatory Update
  - Current regulatory actions (**p 38**)
  - Review of 2022 periodic review changes
  - Consideration of licensure by endorsement proposed regulatory action (**pp 39-47**)
- Guidance Document Update
  - 150-3 Preceptorships & Externships for Veterinary Technician Students (**pp 48-55**)
  - 150-4 Guidance Regarding "Chip" Clinics Outside of Approved Facilities (**pp 56-58**)

Discussion — **Pages 59-71**
- American Association of Veterinary State Boards 2024 Annual Meeting– **Dr. Massie/Kelli Moss**
  - ICVA 2024 Report (**pp 59-66**)
  - ICVA Retake Policy Update & Form (**pp 67-71**)
- Large Animal Veterinarian Shortage Study Workgroup – **Ms. Moss**
- Treatment and Transport of Working Canines Workgroup – **Ms. Moss**
- License reciprocity DC/Maryland/Virginia – **Ms. Moss**

Board Counsel's Report – Brent Saunders

President's Report – Dr. Massie

Board of Health Professions Report – Ms. Moss

Staff Reports — **Pages 72-73**
- Executive Director's Report – **Ms. Moss**
  - Statistics (**pp 72-73**)
  - Staff updates

- ImpactMakers
- Email Notifications
- Outreach Information
- Current Board Meeting Calendar

- Discipline Report - **Claire Foley, JD**

New Business – Dr. Massie **Pages 74-78**
Officer Elections
Legislative/Regulatory Committee

Next Meeting – **Dr. Massie/Ms. Moss** **Page 79**

- 2025 Board Meeting Calendar (**p 79**)
- March 11, 2025 - Next full board meeting

Meeting Adjournment – Dr. Massie

This information is in **DRAFT** form and is subject to change.

Virginia Department of Health Professions
Board of Optometry

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MISSION STATEMENT

Our mission is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.

Outlook

Re: FIP Guidance Request

From Moss, Kelli G. (DHP) <Kelli.Moss@DHP.VIRGINIA.GOV>
Date Mon 10/7/2024 8:00 AM
To Aaron Lopez <aaron@politicalcapitalllc.com>

Good afternoon,

Your email and attachments will be provided as a public comment to the Board of Veterinary Medicine at its October 21, 2024, meeting. The Board does not have any meetings scheduled on October 10.

The Board members do not engage in discussions with the public at board meetings, but members of the public may submit written comments and/or make a comment during the public comment period at the beginning of every board meeting. Any public comment related to a regulatory action must be made during designated periods for those actions. Regulatory actions and associated timeframes are posted under the Board Activity tab on Virginia Regulatory Town Hall.

For all public comments made during a board meeting, the Chair imposes a time limit. If the board members wish to discuss matters related to a public comment, they will consider it at a later meeting after the public has been given appropriate notice.

Sincerely,

Kelli Moss
Executive Director
Board of Audiology & Speech-Language Pathology
Board of Optometry
Board of Veterinary Medicine
Board of Health Professions
9960 Mayland Dr.
Henrico, VA 23233

Phone: (804) 597-4130
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Virginia Department of Health Professions

Under no circumstances shall the Boards, their members, officers, agents, or employees be liable for any actions taken or omissions made in reliance on any information contained in this e mail.

From: Aaron Lopez <aaron@politicalcapitalllc.com>
Sent: Thursday, October 3, 2024 10:50 AM
To: Moss, Kelli G. (DHP) <Kelli.Moss@DHP.VIRGINIA.GOV>
Subject: RE: FIP Guidance Request

Dir. Moss,

I would like to put in a formal request to present to the Board during the Oct 10th meeting, relating to the FDA announcement on access to the FIP treatment. Please see the attached information on which I would like to address the board. I am not seeking legal advice, but wanting to discuss what is available and the need for Veterinarians in Virginia to be aware of what regulated and what is not.

I look forward to your response,

Aaron

Aaron R López JD, FCLS
Political Capital LLC
1300 Pennsylvania 190-604
Washington DC, 20004
(202)753-7975
PoliticalCapitalllc.com

From: Aaron Lopez
Sent: Thursday, August 1, 2024 6:15 PM
To: Moss, Kelli G. (DHP) <Kelli.Moss@DHP.VIRGINIA.GOV>; Corie Hawks <corie@politicalcapitalllc.com>
Subject: RE: FIP Guidance Request

Dir. Moss,

Thank you for your response the links were very helpful. With the statement from the FDA and the Virginia Guidance documents you provided it appears that veterinarians should follow the standard practice of care by first looking to see if there is an FDA approved product, and if not, the veterinarians can turn to a compounded product if it meets state and federal requirements.

We were concerned with the number of prescribers referring patient owners to the black market or to websites that are selling imported unregulated/unapproved products. With the FDA statement now allowing for compounded FIPS treatments we were hoping that the board would remind veterinarians that they should not refer/recommend or encourage patients to use less than lawful products.

If available, we would like to speak with more about this to see how we can educate the veterinarians more about what is available.

Thank you,

Aaron

Aaron R López JD, FCLS
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1300 Pennsylvania 190-604
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(202)753-7975
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From: Moss, Kelli G. (DHP) <Kelli.Moss@DHP.VIRGINIA.GOV>
Sent: Wednesday, July 24, 2024 9:19 AM
To: Corie Hawks <corie@politicalcapitalllc.com>
Cc: Aaron Lopez <aaron@politicalcapitalllc.com>
Subject: Re: FIP Guidance Request

Good morning,

The Board is unable to provide legal advice, but I can confirm the Virginia Board of Veterinary Medicine's regulations do not specifically address the treatment of FIP. The Board's regulations include requirements for drug storage, dispensing, destruction, and records. Pursuant to 18 VAC 150-20-190(A) of this section, veterinarians are required to maintain, administer, dispense, prescribe, and destroy all drugs in compliance with state and federal laws, which include § 54.1-3303 of the Code of Virginia, the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia), applicable parts of the federal Food, Drug, and Cosmetic Control Act (21 USC § 301 et seq.), the Prescription Drug Marketing Act (21 USC § 301 et seq.), and the Controlled Substances Act (21 USC § 801 et seq.), as well as applicable portions of Title 21 of the Code of Federal Regulations.
In addition, the Board has developed guidance documents for the use of compounded drugs and other controlled substances in the practice of veterinary medicine.
I hope this information is helpful to you. Please let me know if you need clarification.
Sincerely,

Kelli Moss

Executive Director

Board of Audiology & Speech-Language Pathology

Board of Optometry

Board of Veterinary Medicine

Board of Health Professions

9960 Mayland Dr.

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kelli.moss@dhp.virginia.gov

Virginia Department of Health Professions

From: Corie Hawks <corie@politicalcapitalllc.com>
Sent: Tuesday, July 23, 2024 1:49 PM
To: Moss, Kelli G. (DHP) <Kelli.Moss@dhp.virginia.gov>
Cc: Aaron Lopez <aaron@politicalcapitalllc.com>
Subject: FIP Guidance Request

Director Moss,

We are seeking guidance from the board regarding FIP treatment. It is our understanding that when seeking a life-saving treatment for feline infection peritonitis (FIP), the FDA clarified on May 10th that in the absence of an FDA approved drug, vet practitioners can prescribe the compounded product GS-441524. Does the board have an official position on the standard of care for FIP or the dangers of black-market products used to treat this disease?

We have clients looking for guidance on this issue and would appreciate your direction. Thank you,

Corie Hawks

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Introduction to Feline Infectious Peritonitis (FIP) and GS-441524

What is Feline Infectious Peritonitis (FIP)?

Feline Infectious Peritonitis (FIP) is a severe, often fatal, viral disease affecting cats, caused by certain strains of the feline coronavirus. While many cats may carry the feline coronavirus without showing symptoms, FIP occurs when the virus mutates into a virulent form. This mutation triggers an intense immune response, leading to the formation of granulomas (masses of immune cells) and fluid buildup in body cavities. There are two main forms of FIP:

- **Wet (Effusive) FIP**: Characterized by fluid accumulation in the abdomen or chest, leading to symptoms like difficulty breathing, distended abdomen, and fever.
- **Dry (Non-Effusive) FIP**: Characterized by granulomas forming in organs such as the liver, kidneys, and nervous system, causing symptoms like weight loss, lethargy, and neurological issues.

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The Need for GS-441524

For many years there has not been a cure for this disease, leaving pet owners with very few options. A couple of years ago with the development of GS-441524 we found that this may not only help but can cure FIP.

GS-441524 is an antiviral drug that has shown promise in treating FIP. It is a nucleoside analog, similar in structure to the antiviral drug remdesivir, and works by inhibiting the replication of the virus. Studies and evidence from veterinarians and pet owners have indicated significant improvements in cats treated with GS-441524, with many cats achieving remission.

However, until recently this was not available in the US and therefore not available for treatment by a veterinarian. We started to see black market websites dedicated to the treatment of FIP with the use of GS/Remdesivir. These sites started to practice medicine by telling pet owners what they should give their cats, how much to give, and then meeting up with the pet owner outside of a pharmacy, often in a random parking lot to get the product.

We have also seen many veterinarians who feel they are helpless when treating FIP, recommend a google search so that the pet owner my find this treatment on their own, or they may just recommend the pet owner to a specific site allowing the pet owner to self-treat their cat.

The Role of Compounding Pharmacists

As recently as May of this year the FDA announced that since there is not an FDA approved product, GS-441524 will be allowed to be compounded for the use in the treatment of FIP.

Compounding pharmacists play a critical role in the treatment of FIP with GS-441524 for several reasons:

1. **Safety and Quality Assurance**: Compounding pharmacists can provide medications that meet strict quality and safety standards, ensuring that the drug is free from contaminants and accurately dosed. This is crucial for the well-being of the cat, as improper dosing or contamination can lead to ineffective treatment or severe side effects.
2. **Customization**: Compounding pharmacists can tailor the formulation of GS-441524 to meet the specific needs of individual cats due to size and weight, such as adjusting the concentration or creating a palatable form that the cat will readily accept.
3. **Legal and Ethical Considerations**: Purchasing GS-441524 from a licensed compounding pharmacy ensures that the medication is obtained legally and ethically. This contrasts with the black market, where the origin and quality of the drug are often questionable, posing significant risks to the animal.

The Dangers of the Black Market

Obtaining GS-441524 from the black market presents several dangers:

- **Unregulated Production**: Black market drugs are often produced without oversight, leading to potential issues with purity, potency, and sterility. These drugs may contain harmful impurities or incorrect dosages, which can harm the cat.
- **Lack of Recourse**: If a black market drug causes harm, there is little recourse for the pet owner, as these transactions are illegal and unregulated. In contrast, a licensed compounding pharmacy operates under strict regulations, providing a layer of accountability and consumer protection.
- **Ethical Concerns**: Supporting the black market undermines efforts to regulate and ensure the safe production of medications. It also perpetuates illegal activities that can have broader negative implications for public health and safety.

Conclusion

Feline Infectious Peritonitis is a devastating disease that requires effective and safe treatment options. GS-441524, when sourced from a reputable compounding pharmacist, offers a promising solution for affected cats. By opting for a licensed compounding pharmacy, pet owners can ensure the highest standards of safety, efficacy, and ethical responsibility, thereby providing the best chance for their cats to recover from this challenging condition.

We are requesting the Board to notify veterinarians they can prescribe GS-441524 from a licensed compounding pharmacy, and to deter pet owners from sourcing products from the black market, which may even put their license in jeopardy. These websites that are practicing medicine without a license and without oversight will do major harm, as we have seen in the past.

Questions?

Contact

Aaron Lopez, JD

aaron@politicalcapitalllc.com

Stokes Pharmacy®
Precision Compounding - Nationwide.

BOVA

6000 Commerce Pkwy, Suite A
Mount Laurel, NJ 08054

Bova GS-441524

Formulations Available at Stokes Pharmacy:
- 50 mg quad scored tablet*
- 50 mg/mL suspension (almond oil)

Flavor: Tuna

Summary
Drug Class: Antiviral (nucleoside analogue)
Target Species: Cats

Tablets available for office use in most states.

Tablet sizing compared to a U.S. dime

Diagnosis	GS-441524 PO Dosage Rate
Effusion(s) and <u>without</u> ocular or neurological signs	15 mg/kg q 24 hrs or split q 12 hrs
No effusion and without ocular or neurological signs	15 mg/kg q 24 hrs or split q 12 hrs
Ocular signs present (± effusion)	15-20 mg/kg q 24 hrs or split q 12 hrs
Neurological signs present (± effusion)	10 mg/kg q 12 hrs

The current recommendation is to treat for 84 days minimum. Dosing provided by feline experts based on clinical study findings.

- **<u>Very important:</u> Cat should be weighed weekly to update dose (mg)**, but the dosage (mg/kg) should remain consistent in most cases
- When prescribing tablets, dose should be rounded UP to nearest quarter pill
- FIP symptoms should improve within 48-72 hours. If there is no improvement after 48-72 hours it is suggested to increase the dose by 5mg/kg/day or re-evaluate the diagnosis/look for comorbid diseases

Monitoring and Contraindications

It is very important to weigh cats weekly during treatment, using accurate scales – weight gain and/or growth in kittens will occur with successful treatment necessitating an increase in dose to ensure that the dosage of antiviral administered is still appropriate for the type of FIP being treated. If the cat is on prednisolone treatment, this should be stopped while giving Bova GS-441524, unless it is required for short term management of specific immune-mediated disease arising as a result of FIP e.g. haemolytic anemia. Supportive therapies such as antiemetics, appetite stimulants, fluid therapy, and analgesics can be given with Bova GS-441524 as required.

Storage Requirements

Store at 77°F or below.

Stokes Pharmacy®
Precision Compounding - Nationwide.

BOVA

NEW!

FIP Treatment is Now Available in the U.S.

The only oral formula identical to the Bova formula used in clinical studies.

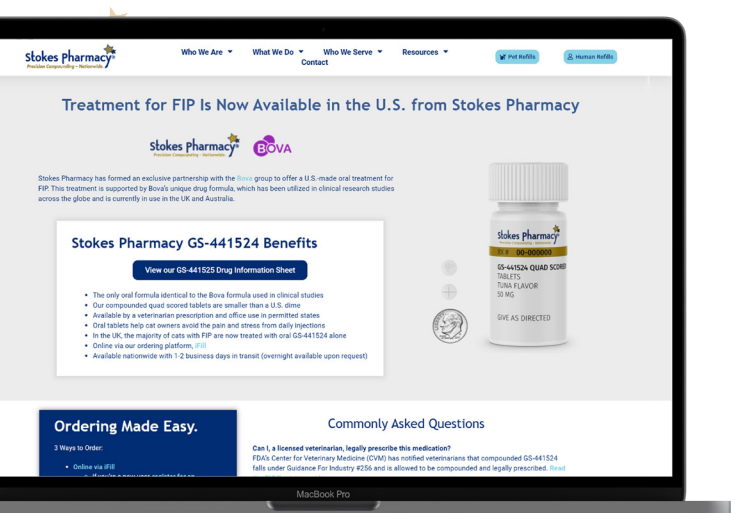
Stokes Pharmacy has formed an exclusive partnership with the Bova group to offer a U.S.-made compounded oral treatment for FIP. This treatment is supported by Bova's unique drug formula, which has been utilized in clinical research studies across the globe and is currently in use in the UK and Australia.

FIP Veterinary Resources

Feline experts have provided educational materials that veterinarians need when it comes to diagnosing and treating FIP.

Resources Include:

- Disease info/treatment
- Educational webinars
- Clinical studies and downloads
- How to order Bova GS-441524 in the U.S.
- FAQs
- Dosing calculator



SCAN TO VIEW!

Plumb's™
Drug Handouts

Prescription Label

Patient Name:
Species:
Drug Name & Strength:
Directions (amount to give how often & for how long):

Prescribing Veterinarian's Name & Contact Information:

Refills:

[Content to be provided by prescribing veterinarian]

GS-441524

Description:
Antiviral

Other Names for this Medication:
None.

Common Dosage Forms:
Veterinary: Oral tablets and liquids, injectable liquids. **Human**: None.

This information sheet does not contain all available information for this medication and has not been reviewed by FDA Center for Veterinary Medicine. This sheet can help answer commonly asked questions but is not a substitute for medical advice. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- Used to treat feline infectious peritonitis (FIP)
- There are no approved or licensed GS-441524 products.
- When giving by mouth, give in the morning about 30 to 60 minutes before a meal.
- When injected under the skin, this medication can cause pain or injection reactions.
- Carefully monitor your cat during treatment with this medication and contact your veterinarian if you notice any unexpected changes.

How is this medication useful?

GS-441524 is used to treat feline infectious peritonitis (FIP). This medication has NOT been approved by the FDA (U.S. Food & Drug Administration).

What should I tell my veterinarian to see if this medication can be safely given?

Many things might affect how well this medication will work in your cat. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- Be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your cat, including the amount and time you give each.
- Tell your veterinarian about any conditions or diseases your cat may currently have or has had in the past.
- If your cat has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or did not work.

P011

- If your cat is pregnant or nursing, talk to your veterinarian about the risks of using this medication.
- Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your cat has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

This medication usually dramatically improves signs within 1 to 2 weeks. The effects of this medication are short-lived, meaning it will stop working within 24 hours.

When should this medication not be used or be used very carefully?

No medication is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this medication in your cat.

This medication **SHOULD NOT** be used in cats that:

- Are allergic to it or a related medication, remdesivir

What are the side effects of this medication?

- Pain on injection
- Injection site reactions, including redness or swelling

Because this medication is not approved or licensed, there may be side effects that have not yet been identified. Carefully monitor your cat and contact your veterinarian if you notice any unexpected changes.

If my animal gets too much of this medication (an overdose), what should I do?

If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include **ASPCA Animal Poison Control Center** (888-426-4435) and **Pet Poison Helpline** (855-764-7661); a consultation fee is charged for these services.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has directed.

- When giving by mouth, give in the morning 30 to 60 minutes before a meal. If your cat vomits after receiving the medication on an empty stomach, try giving the next dose with a small amount of food or a treat.
- When injected, this medication should be given under the skin. Place used needles and syringes directly into a sharps disposal container immediately after injection. Do not recap the needle or disconnect it from the syringe.
- This medication may need to be given for as long as 12 weeks.

What should I do if I miss giving a dose of this medication?

If you miss a dose, give it when you remember and then return to the regular dosing schedule. Do not double-up or give extra doses.

How should I store this medication?

- Follow the storage instructions on the product.
- Keep out of reach of children and animals.

Can handling this medication be hazardous to me, my family, or other animals?

- Wash your hands after handling any medication.
- Accidental needlesticks can lead to pain and infection. Contact your physician if you experience a needlestick injury

How should I dispose of this medication if I don't use it all?

- Do not flush this medication down the toilet or wash it down the sink. If a community drug "take-back" program is available, use this option. If there is no take-back program, mix the medication with coffee grounds or cat litter, place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash.
- Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

- Use of this medication may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.
- Contact your veterinarian if your cat's condition worsens or does not improve over the first 1 to 2 weeks of treatment.
- There have been problems with the quality of GS-441524 sold through unregulated sources. GS-441524 may be available through certain pharmacies in some areas. Discuss with your veterinarian how to find a reliable source for this medication.

If you have any other questions about this medication, contact your veterinarian or pharmacist.

P012

VIN Veterinary Drug Handbook

Remdesivir and its active metabolite GS-441524

Revised: July 31, 2024
Published: January 25, 2024

Expand All | Collapse All

Prescriber Highlights

- Remdesivir is a nucleotide analog RNA polymerase inhibitor. It is referred to as a protide, a prodrug of a nucleotide
- Remdesivir enters the cell where it is converted to GS-441524, which is the active form of the drug
- Both drugs, remdesivir and GS-441524, have been used as an extra-label for treatment of corona-virus-induced Feline Infectious Peritonitis (FIP)
- Originally approved (August 2020) for Emergency Use Only for the treatment of coronavirus disease 2019 (COVID-19) in adult and pediatric human patients; remdesivir received full FDA approval in April of 2022 and most recently in August of 2023 for treatment of various syndromes associated with COVID-19 infections in people. Because it is now fully approved, veterinarians can legally use this drug according to the Animal Medicinal Drug Use Clarification Act
- Remdesivir must be given by injection, but much of the research demonstrating efficacy of the drug in cats with FIP is based on administration (subcutaneous or oral) of GS-441524
- Limited pharmacokinetic information of GS-441524 in cats supports once daily oral or subcutaneous administration based on plasma drug concentrations that persist above the inhibitory concentration of the FIP coronavirus
- Multiple clinical trials support safe and effective use of remdesivir and/or GS-441524 with treatment durations ranging from 8 to 12 weeks (more common)
- Largely due to ethical constraints, efficacy of remdesivir or GS-441524 is primarily based on uncontrolled clinical trials
- The far majority of studies focus on GS-441524, usually with remdesivir induction (IV for 4 days)

- Oral doses of GS-441524 generally are equivalent to or slightly higher than parenteral doses of remdesivir
- Differences in doses have been suggested although not clinically proven, based on the clinical manifestations/type of FIP. The highest dose is indicated for patients with ocular or neurologic manifestations, and the lowest dose for patients with dry or wet disease without ocular or neurologic signs
- Subsequent treatment with higher doses of either drug are recommended for non-responding cats
- Effective use of GS-441524 will remain complicated as long as it remains unregulated due to variability in the amount and bioavailability of different products.
- Studies using legal sources of either drug should be given more consideration
- The most common adversity of remdesivir GS-441524 in cats appears to be related to injection site reactions

Clinical Pearls — Insights from VIN Consultants

- Stokes Pharmacy has announced an exclusive partnership with BOVA in that will make compounded GS-441524 available in the United States for individual patient need. The status of availability for office stock is not clear at the time of this publication
- The compounded remdesivir GS-441524 formulations will be a quarter-scored 50 mg table that will allow dosing to the nearest 12.5 mg. The formulation is similar to the oral tablet used in the limited clinical trials See “Pharmacology" section. Oral bioavailability in other compounded preparations is not known
- Dosing protocols recommended by BOVA for GS-441524 oral, or Remdesivir injectable, either given as sole agent, are included in the dosing protocols below
- Currently, both remdesivir and GS-441254 are available for use in Canada under an Emergency Drug Release
- All dosing regimens are based on limited information from a limited number of clinical trials. Whether or not lower doses or a shorter time period will be effective is not clear. However, caution is recommended in using doses that are too low
- Regarding dosing, a “general consensus” is to use remdesivir (injectable) as a loading dose, usually for 4 days (either as a CRI, a 12 to 15 minute IV infusion (BOVA recommends a 20 to 30 minute infusion of the remdesivir dose diluted in 10 ml of saline), or SQ; see clinical trials below), followed by either remdesivir or, particularly in cats that will not tolerate daily injections, GS-441524 (oral) to total up to the 12 weeks
- However, BOVA provides doses for use of oral GS-441524 alone
- The doses of either remdesivir or GS-441524 vary with the type of FIP upon presentation: Effusive or non-effusive, with or without ocular or neurologic signs. Those doses recommended by BOVA (personal communication, Emma Jones, Sales Director) include options for sole therapy with either GS-441524 (oral) or Remdesivir (IV or SC)
- For IV administration, remdesivir should be diluted with 10 ml of saline and infused slowly over 20 to 30 minutes
- GS-441524 may be more effective, although there are no head-to-head clinical trials comparing the two (remdesivir vs GS-441524 as sole therapy)
- If using GS-441524 only, using oral GS-441524 is preferable to injectable for induction followed by oral, because it is likely equally effective to parenteral treatment and avoids the adverse effects associated with parenteral treatment.
- In severely ill cats, there is concern that oral bioavailability may be poor, which is why an initial course of remdesivir is commonly used. However, in more stable cats or where parenteral treatment is impossible, using only oral GS-441524 is possible. The dosing is the same as above, but for the entire 84 days treatment course
- Consider using weekly weigh-in to assure that you are not underdosing. For example, treatment failures may not be uncommon at 6 mg/kg, but success is much higher using at least 10 mg/kg (and 15 to 20 mg/kg for neurological signs)

- Improvement in some clinical signs (fever, appetite, attitude) should be evident in the first 2 to 5 days, although some clinical signs (effusion, neurologic signs) may still worsen during this initial period
- Effusions generally resolve within 2 weeks. If still present, consider increasing the dose by 5 to 10 mg/kg daily
- 20 mg/kg oral doses should be divided and given q 12 hr
- Decreases in serum globulin and increases in serum albumin may take several weeks
- Lymphoenia and anemia may take up to 10 weeks to resolve
- Lymph node enlargement may not resolve in some animals
- Veklury® (remdesivir) is approved in the United States and can be used extra label by veterinarians in the United States although access may be difficult
- Currently, there is no intended barrier to veterinary access to Veklury®, the human drug approved in the United States manufactured by Gilead. Distributors of Veklury® in the United States include: AmeriSource Bergen (the parent company of MWI): 800-746-6273; Cardinal Specialty 855-855-0708; and McKesson 877-625-2566. The companies can be called so that an account can be set up for product purchase. Legal products are available in Australia and the UK (BOVA)
- Consider molnupiravir if patient has not responded to either remdesivir or GS-441524 at appropriate doses
- Owners of cats with FIP have been accessing (generally non-veterinary) support for FIP treatment, including doses and non-legal sources of remdesivir and/or GS-441524 through a website dedicated to treating FIP. The average cost of the products approximates US $5,000 but is markedly variable

Drugs Included

- Remdesivir
- GS-441524

Doses

Cats

General Comments (see also Clinical Pearls)

- In the United States, the only legal source of remdesivir is an injectable product. This product can be used legally by veterinarians
- Stokes Pharmacy has announced an exclusive partnership with BOVA in that will make compounded GS-441524 available in the United States for individual patient need. The status of availability for office stock is not clear at the time of this publication
- Ideally, compounded remdesivir or GS-441524 formulations will be similar to those used in the limited clinical trials. Oral bioavailability in other preparations is not known
- In Australia and the UK, a legal source of GS-441524 is available for veterinarians through BOVA. This includes 50 mg tablets that should be dosed to the nearest 25 mg
    - In Australia and the UK, a legal compounded source of remdesivir (10 mg/mL) is available
- Doses for either remdesivir or GS-441524 or the sequential combination are based on limited number of clinical trials in cats with FIP [2,5]
- Dosing recommendations from clinical trials are generally considered more credible if the source of the product used in the study can be verified
- Dosing recommendations are for remdesivir only, GS-441524 only, or initial remdesivir with transition to oral GS-441524

- Dose recommendations differ based on the type of (clinical signs) FIP presented in the cat. Dosing for both remdesivir and GS-441524 increase, based on the presenting type or clinical signs of FIP with mg/kg dose lowest for: Wet < Dry < Ocular < Neurological
- Oral doses of GS-441524 generally are equivalent to or slightly higher than parenteral doses of remdesivir, and treatment duration ranges from 8–12 weeks
- A common approach is to start therapy with an induction dose of remdesivir (injectable) as a loading dose, usually for 4 days, followed by GS-441524 (oral) to total up to 12 weeks. However, GS-441524 may be equally effective as an inducing agent. Oral GS441524 may be preferred
- A higher dose is generally recommended for treatment of relapse. However, this recommendation is not based on a well designed clinical trial in cats with spontaneous FIP [2]
- The initial dosing period is generally 12 weeks, with dose adjustment as needed at 4, 8, and 12 weeks into therapy, depending on patient response
- If at 12 weeks, response is not considered sufficient, treatment should be extended for at least 1 and ideally 2 weeks

From published clinical trials [2,5]

Treatment of coronavirus infection in cats as a cause of all forms of feline infectious peritonitis

Remdesivir alone

- Product source
  - Compounded remdesivir (BOVA Australia) [2]
- Dosing protocol [2]
  - Induction: 10 to 15 mg/kg q 24 hr, day 1 through 4, either SC or as an IV infusion over 10 to 15 minutes
  - Maintenance: 6 to 15 mg/kg SC q 24 hr x 12 wk or 2 wk beyond clinical remission. An option to transition to maintenance dosing with GS-441524 is described below
  - Ocular/Neurologic: 10 to 20 mg/kg q 24 hr x 12 wk or 2 wk beyond clinical remission. The 20 mg/kg dose is divided q 12 hr. An option to transition maintenance dosing to GS-441524 is described below
  - Secondary treatment: 15 to 20 mg/kg (divided 20 mg/kg into 10 mg/kg q 12 hr)
- Dosing protocol Remdesivir as sole agent, IV or SQ
  - Recommended by BOVA Pharmaceuticals (Personal Communication, Emma Jones, Sales Director, 6/7/2024)
  - IV remdesivir should be diluted to a total volume of 10 ml with saline and administered slowly over 20 to 30 minutes
  - Effusive, without ocular or neurological signs
    - 10 to 15 mg/kg q 24 hr
  - Non effusive, without ocular or neurologic signs
    - 12 to 15 mg/kg q 24 hrs
  - Either of the above, with ocular signs
    - 15 mg/kg q 24 hr
  - Either of the above, with neurologic signs
    - 20 mg/kg q 24 hr

GS-441524 alone

- Product source [5]
  - Compounded

        - GS-441524 obtained from Gilead as pure substrate, diluted 10–15 mg/mL in 5% alcohol, 30% propylene glycol, 45% PEG400, 20% water (pH 1.5 HCl)
        - A 4-week supply of preloaded syringes was sent to clients. Syringes were to be kept in the refrigerator and warmed to room temperature prior to injection
        - Dosing protocol (this dosing protocol is likely too low [Boothe, 05/09/2024])
            - Initial dosing: 2 mg/kg SC q 24 hr x 12 wk [5]
            - Extended treatment/relapse: 4 mg/kg SC q 24 hr [5]
- Product source [2]
    - Compounded GS-441524 (BOVA Australia) [2]
        - Dosing protocol with IV and oral GS-441524
            - This is the same protocol as for remdesivir, PO, but once transitioned to oral, GS441524 is dosed to the nearest 25 mg (half of a 50 mg tablet) [2]
            - Induction: 10 to 15 mg/kg q 24 hr IV infusion, over 10–15 minutes, days 1 through 4
                - PO administration of GS-441524, at the same dose (10 to 25 mg/kg) may be preferred
            - Maintenance: 6 to 15 mg/kg PO q 24 hr x 12 wk or 2 wk beyond clinical remission
            - Ocular/Neurologic: 10 to 20 mg/kg PO q 24 hr x 12 wk or 2 wk beyond clinical remission. The 20 mg/kg dose is divided q 12 hr
        - Dosing protocol for oral GS441524 as sole agent
            - Recommended by BOVA (personal communication 6/7/2024, Emma Jones, Sales Director)
                - Effusive or non effusive, without ocular or neurological signs
                    - 15 mg/kg q 24 hr or split q 12 hr
                - As above, with ocular signs
                    - 15 to 20 mg/kg q 24 hrs or split q 12 hr (recommended to split the 20 mg/kg dose)
                - As above, with neurologic signs
                    - 20 mg/kg split q 12 hr

Remdesivir followed by GS-441524: allows for oral dosing with GS-441524 after induction with injectable remdesivir [2]

- Product source [2]
    - Compounded remdesivir (injectable; 10 mg/mL; BOVA Australia) [2]
    - Compounded GS-441524 (oral; 50 mg tablets: BOVA Australia) [2]
- Dosing protocol
    - Induction with remdesivir: 10 mg/kg q 24 hr IV infusion, over 10–15 minutes, days 1 through 4
    - Maintenance with GS-441524
        - 6 mg/kg PO q 24 hr x 12 wk or 2 weeks beyond clinical remission
        - Ocular/Neurologic: 10 mg/kg PO q 24 hr x 12 wk or 2 wk beyond clinical remission

A website dedicated to feline infectious peritonitis has been used by owners of cats with FIP to treat their pets, often without veterinary support. This website provides dosing regimens. In general, the doses are higher than doses cited in published, peer reviewed, clinical trials. The basis of the doses listed on the web site is not clear, and should be questioned given the lack of confirmation of diagnosis of FIP or the product used, which

often is non-legal sources, which presumably were based on both legal and non-legal (non-validated) sources of either drug

Treatment of coronavirus infection in cats as a cause of all forms of feline infectious peritonitis. If the condition is severe:

- Wet/effusive
  - Remdesivir: 10 mg/kg SC q 24 hr x 84 d (12 wk)
  - GS-441524: 6–8 mg/kg PO q 24 hr x 84 d (12 wk)
- Dry
  - Remdesivir: 12 mg/kg SC q 24 hr x 84 d (12 wk)
  - GS-441524: 8–9 mg/kg PO q 24 hr x 84 d (12 wk)
- Ocular
  - Remdesivir: 15 mg/kg SC q 24 hr x 84 d (12 wk)
  - GS-441524: 10 mg/kg PO q 24 hr x 84 d (12 wk)
- Neurologic
  - Remdesivir: 20 mg/kg SC q 24 hr x 84 d (12 wk)
  - GS-441524: 12 mg/kg PO q 12 hr x 84 d (12 wk)
- Treatment failure/relapse
  - GS-441524: 15 mg/kg SC, PO q 24 hr x 84 d (12 wk)

Dosage Form

- The availability of compounded GS-441524 in the United States has recently been announced by Stokes Pharmacy, in partnership with the BOVA group. The compounded GS-441524 formulations will be a quarter-scored 50 mg tablet that will allow dosing to the nearest 12.5 mg. The product is not approved and as such, is not included in Table 1
- Because of the availability of FDA approved remdesivir in the United States, it should not be compounded unless the criteria for compounding of animal drugs (21 CFR 530.13), or if compounding from a bulk substance, compounding of animal drugs from bulk substances (GFI #256) are met
- Both remdesivir and GS-441254 are available under Emergency Drug Use in Canada
- A number of unregulated, non-legal oral GS-441524 products are marketed through internet sources. The content of these products has not been validated and as such, are not enumerated here
- However, a report on the Quality Assessment of 30 vials of 17 different brands of non-legally sourced GS-441524 showed 13/17 brands closely matched the labeled content whereas 3 were 10 to 25% more concentrated than labeled and one was 50% below the labeled content [15]

Table 1. Drug Formulations of Remdesivir* in approved in the US

Dosing Form	Mg/Unit	Product Size	Pioneer Proprietary Name (Generic Available Yes/No)	Manufacturer & Application #
Humans				
Injection solution	100 mg/20 mL (5 mg/mL)	20 mL single injection	Veklury [16] (N)	Gilead (N214787)
Lyophilized powder for injection				
*https://www.fipwarriors.eu/en/calc/				

Table 2. Approved Dosing Formulations of Remdesivir* in Non-US Countries					
Species	**Dosing Form**	**Mg/Unit**	**Product Size**	**Company**	**Proprietary Names**
Australia					
*Veterinary	Solution	10 mg/mL	10 mL	Bova	
Human	Powder for injection	5 mg/mL	20 mL	Gilead	Veklury [16]
****Canada**					
UK					
*Veterinary	Solution	10 mg/mL	10 mL	Bova	
	Suspension	50 mg/ml	30 ml	Bova	
	Tablet	50, quad scored	6, 10, 20 pack	Bova	
*https://www.fipwarriors.eu/en/calc/ **Remdesivir (Veklury); No access. Compounded remdesivir/GS-441524 by BOVA: applications for Emergency Drug Release ongoing (Personal Communication, J. Scott Weese, Guelph, Ontario, CA 1/11/2024.					

Pharmacological Classification

- Antiviral

Pharmacology

- Remdesivir (GS-5734) is the phosphonamidite prodrug of a 1'-cyano-substituted adenosine nucleotide analogue and analogue of the prodrug of the nucleotide adenosine [6]
- Remdesivir enters the cell where it is converted to GS-441524
- Remdesivir is an RNA-dependent RNA polymerase (RdRp) inhibitor
- Structure-activity relationship: Remdesivir is considered a broad-spectrum antiviral, with demonstrated activity against RNA viruses. Impacted families include *Coronoviridae* (including SARSCoV, MERS-CoV), *Paramyxoviridae,* and *Filoviridae* (Ebola virus)
- Coronaviruses are enveloped, positive-sense, single stranded RNA viruses [6]
  - Coronaviruses exhibit marked genetic diversity
  - Viruses within the *Orthocoronovirinae* subfamily include four generic (alpha through gamma coronavirus) and can infect a wide variety of host species with host specificity dependent upon variation in the CoV spike attachment glycoprotein
  - The virus underlying COVID-19 (SARS-CoV-2) is a beta coronavirus
  - The virus underlying FIP is an alphacoronavirus; it only infects wild and domestic cats [6]
  - Remdesivir is metabolized into the active nucleotide triphosphate (GS-441524) which competes with adenosine triphosphate (ATP) for incorporation into RNA, ending growth of the RNA strand and termination of RNA synthesis
  - Inhibition by remdesivir appears to outpace the proof-reading capability of coronaviruses which would otherwise remove the altered nucleotides
  - The EC_{50} of remdesivir for inhibition of feline infections peritonitis (FIP) virus is 0.78 microM (μM). For comparison, the EC_{50} for SARS-CoV ranged from 0.07 to 0.77 microM (μM) and for MERS-CoV, 0.07 to 0.86 microM (μM)

- GS-441524 at concentrations of 1 microM (μM) (equivalent to 291 ng/mL) is the effective concentration (e.g., EC_{50}) to inhibit the viral replication *in vitro*
- Using a bioassay that measured a virus-associated cytopathic effect of FIP[11], the EC_{50} toward FIP of remdesivir and GS-441524, were respectively, 0.03 microM and 0.02 microM. For comparison, the EC50 for molnupiravir was 0.016 microM and 0.05 microM for its active metabolite, NHC, and for GC376, which was the most potent, at 0.01 microM
- An *in vitro* study using Crandall Reese Feline Kidney Cells compared the 50% Effective Concentrations (EC_{50}), the 50% Cytotoxic Concentrations (CC_{50}),and a selectivity index (SI: (CC_{50}/EC_{50}) of molnipuravir [17]
  - The EC_{50} were for GS-441524 and molnupiravir were 1.6 and 8 microM, respectively
  - The CC_{50} for GS-441524 and molnupiravir were 260 and 235, microM, respectively. No cytotoxicity occurred at 125 microM and 63 microM for GS-441524 and molnupiravir, respectively
  - GS-441524 had the least detrimental effects on the CRFK cells
  - The SI for FIPV for GS-441524 and molnupiravir were 166 and 29, respectively

- Evidence of efficacy of remdesivir and/or GS-441524
  - *In vitro* studies
    - GS-441524 was demonstrated to inhibit replication of FIP in naturally infected feline macrophages, culture feline monocytes at concentrations as low as 1 μM [9]
    - It lacked cytotoxicity in Crandal Rees Feline Kidney cells at concentrations of 100 μM [9]
  - Clinical trials (prospective)
    - Remdesivir load and followed by remdesivir or GS-441524 maintenance [2]
      - Remdesivir was administered to cats (n=28) with naturally occurring FIP using a 4-day loading dose of remdesivir (IV or SC) followed by a maintenance dose of either remdesivir or GS-441524 for at least 84 days [2]
        - Remdesivir or GS-441524 were acquired by BOVA Aus and compounded into either an injectable (remdesivir) or oral (GS-441524; 50 mg tablet) preparation
        - Outcome indicators for response included resolution of pyrexia, effusion, and clinical signs of FIP in the first half of treatment, normalization of globulin concentrations and continued body weight gain in the latter half of the treatment period
      - Treatment groups
        - Remdesivir throughout study period (n=15)
          - Standard (“lo”) dosing
            - Induction: 10 mg/kg q 24 hr X 4, slow (10 to 15 minutes) IV infusion
            - Maintenance , 6 mg/kg SQ, q 24 hr
        - Remdesivir “high dose” for non-responders
          - Effusive (n=23): induction of 10 mg/kg IV or SC q 24 X 4 followed by 8 to 10 mg/kg SC q 24 maintenance
          - Non-effusive (n=5); induction of 15 mg/kg IV or SC q 24 X 4 followed by 10 to 12 mg/kg SC q 24 maintenance
          - Neurologic or ocular clinical signs: induction of 15 mg/kg q 24 X 4 IV or SC q 24 X 4 followed by 12 to 15 mg/kg SC q 24 maintenance
        - Remdesivir lo or hi followed by GS-441524 (n=13)

- Once a legal source of oral GS-441524 became available, patients for which remdesivir injection site reactions occurred, were allowed to transition to oral GS-441524 at the same dosing rate as remdesivir but rounded up to the nearest 25 mg tablet. If the daily dose was >20 mg/kg, the dose was divided and given q 12 hr
- Response to treatment
  - Overall
    - Three cats died within 48 hours, but 24/25 cats survived up to the 6 months study period
    - Remission occurred in 14/25 (56%) cats by day 84
    - FIP remerged in 3 cats but resolved upon retreatment at a higher dose (15 to 20 mg/kg)
  - Remdesivir Lo only (n=10): 30% recurrence; inadvertent lowering of dosing acknowledged
  - Remdesivir Hi (n=2): no recurrence
  - Remdesivir/GS-441524 (n=13): no recurrence

- GS-441524 as sole therapy [5,9]
  - Experimentally infected cats
    - Cats (n=10/10) were treated with GS-441524. Cats were observed for at least 8 mo for evidence of recurrence of FIP [9]
    - Clinical signs rapidly reversed in 10/10 cats within 2 wk of administration of 2 or 5 mg/kg once daily SC [9]
    - Two of the 10 cats had recurrence at 4- and 6-weeks post treatment and required another 2-week period of treatment
  - Cats with naturally occurring FIP, treated for at least 84 days [5]
    - Cats (n=31) were treated with GS-441524 at 2 mg/kg orally once daily
    - Five cats died or were euthanized within 26 days, while 28 cats completed 12 weeks of therapy
    - Dose escalation to 4 mg/kg was required for 5 cats
    - Relapse occurred in cats after GS-441524 was discontinued. Of these, 25 cats survived for 44 weeks of follow up
  - Cats with naturally occurring FIP (n=31) were treated with GS-441524 at 2 mg/kg orally once daily [5]
    - Five cats died or were euthanized within 26 days, while 28 cats completed 12 weeks of therapy
    - Dose escalation to 4 mg/kg was required for 5 cats
    - Relapse occurred in cats after GS-441524 was discontinued. Of these, 25 cats survived for 44 weeks of follow up [5]
  - Cats with naturally occurring FIP, treated for 42 or 84 days [19]
    - Cats (n= 40) with effusive FIP_ were randomly assigned to receive GS-441524 at 15 mg/kg PO q 24 hr for either 42 or 84 days (n=20/group)
      - Diagnosis was based on RT-qPCR in effusion and clinical pathologic abnormalities typical of FIP (35/40 cats positive)
      - Treatments were blinded up to day 7
      - BOVA GS441524 compounded product was administered as 50 mg tablets
    - Outcome measures were determined on days 14, 28, 42, 56 and 84
      - Complete remission was considered with a body condition score > 4/9), normothermia and absence of clinical signs a modified Karnofsky score of at least 90% and

normalization of laboratory parameters typically abnormal with FIP)
        - Clinical remission occurred between 14 and 84 days (median 28 days)
            - 92.5% (37/40) of cats achieved complete clinical remission by day 42
                - These cats remained in remission throughout the study period (168 days)
            - Two cats were euthanized (day 3 and 31) due to secondary complications
                - Adverse events included
                    - Diarrhea (80%; considered severe in 5 of the 25 cats)
                    - Increased liver enzymes (60) considered mild to moderate with normalization occurring in most cats by day 84 (treated with silymarin or SAMe)
                    - An increase in SDMA (62.5%)
    - GS-441524 in combination or in sequence with a similar drug [8]
        - Cats with spontaneous FIP (n=46, 29, and 6 with abdominal or thoracic effusions respectively) were randomly assigned to 4 different groups [8] (Lv GC376 2022)
            - Cats were treated for 4 weeks with GS-441524 (SC, q 24 hr) and or GC376 (SC, q 12 hr). GC376 (nirmatrelvir: Paxlovid®) is a 3C-like protease inhibitor with demonstrated antiviral activity toward coronaviruses. It blocks replication in SARS CoV-2 [8]
            - The four treatment doses were, in mg/kg, GS-441524 followed by GC376
                - 5 and 20 mg/kg
                - 2.5 and 20 mg/kg
                - 2.5 and 10 mg/kg
                - 5 and 10 mg/kg
            - 45 of 49 cats survived; 43 became clinically normal
        - GS-441524 combined with herbal medications [14]
- Retrospective studies
    - Remdesivir or GS-441524 as sole therapy [10]
        - Cats (n=307; 105 multinational clinics from UK, Australia, Sweden, South Africa, and Japan)
        - Treatments were largely based on availability of legally sourced products
        - Response was based on medical records
        - Dosing in 3 treatment groups was largely based on previous studies [5]
            - Treatments included
                - Remdesivir (IV or SC) alone (n=34%; 5–20, median 10 mg/kg SC)
                - Remdesivir (IV or SC) (5 to 27, median 10 mg/kg) followed by GS445124 (n=56%; 5 to 27, median 12 mg/kg PO)
                - GS-441524 alone (n=10%; 8.3–20, median 12.9 mg/kg)
            - Cats were treated initially for up 330 days (84 days being the target) and for up to 814 days total
                - 17% were treated for longer than 84 days
            - Response
                - 88.6% were alive at the end of the initial treatment period, with 84% considered to be a complete response

                - Cats achieving complete response within 30 days of treatment (28%) were more likely to be alive (98%) at study end compared to cats that did not respond within 30 days (82% were still alive at study end)
            - 8.9% were considered as “no response” and did not survive the initial treatment period
            - 11% relapsed during the initial treatment period
                - Of the partial responders, 55% were still alive at the longest follow-up point for each cat
    - Remdesivir and GS-441524 in combination [14]
        - Cats (n=32) diagnosed with any form of FIP
            - Diagnosis was based on:
                - Treatments included differing combinations of drug
                - Starting dose: remdesivir IV (diluted 1:1 with saline, given as CRI over 1 hr) at a median of 15 (10 to 20) mg/kg
                - Maintenance dose: remdesivir SQ at 10 (10 to 15) mg/kg or GS-441524 (median dose 15 (10 to 20) mg/kg PO. Cats that transitioned to GS-441524 after starting SC remdesivir received the same dose of GS-441524
                    - Drugs were legally sourced
                    - Duration of treatment was 12 weeks
        - Clinical response
            - Occurred in 28/32 cats (87.5%) at a median of 2 (1 to 5) days
            - 26/32 (81%) of cats were in clinical and biochemical remission at the end of the 12 week study period
            - 6/32 (18%) died or were euthanized during the treatment period (4 within the first 3 days)

- Surveys
    - An owner response survey reported on the efficacy of nonlicensed “GS-445124-like” products used to treat cats with FIP (n=393; US [78%] and Canada [7%]). There are important limitations to this study (evidence level 3/4 assigned) [1]
        - The owners were identified through a social media support and drug distribution group dedicated to treatment of FIP
            - Although inclusion criteria required a presumptive diagnosis of FIP, diagnosis was often based on clinical signs
            - To be included, cats had to have been treated at least 84 days or died after treatment was started
        - The most common source of unlicensed GS-445124 was from a company that listed it as a dietary supplement. Because the content could not be verified, the term “GS-445124-like” was used
            - The median starting dose (mg/kg) was 5 (range 2 to 16) and the median ending dose was 8 (range 3 to 25) q 24 hr
            - The mean cost (US dollars) of the unlicensed product was $4920+ 3115 (range $500 to 21,000)
            - Treatment in 25% of cats occurred after a diagnosis of FIP but without the knowledge of the diagnosing veterinarian
        - Given these limitations, owners reported improvement within 1 week of therapy (88%) with 97% of cats being alive at the time of the survey and 54% considered cured. Relapse occurred in 13% of the cats, with 4% dying despite continued therapy
    - A survey-based retrospective study in GS-441524-nonresponders treated with other drugs [7]
        - Participants seeking information on molnupiravir were solicited through social media. The efficacy of molnupiravir (unapproved/unregulated) was

reported in cats (n=26) with FIP that failed therapy prior therapy with oral GS-441524 or GC376 [7]
    - GC376 (nirmatrelvir: Paxlovid®) is a 3C-like protease inhibitor with demonstrated antiviral activity toward coronaviruses
    - Molnupiravir (Lagevrio®) is the isopropylester prodrug of N1-hydroxycytidine (EIDD-2801)
        - It is subsequently activated to a triphosphate which is incorporated into viral RNA
        - The presumed use of molnupiravir or its metabolite EIDD-2801, for treating FIP in cats, is based on unpublished studies [12]
- Some cats had failed up to 3 courses of GS-441524 therapy prior to starting molnupiravir. Therapy with GS-441524
    - 50% had received injectable therapy, the remainder either oral or a combination or oral and injection
    - Reported starting doses of GS-441524 were 2 to 10 mg/kg. The median duration of therapy was 12 weeks
- Therapy with molnupiravir: Cats were treated for 8 to 10 weeks of molnupiravir at an average starting q 12 hr oral dose of 12 mg/kg and an ending dose of 15 mg/kg
- 24 of 26 nonresponders to GS-441524, and subsequently treated with molnupiravir, were alive after treatment at study publication

NAVIGATION

Indications

- Treatment of coronavirus infection in cats as a cause of all forms of feline infectious peritonitis

Drug Interactions

- No known drug interactions have been reported in cats. Cats participating in clinical trials have been treated with a variety of drugs; no adverse events were reported in association with these drug combinations
- A potential antagonistic interaction has been reported in vitro with chloroquine or hydrocholoroquine [13]
- Based on a drug interaction study conducted with Veklury®, no clinically significant drug interactions are expected in humans with inducers of cytochrome P450 (CYP) 3A4 or inhibitors of Organic Anion Transporting Polypeptides (OATP) 1B1/1B3, and P-glycoprotein (P-gp) [13]

Pharmacokinetics

- Pharmacokinetic studies are not yet available for remdesivir but are available for administration of its active metabolite, GS-441524 in cats [9,11]
- Pharmacokinetic studies for remdesivir reflect appearance and subsequent elimination of its active metabolite, GS-441524

Absorption
• A dosage of 5 mg/kg of the parent drug sustained blood levels over 24 hours in the PK study, which was 8–20X higher than an EC_{50} of the calculated from cell culture experiments. Based on this, 2 mg/kg was assumed to be effective while reducing potential toxicity [9]
Bioavailability

Cats	• GS-441524: SC: 89% [9]
	• GS-441524 (n=3 male; 25 mg/kg PO of GS-441524) [18]
	  ◦ 160 ± 69 (relative to 5 mg/kg IV GS-441524)
	• GS-441524 (n=3 male; 25 mg/kg remdesivir PO) [18]
	  ◦ 120 ± 17 (relative to 5 mg/kg IV GS-441524)

Peak plasma levels (C_{max})	

Cats	• GS-441524 (n=2; 10 mg/kg SC of GS-441524) [9]
	  ◦ Blood: 11, 12.8 microM (6622, 7705 ng/mL)
	  ◦ Ocular aqueous humor: 2.4, 4.3 microM (1,448, 2,588 ng/mL)
	  ◦ CSF: 0.8, 2.7 microM (481, 1,625 ng/mL)
	• GS-441524 (cat [n=1] with FIP treated with 15 mg/kg IV GS-441524) [11]
	  ◦ C_{max}: 3,776 ng/mL
	  ◦ C_{min}: 23.7–190 ng/mL (85 ± 62 ng/mL)
	• GS-441524 (n=3 male; 25 mg/kg PO of GS-441524) [18]
	  ◦ C_{max}: 10,290 ± 2625 ng/mL (35 ± 9 microM)
	• GS-441524 (n=3 male; 25 mg/kg remdesivir PO) [18]
	  ◦ C_{max}: 2,480 ± 423 ng/mL (8.51 ± 1.48 microM)
	• GS-441524 (n=3 male; 7 mg/kg remdesivir IV) [18]
	  ◦ C_{max}: 2003 ± 4297 ng/mL (6.88 ± 1.0) microM)

In vitro Therapeutic (EC_{50}), Cytotoxic Concentrations (CC_{50}), and Selectivity Index (SI: CC_{50}/EC_{50})	

Cats	• GS-441524 [17]
	  ◦ CC_{50}: 260 microM
	  ◦ EC_{50}: 1.6 microM
	  ◦ SI: 166

T_{max}	

Cats	• GS-441524 (n=3 male; 25 mg/kg PO of GS-441524) [18]
	  ◦ 4.7 ± 2.9 hr
	• GS-441524 (n=3 male; 25 mg/kg remdesivir PO) [18]
	  ◦ 7.3 ± 1.2 hr
	• GS-441524 (n=3 male; 7 mg/kg remdesivir IV) [18]
	  ◦ 0.83 ± 0.29 hr

Area under the curve	

Cats	• GS-441524 (n=2; 5 mg/kg GS-441524 route either IV or SC) [9]
	  ◦ SC: 38.9 microM/hr (23,417 ng/mL/hr)
	  ◦ IV: 43.8 microM/hr (26,367 ng/mL/hr)
	• GS-441524 (n=3 male; 25 mg/kg PO of GS-441524) [18]
	  ◦ 89,709 ± 32,028 ng/mL/hr
	• GS-441524 (n=3 male; 25 mg/kg remdesivir PO) [18]
	  ◦ 32,038 ± 4077 ng/mL/hr
	• GS-441524 (n=3 male; 7 mg/kg remdesivir IV) [18]
	  ◦ 131,654 ± 2854 ng/mL/hr

Distribution

NAVIGATION

- Concentrations of GS-441524 appear to increase proportionately with dose in cats [11]
- Concentrations of GS-441524 in the aqueous humor and cerebral spinal fluid approximated 20% of that in plasma in cats treated with 10 mg/kg SC [9]

Elimination	
Elimination half-life	

Cats	• Based on the terminal component of a plasma elimination curve after IV or SQ administration, the elimination half-life appears to approximate 4–5 hours [9]
	• GS-441524 (n=3 male; 25 mg/kg PO of GS-441524) [18]
	  ◦ 6.3 ± 2.2 hr
	• GS-441524 (n=3 male; 25 mg/kg remdesivir PO) [18]
	  ◦ 5.5 ± 0.8 hr
	• GS-441524 (n=3 male; 7 mg/kg remdesivir IV) [18]
	  ◦ 5.2 ± 0.6 hr

Duration of action	
Cats	• A dosage of 5 mg/kg of the parent drug sustained blood levels over 24 hours in the PK study, which was 8–20X higher than an EC_{50} of the calculated from cell culture experiments. Based on this, 2 mg/kg was assumed to be effective while reducing potential toxicity [9]

NAVIGATION

Monitoring Parameters

- Based on clinical trials
  - Clinical Signs (and expected time of resolution based on clinical trial): Temperature/fever (usually resolved within 12 to 36 hr), appetite, activity, weight gain (marked daily improvement), abdominal effusions (rapidly disappeared over 1 to 2 weeks, starting 10 to 14 days into therapy), respiratory (dyspnea usually resolved within 7 days), ocular signs (24 to 48 hr), ophthalmic exam (normal by 7 to 14 days) [5]
  - Clinical laboratory tests: hematocrit, total protein, bilirubin, white blood cell count and differential [5]
  - Other: ascites samples: FIBP7bRNA (immunohistochemistry) [5]
  - Complete blood count, serum biochemistries, triglycerides, electrolytes, total T4 were monitored [2]
  - In a multinational, 107 clinic retrospective study of 307 cats with various forms of FIP, and treated with either remdesivir, remdesivir followed by GS-441524, or GS-441524 alone, the approximate median time to normalization was as follows for various tests [10]
    - Temperature: 12 d; clinical signs: 24 d; serum bilirubin: 28 d; effusion: 28 d; hematocrit: 35 d; albumin to globulin ration, 40 d; globulin: 60 d
- Based on the website, the following timetable is recommended for monitoring
  - Baseline
    - Basic biochemistry and hematology
    - FIV/FeLV
    - Electrophoresis serum proteins
    - Serum amyloid A (SAA)
    - Medical ultrasound
    - For FIP: fluid sample collection, Rivalta's test, and PCR
  - 4 and 8 weeks into therapy

        - Basic biochemistry and hematology
        - Ultrasound
    - 12 weeks into therapy
        - As with 4 and 8 weeks
        - SAA

Laboratory Interactions

- None known at the time of publication

Adverse Effects/Warnings

- No studies at the time of monograph publication have reported a dose titration study or animal safety studies
- In a clinical trial of 34 cats with FIP treated with GS-441524, no adverse events were recorded except for 1 cat in which BUN and SDMA increased 8 weeks into a third round of treatment at 4 mg/kg [5]
- In a clinical trial of 28 cats with FIP, treated with a loading dose of remdesivir for 4 days followed by a maintenance dose of either remdesivir or GS-441542, reported the following adverse events based on a worsening compared to baseline
    - Increased serum ALT greater than 2X the Upper Reference Interval (n=8)/16. These resolved either prior to or upon remission
        - Hepatoprotectants are recommended
    - Eosinophilia in 13/25 cats at least one time point during or immediately after treatment
    - Pain on injection ranked as mild to severe (n=2; leading to aggressive behavior; these cats were transitioned to oral therapy). No adverse reactions occurred in cats receiving GS-441524 orally
- Humans [13]
    - Overall, the incidence of adverse events, including serious, was higher in placebo (numerically) than in remdesivir treated COVID-19 patients
    - Hypersensitivity and anaphylactic reactions, particularly after IV infusion
    - Increased transaminase elevations considered mild to moderate resolved upon discontinuation of the drug. Increases have been reported in both healthy volunteers and patients with COVID-19 infections
        - Recommendations are to discontinue therapy in humans if increases are more than 10X the upper limit of normal, or if accompanied by signs or symptoms of liver inflammation

Overdosage

- No information is available regarding the safety of remdesivir or GS-441524 in healthy cats or cats with FIP
- There is no human experience of acute overdosage with Veklury® [13]
- Treatment in the event of overdosage should be supportive, based on monitoring of appropriate clinical signs and diagnostics
- In case of toxicity, consultation with the ASPCA Animal Poison Control Center is recommended. A fee may be charged for consultation. See https://www.aspca.org/pet-care/animal-poison-control or call 888-426-4435

Reproduction/Nursing Safety

- Available data from a clinical trial, published reports, the ongoing COVID-PR pregnancy exposure registry, and compassionate use of remdesivir in pregnant individuals have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following exposure in the second and third trimester [13]

- However, there are insufficient pregnancy data available to evaluate the risk of remdesivir exposure during the first trimester [13]
- In nonclinical reproductive toxicity studies in pregnant rats and rabbits, remdesivir demonstrated no adverse effect on embryo-fetal development when administered at 4X systemic exposures of the predominant circulating metabolite of remdesivir (GS-441524) achieved in humans at the recommended human dose [13]

Safety and Handling

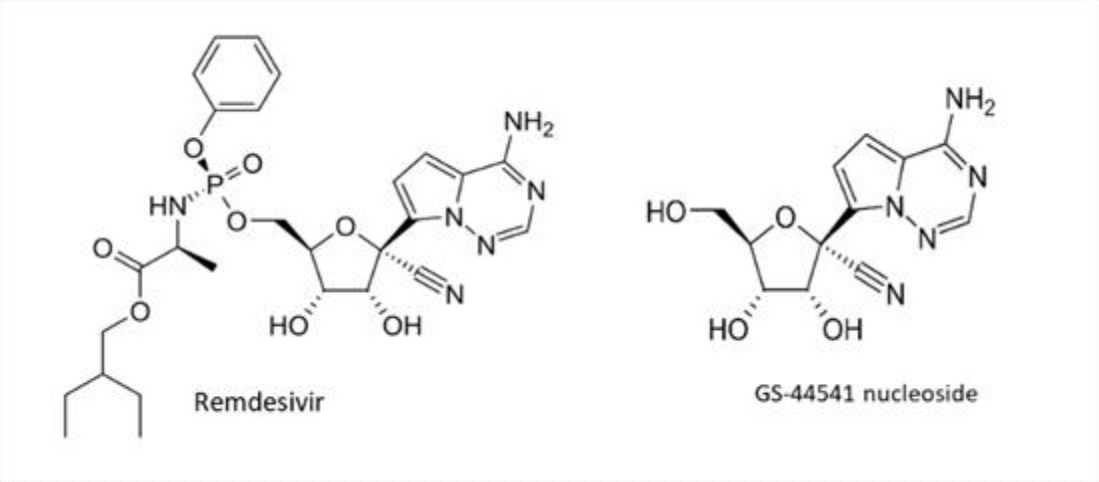
- Keep out of reach of children

Storage/Stability/Compatibility

- General: Do not reuse or save reconstituted or diluted VEKLURY for future use. These products contain no preservative; therefore, partially used vials should be discarded [13]
- No evidence could be found to support maintenance of potency/strength after freezing
- Solution [13]
  - Store Veklury® injection vials at refrigerated temperature 2°C–8°C (36°F–46°F) until required for use
  - Dilute within the same day as administration
  - Prior to dilution, equilibrate Veklury® injection to room temperature 20°C–25°C (68°F–77°F)
  - Sealed vials can be stored up to 12 hours at room temperature prior to dilution
  - Store Veklury® injection after dilution in the infusion bags for no more than 24 hours at room temperature 20°C–25°C (68°F–77°F) or 48 hours at refrigerated temperature 2°C–8°C (36°F–46°F)
- Lyophilized powder for solution [13]
  - After reconstitution of lyophilized powder, use vials immediately to prepare diluted solution
  - Dilute the reconstituted solution in 0.9% sodium chloride injection, USP within the same day as administration
  - The diluted Veklury® solution in the infusion bags can be stored up to 24 hours at room temperature 20°C–25°C (68°F–77°F) prior to administration or 48 hours at refrigerated temperature 2°C–8°C (36°F–46°F)
- For compounded products: refer to compounder's recommendations and/or USP Guidelines for Beyond-Use Dates (BUDs)

Chemistry

- IUPAC: 2-ethylbutyl (2S)-2-[[[(2R,3S,4R,5R)-5-(4-aminopyrrolo[2,1-f][1,2,4]triazin-7-yl)-5-cyano-3,4-dihydroxyoxolan-2-yl]methoxy-phenoxyphosphoryl]amino]propanoate [4]
- Chemical structures unique to MOA should be described in MOA (e.g., beta lactam rings)
- Molecular formula: $C_{27}H_{35}N_6O_8P$ [4]
- Molecular weight: 602.6 g/mol [4]
- pKa: strongest acidic 10.0' strongest basic 0.66 [3]
- LogP: 2.01 [3]
- Water solubility



Trade Names

- Veklury

Synonyms

- (13C3)-GS-5734
- 13C3 GS-5734
- 13C3-GS-5734
- 2-ethylbutyl (2S)-2-(((2R, 3S, 4R, 5R)-5-(4-aminopyrrolo(2,1-f) (1,2,4)triazin-7-yl)-5-cyano-3,4-dihydroxytetrahydrofuran-2-yl) methoxy)(phenoxy) phosphoryl) amino) propanoate
- GS 5734
- GS-465124
- GS-5734
- GS-829143
- l-alanine, N-((S)-hydroxyphenoxyphosphinyl)-, 2-ethylbutyl ester, 6-ester with 2-C-(4-aminopyrrolo(2,1-f)(1,2,4)triazin-7-yl)-2,5-anhydro-d-altrononitrile
- Remdesivir

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VIN Veterinary Drug Handbook Team

URL: https://www.vin.com/doc/?id=11900417&pid=13468
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Images posted by VIN community members and displayed via VIN should not be considered of diagnostic quality and the ultimate interpretation of the images lies with the attending clinician. Suggestions, discussions and interpretation related to posted images are only that -- suggestions and recommendations which may be based upon less than diagnostic quality information.

Virginia Department of Health Professions
Board of Veterinary Medicine

Draft Meeting Minutes

Call to Order

The June 3, 2024, Virginia Board of Veterinary Medicine (Board) meeting was called to order at 9:00 a.m. at the Department of Health Professions (DHP), Perimeter Center, 9960 Mayland Drive, 2nd Floor, Board Room 3, Henrico, Virginia 23233.

Presiding Officer

Thomas B. Massie, Jr., DVM, President

Members Present

Richard G. Bailey, DVM
Patricia Seeger, LVT
Tregel Cockburn, DVM, Secretary
Jeffery B. Newman, DVM, Vice-President
Steve Karras, DVM
Steve Linas, OD, Citizen Member

Staff Present

Arne W. Owens, Director, DHP
James L. Jenkins, Jr., Chief Deputy Director
Erin Barrett, Director of Legislative and Regulatory Affairs
Kelly Smith, Director of Communications
Barbara Hodgdon, PhD, Deputy Director, Healthcare Workforce Data Center
Laura Booberg, Assistant Attorney General, Board Counsel, Office of the Attorney General
Kelli G. Moss, Acting Executive Director, Board of Veterinary Medicine
Laura Jackson, Board Administrator
Laura D. Paasch, Senior Licensing & Operations Specialist
Heather Pote, Senior Discipline Case Specialist
Taryn Singleton, LVT, Discipline Case Specialist
Mary Church, Senior Inspector, DHP

Public Present

Jake Tabor, Legislative Specialist, Virginia Farm Bureau Federation
Victoria Staples, Associative Director, Virginia Veterinary Medical Association

Establishment of Quorum
With seven out of seven board members in attendance, a quorum was established.

Introductions
Dr. Massie announced that since the Board's last meeting Leslie Knachel transitioned from her role as Executive Director of the Board held since 2009 to the role of DHP's Chief Operating Officer. Dr. Massie stated Ms. Knachel's leadership and guidance have been invaluable to the Board and expressed the Board's appreciation of her service and dedication. He congratulated Kelli Moss, the Board's Deputy Executive Director since 2018 and currently its Acting Executive Director, who will be the new Executive Director of the Board effective June 10, 2024.

Ordering of Agenda
Dr. Massie opened the floor to any edits or corrections regarding the agenda. Hearing none, the agenda was accepted as presented.

Public Comment
No public comment was provided.

Approval of Minutes
Dr. Massie opened the floor to any additions or corrections regarding the draft minutes from the January 25, 2024, full Board meeting. Hearing no additions or corrections, the minutes were approved as presented.

Agency Director's Report
Mr. Owens provided an update on the agency's activities.

Legislative/Regulatory Report
Ms. Barrett provided the report on regulatory actions as follows:

- Closure of the periodic review period for 18VAC150-11, Public Participation Guidelines.

  Dr. Bailey moved to retain 18VAC150-11 as is, which was seconded by Dr. Cockburn. The motion carried unanimously.

- Interpretation of posting a license pursuant to 18VAC150-20-30.
  The Board discussed updating the interpretation of this regulation that requires licenses and registrations issued by the Board to be publicly posted. Ms. Singleton was recognized by the chair and informed the Board that the current inspection report for inspections includes guidance that an original license should be posted.

Dr. Karras moved to interpret 18VAC150-20-30 to be satisfied by the posting of a legible copy of the current listing found under License Lookup for the applicable credential, and to revise the Board's inspection report guidance document to reflect this change. The motion was seconded by Dr. Bailey and carried unanimously.

- Emergency regulations/Notice of Intended Regulatory Action (NOIRA) for veterinarian traineeships.

  Dr. Karras moved to adopt the draft emergency regulations for veterinarian trainees as amended by the Board to permit an applicant for licensure as a veterinarian to practice as a veterinarian trainee, and to issue a NOIRA. The motion was seconded by Dr. Newman and carried unanimously.

- Emergency regulations/NOIRA for regulation of satellite offices.

  Dr. Newman moved to adopt the draft emergency regulations as amended by the Board to regulate satellite offices of registered veterinary establishments and to issue a NOIRA. The motion was seconded by Dr. Karras and carried unanimously.

Discussion Items

- Dr. Hodgdon presented the 2023 Veterinarian and Veterinarian Technician Healthcare Workforce Data Center Reports.

- Ms. Moss provided information on the Veterinarian Shortage Study Workgroup.

- Ms. Moss stated there were no updates at this time to a licensing reciprocity agreement between Washington, D.C., Maryland and Virginia.

- Ms. Moss provided a request by the Equine Dental Providers of America for the Board to recognize it as an approved certifying entity to qualify for registration as an equine dental technician (EDT) in Virginia. Ms. Barrett informed the Board that regulatory action is required for the Board to consider this request, which may be initiated stakeholders by filing a Petition for Rulemaking. The Board took no action.

Board Counsel's Report

Ms. Booberg provided an update on the appeal status of a 2022 disciplinary case.

President's Report

Dr. Massie had no information to report to the Board.

Board of Health Professions' Report
Dr. Karras reported that no BHP meeting has been held since the last Board meeting due to an inability to reach a quorum absent new appointments.

Staff Reports
Ms. Moss provided information about the Board's outreach and education efforts, opportunities to attend the American Association of Veterinary State Boards' annual meeting in September, licensing and discipline case statistics and Board staff updates.

Ms. Moss recognized Dr. Karras and Dr. Cockburn for their eight years of service each to the Board and the Commonwealth.

New Business
There was no new business to report.

Next Meeting
The next full board meeting is scheduled for October 21, 2024.

Adjournment
Dr. Karras moved to adjourn the meeting at 12:37 PM. The motion was seconded by Dr. Cockburn and carried unanimously.

_____ _____

Board President

Kelli Moss
Acting Executive Director

VIRGINIA BOARD OF VETERINARY MEDICINE
POSSIBLE SUMMARY SUSPENSION TELEPHONE CONFERENCE CALL
JULY 3, 2024

CALL TO ORDER: Pursuant to §54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Veterinary Medicine was called to order on July 3, 2024, at 11:08 a.m., to consider a possible summary suspension, after a good faith effort failed to assemble a quorum of the board in person.

PRESIDING: Thomas Massie, DVM, Chairperson

MEMBERS PRESENT: Richard Bailey, DVM
Tregel Cockburn, DVM
Steve Karras, DVM
Steven Linas, OD
Jeff Newman, DVM
Patricia Seeger, LVT

QUORUM: With 7 members of the Board participating in the telephone conference, a quorum is established.

STAFF PRESENT: Kelli Moss, Executive Director
Heather Pote, Acting Deputy Executive Director
Emily Tatum, Sr. Adjudication Specialist, Administrative Proceedings Division

OTHERS PRESENT: Mandy Wilson, Assistant Attorney General

BOARD COUNSEL: Laura Booberg, Assistant Attorney General

Chelsey LaMendola, Veterinary Technician
Case 235648: Ms. Wilson presented a summary of the evidence that the continued practice of Ms. LaMendola may present a substantial danger to the health and safety of the public.

CLOSED SESSION: Dr. Bailey moved that the Board convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia (Code") for the purpose of deliberation to reach a decision in the matter of Chelsey LaMendola, Veterinary Technician. Additionally, he moved that Ms. Moss, Ms. Pote, and Ms. Booberg attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberation. The motion was seconded by Dr. Newman and carried unanimously.

RECONVENE: Dr. Bailey moved that the Board certify that it heard, discussed or considered only public business matters

lawfully exempted from the open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion by which the closed meeting was convened. The motion was seconded by Dr. Newman and carried unanimously.

DECISION: Dr. Linas moved to summarily suspend the license of Chelsey LaMendola, Veterinary Technician to practice veterinary medicine pending a formal administrative hearing. The motion was seconded by Dr. Cockburn and carried unanimously.

ADJOURNMENT: The meeting was adjourned at 11:36 a.m.

_____

Kelli G. Moss, Executive Director

Board of Veterinary Medicine
Current Regulatory Actions
As of October 1, 2024

In the Governor's Office

None.

In the Secretary's Office

None.

In the Department of Planning and Budget

None.

In the Office of the Attorney General

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC150-20	Emergency/ NOIRA	Limited practice as a veterinarian trainee	6/6/2024	117 days	Emergency regulations required pursuant to legislation
18VAC150-20	Emergency/ NOIRA	Regulation of satellite offices of veterinary establishments	6/6/2024	117 days	Emergency regulations required pursuant to legislation

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date/ next steps
18VAC150-20	NOIRA	Reduction of requirements for licensure by endorsement	6/17/2024	Public comment period 6/17/2024 – 7/17/2024; proposed action before Board
18VAC150-20	NOIRA	Implementation of 2022 Periodic Review	8/12/2024	Public comment period 8/12/2024 – 9/11/2024; proposed action before Board
18VAC150-20	Fast-track	Regulatory amendments to allow agency subordinates to hear credentials cases	8/12/2024	Effective 9/26/2024

Agenda Item: Proposed regulatory action regarding reduction of licensure by endorsement requirements for veterinarians

Included in your agenda package:

- Proposed language;
- Town Hall summary page showing no comments at the NOIRA stage;
- NOIRA agency background document approved through executive branch review; and
- Recommendations for changes to 18VAC150-20-120 made by the Regulatory Committee in March 2023.

Staff note: The Board accepted a petition for rulemaking in 2023 that requested a reduction of requirement for clinical practice from two of the last four years to one of the last four years. The NOIRA adopted by the Board at that time made additional changes reflected in the proposed regulatory language included in this section.

Separately, as part of the 2022 periodic review of regulations, the Regulatory Committee considered changes to the licensure by endorsement provision.

The Board should review both provisions and determine how to proceed with this action.

Action needed:

- Motion to adopt proposed regulatory language reducing requirements for licensure by endorsement of veterinarians.

Project 7726 - Proposed

Board of Veterinary Medicine

Reduction of requirements for licensure by endorsement

Chapter 20

Regulations Governing the Practice of Veterinary Medicine

18VAC150-20-120. Requirements for licensure by endorsement as a veterinarian.

The board may, in its discretion, grant a license by endorsement to an applicant who is licensed to practice veterinary medicine in another jurisdiction of the United States, provided that the applicant:

1. Holds at least one current, unrestricted license in another jurisdiction of the United States ~~and is not a respondent in any pending or unresolved board action in any jurisdiction~~;

2. Provides documentation of having been regularly engaged in clinical practice for at least ~~two~~ one of the past four years immediately preceding application;

3. ~~Provides documentation of completion of at least 30 hours of continuing education requirements during the preceding four years;~~

~~4.~~ Submits the application fee specified in 18VAC150-20-100 and a complete application on a form obtained from the board; and

~~5. Signs a statement attesting that the applicant has read, understands, and will abide by the statutes and regulations governing the practice of veterinary medicine in Virginia; and~~

~~6.~~ 4. Has committed no acts that would constitute a violation of § 54.1-3807 of the Code of Virginia.

VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Veterinary Medicine

Chapter Regulations Governing the Practice of Veterinary Medicine [18 VAC 150 - 20]

Action: Reduction of requirements for licensure by endorsement

Notice of Intended Regulatory Action (NOIRA)

Action 6364 / Stage 10178

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Preliminary Draft Text	None submitted	Sync Text with RIS
Agency Background Document	11/2/2023	Upload / Replace
Governor's Review Memo	5/14/2024	
Registrar Transmittal	5/16/2024	

Status	
Public Hearing	Will be held at the **proposed** stage
DPB Review	Submitted on 11/2/2023 Policy Analyst: Melanie West Review Completed: 11/16/2023
Secretary Review	Secretary of Health and Human Resources Review Completed: 5/9/2024
Governor's Review	ORM Review: ORM Approved 5/14/2024 Governor Review Completed: 5/14/2024 Result: Approved
Virginia Registrar	Submitted on 5/16/2024 **The Virginia Register of Regulations** Publication Date: 6/17/2024 **Volume: 40 Issue: 22**
Comment Period	Ended 7/17/2024 0 comments

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P041

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This person is the primary contact for this board.

This stage was created by Erin Barrett on 10/31/2023 at 11:13am
This stage was last edited by Erin Barrett on 10/31/2023 at 11:14am

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Veterinary Medicine, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC150-20
VAC Chapter title(s)	Regulations Governing the Practice of Veterinary Medicine
Action title	Reduction of requirements for licensure by endorsement
Date this document prepared	October 31, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

Following receipt of a petition for rulemaking to reduce the requirements for licensure by endorsement as a veterinarian to only one year of active practice, the Board voted to initiate a regulatory change which will accept the request of the petitioner and reduce other requirements for licensure by endorsement.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation, (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for this action was a petition for rulemaking received by the Board in August of 2023 and considered by the Board on October 26, 2023.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Veterinary Medicine are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The licensure of veterinarians was determined to be essential to protect the health, safety, and welfare of citizens by the General Assembly when it required licensure of these practitioners. Thus, the General Assembly made this determination rather than the Board. The Board is not imposing new requirements or creating new regulation, and therefore does not justify the regulatory action in this manner.

There are no potential issues that will need to be addressed.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

The Board intends to make the following changes to 18VAC150-20-120(2):

- Eliminate the requirement in (1) that an applicant not be a "respondent in any pending or unresolved board action in any jurisdiction," because this information is difficult to obtain and often does not change licensing decisions;
- Reduce the active practice requirement in (2) to regularly engage in clinical practice for one year out of the last four;
- Eliminate (3), which requires completion of at least 30 hours of continuing education in the preceding four years, as any individual with an active license in another jurisdiction will have complied with that jurisdiction's renewal requirements; and
- Eliminate (5), which requires an attestation that the applicant has read and will abide by all laws and regulations affecting veterinary medicine in the Commonwealth, as this requirement is pointless and impossible to verify.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There are no alternatives to regulatory action. Licensure by endorsement requirements exist in regulation; therefore to be altered a regulatory action must be filed.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia, describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Veterinary Medicine is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.

Regulatory Committee recommendation on licensure by endorsement from March 2023

18VAC150-20-120. Requirements for licensure by endorsement as a veterinarian.

The board may~~, in its discretion,~~ grant a license by endorsement to an applicant who is licensed to practice veterinary medicine in another jurisdiction of the United States or Canada, provided that the applicant:

1. Holds at least one current, unrestricted license in another jurisdiction of the United States or Canada and is not a respondent in any ~~pending or unresolved~~ board action in any jurisdiction;

2. ~~Provides documentation of having been regularly engaged in clinical practice for at least two of the past four years immediately preceding application;~~

~~3.~~ Provides documentation of completion of at least 30 hours of continuing education requirements during the preceding four years;

4. Submits the application fee specified in 18VAC150-20-100 and a complete application on a form obtained from the board; and

5. ~~Signs a statement attesting that the applicant has read, understands, and will abide by the statutes and regulations governing the practice of veterinary medicine in Virginia; and~~

~~6.~~ Has committed no acts that would constitute a violation of § 54.1-3807 of the Code of Virginia.

Agenda Item: Consideration of amendments to Guidance Document 150-3 regarding preceptorships and externships for veterinary technician students

Included in your agenda package:

- Guidance Document 150-3 with suggested changes included;
- Redline version of suggested changes to Guidance Document 150-3.

Action needed:

- Motion to revise Guidance Document 150-3 as presented or with additional amendments discussed by the Board.

BOARD OF VETERINARY MEDICINE

Preceptorships and Externships for Veterinary Technician Students

Q: How does an individual qualify for a preceptorship or externship in Virginia?

A: In order to be considered a veterinary technician preceptee or extern ("VTP/E"), an individual must be enrolled and in good standing in a campus or distance learning veterinary technology program accredited or approved by the American Veterinary Medical Association ("AVMA").

Q: What duties may a VTP/E perform during a veterinary technology preceptorship or externship?

A: A VTP/E may perform duties that constitute the practice of veterinary technology for which he has received adequate instruction by the program and under the on-premises supervision prior to receiving a license from the Board of Veterinary Medicine.

Q: May a VTP/E have access to Schedule II through V drugs?

A: The regulations specifically state that only the veterinarian, veterinary technician, pharmacist, or pharmacy technician shall have access to Schedule II through V drugs. Therefore, students may not have access (keys, combinations, etc.) to Schedule II through V drugs.

Q: May a VTP/E administer rabies vaccinations?

A: Pursuant to Virginia Code § 3.2-6521, a rabies vaccination may be administered by a licensed veterinarian or licensed veterinary technician who is under the immediate and direct supervision of a licensed veterinarian on the premises. A VTP/E is unlicensed and may not administer a rabies vaccination.

Q: What are the supervision requirements for a VTP/E?

A: Duties may only be performed under the on-premises supervision of a licensed veterinarian or licensed veterinary technician. It is the responsibility of the supervising licensed veterinarian or licensed veterinary technician and the VTP/E to obtain information from the campus or distance learning program to determine whether the preceptee or extern has received adequate instruction by the program.

Q: What does "formal arrangement" found in the definition of preceptorship and externship mean?

A: A licensed veterinarian or veterinary technician may provide on-premises supervision of a VTP/E. However, a licensed veterinarian who is assuming the overall responsibility of assuring appropriate supervision of a VTP/E must have a formal arrangement with the faculty of a

campus or distance learning program. A formal arrangement is a written document that includes, but is not limited to, supervision expectations. The supervising veterinarian and the VTP/E are jointly responsible for obtaining the necessary oversight by faculty of the campus or distance program. The lack of documentation related to a preceptorship or externship may result in disciplinary action.

Q: May a veterinary technology student continue to do activities that constitute the practice of veterinary technology after conclusion of a preceptorship or externship prior to graduation from the program?

A: A veterinary technology student may continue to do activities that constitute the practice of veterinary technology if the following conditions are met:

- The student is enrolled and in good standing in a campus or distance learning veterinary technology program accredited or approved by AVMA;
- The student is supervised by a veterinarian who is licensed in Virginia and is assuming the overall responsibility of assuring appropriate supervision of the student;
- The student has received adequate instruction by the program prior to performing the activity; and
- The student is performing those duties at the same establishment where the preceptorship or externship occurred, or, if performing those duties in a subsequent facility or facilities, the student is supervised by a veterinarian who is licensed in Virginia who assumes the overall responsibility of assuring appropriate supervision of the student and who is familiar with the activities performed during the preceptorship or externship.

Q: May a graduate of a veterinary technology campus or distance learning program perform duties that constitute the practice of veterinary technology if the requirements of the supervising veterinarian are met?

A: Once a student has graduated, the "enrolled and in good standing" requirement is no longer satisfied. Therefore, the graduate of a veterinary technology program may not perform activities that constitute the practice of veterinary technology in Virginia until properly licensed.

Q: Will the Board allow a veterinary technology student to take the Veterinary Technician National Exam (VTNE) prior to graduation?

A: The Board will approve students enrolled and in good standing in a Virginia veterinary technology program or a resident of Virginia to take the VTNE prior to graduation.

Q: May a veterinary technology student submit an application for licensure prior to having received school transcripts and national examination scores?

A: The Board will accept applications for licensure submitted prior to receipt of transcripts and national examination scores. Following the receipt of all required documents and the application is deemed complete, a license is generally issued within 24 hours.

References

Va. Code § 54.1-3804
18VAC150-20-10
18VAC150-20-130

Guidance document: 150-3 ~~Reaffirmed: March 11, 2021~~

Revised: October 21, 2024

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~~VIRGINIA~~ BOARD OF VETERINARY MEDICINE

Preceptorships and Externships for Veterinary Technician Students

~~Applicable Laws and Regulations~~

~~***§ 54.1-3804. Specific powers of Board.***~~

~~*In addition to the powers granted in § 54.1-2400, the Board shall have the following specific powers and duties:*~~

~~*2. To establish and monitor programs for the practical training of qualified students of veterinary medicine or veterinary technology in college or university programs of veterinary medicine or veterinary technology.*~~

~~***18VAC150-20-10. Definitions.***~~

~~*The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:*~~

~~*"Preceptorship or externship" means a formal arrangement between an AVMA accredited college of veterinary medicine or an AVMA accredited veterinary technology program and a veterinarian who is licensed by the board and responsible for the practice of the preceptee. A preceptorship or externship shall be overseen by faculty of the college or program.*~~

~~***18VAC150-20-130. Requirements for practical training in a preceptorship or externship.***~~

~~*A. The practical training and employment of qualified students of veterinary medicine or veterinary technology shall be governed and controlled as follows:*~~

~~*2. A veterinary technician student who is enrolled and in good standing in a veterinary technology program accredited or approved by the AVMA may be engaged in a preceptorship or externship. A veterinary technician preceptee or extern may perform duties that constitute the practice of veterinary technology for which he has received adequate instruction by the program and only under the on-premises supervision of a licensed veterinarian or licensed veterinary technician.*~~

~~Guidance~~

Q: How does an individual qualify for a preceptorship or ~~/~~externship in Virginia?

A: In order to be considered a veterinary technician preceptee or extern ("VTP/E"), an individual must be enrolled and in good standing in a campus or distance learning veterinary technology program accredited or approved by the American Veterinary Medical Association ("AVMA").

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Q: What duties may a VTP/E perform during a veterinary technology preceptorship~~/~~ or externship?

A: A VTP/E may perform duties that constitute the practice of veterinary technology for which he has received adequate instruction by the program and under the on-premises supervision prior to receiving a license from the ~~Virginia~~ Board of Veterinary Medicine.

Q: May a VTP/E have access to Schedule II through V drugs?

A: The ~~R~~regulations specifically state that only the veterinarian, veterinary technician, pharmacist, or pharmacy technician shall have access to Schedule II through V drugs. Therefore, students may not have access (keys, combinations, etc.) to Schedule II through V drugs.

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Q: May a veterinary technology student continue to do activities that constitute the practice of veterinary technology after conclusion of a preceptorship or ~~/~~externship~~.~~ prior to graduation from the program?

A: A veterinary technology student may continue to do activities that constitute the practice of veterinary technology if the following conditions are met:

- ~~Must~~ The student is~~be~~ enrolled and in good standing in a campus or distance learning veterinary technology program accredited or approved by AVMA;
- The student is supervised by a ~~Have a supervising~~ veterinarian who is licensed in Virginia and is assuming the overall responsibility of assuring appropriate supervision of the student ~~who has a formal arrangement with the faculty of the campus or distance learning program~~; ~~and~~
- ~~Have~~ The student has received adequate instruction by the program prior to performing the activity.; and
- The student is performing those duties at the same establishment where the preceptorship or externship occurred, or, if performing those duties in a subsequent facility or facilities, the student is supervised by a veterinarian who is licensed in Virginia who assumes the overall responsibility of assuring appropriate supervision of the student and who is familiar with the activities performed during the preceptorship or externship.

Q: May a graduate of a veterinary technology campus or distance learning program perform duties that constitute the practice of veterinary technology if the requirements of the supervising veterinarian are met?~~.~~

A: Once a student has graduated, the "enrolled and in good standing" requirement ~~cannot be~~is no longer satisfied. Therefore, the graduate of a veterinary technology program may not perform activities that constitute the practice of veterinary technology in Virginia until properly licensed.

Q: Will the ~~Virginia~~ Board ~~of Veterinary Medicine~~ allow a veterinary technology student to take the Veterinary Technician National Exam (VTNE) prior to graduation?

A: The ~~Virginia~~ Board ~~of Veterinary Medicine~~ will approve students enrolled and in good standing in a Virginia veterinary technology program or a resident of Virginia to take the VTNE prior to graduation.

Q: May a veterinary technology student submit an application for licensure prior to having received school transcripts and national examination scores?

A: The Board ~~of Veterinary Medicine~~ will accept applications for licensure submitted prior to receipt of transcripts and national examination scores. Following the receipt of all required documents and the application is deemed complete, a license is generally issued within 24 hours.

References

Va. Code § 54.1-3804

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Guidance document: 150-3 ~~Reaffirmed: March 11, 2021~~

Revised: October 21, 2024

18VAC150-20-10
18VAC150-20-130

~~Adopted: October 18, 2011~~
~~Revised: May 17, 2012; February 7, 2013; October 25, 2017~~

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Agenda Item: Consideration of amendments to Guidance Document 150-4 regarding "chip" clinics outside of approved facilities

Included in your agenda package:

- Guidance Document 150-4 with suggested changes included;
- Redline version of suggested changes to Guidance Document 150-4.

Action needed:

- Motion to revise Guidance Document 150-4 as presented or with additional amendments discussed by the Board.

VIRGINIA BOARD OF VETERINARY MEDICINE

GUIDANCE REGARDING "CHIP" CLINICS OUTSIDE OF APPROVED FACILITIES

The Board has determined that "chip" clinics cannot be held in unlicensed facilities aside from rabies clinics approved by the local health department pursuant to Virginia Code § 3.2-6521(C). Animal shelters can inject their own animals with the microchips but cannot do so to animals once they are adopted out in accordance with Virginia Code § 54.1-3801.

In the event of an emergency declared by the proper local, state, or federal authority, animals separated from their owners may be microchipped in a non-registered establishment. Microchips may be injected into animals that are under the care of an attending veterinarian and housed in temporary, emergency facilities. The microchips should be placed by the attending veterinarian or by a licensed veterinary technician or non-licensed person under the supervision of the attending veterinarian. Individual records should be maintained and should include the microchip type, number and location of the microchip placement. When feasible, information about where and how the animal was obtained or inducted into the emergency facility should be noted on the individual animal record.

References

Va. Code § 3.2-6521
Va. Code § 54.1-3801

VIRGINIA BOARD OF VETERINARY MEDICINE

GUIDANCE REGARDING "CHIP" CLINICS OUTSIDE OF APPROVED FACILITIES

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References

Va. Code § 3.2-6521
Va. Code § 54.1-3801

International Council for Veterinary Assessment

2024 REPORT TO LICENSING BOARDS

NAVLE®

NAVLE SELF-ASSESSMENT

SPECIES SPECIFIC EXAMS

SETTING A HIGHER STANDARD TOGETHER®

P059

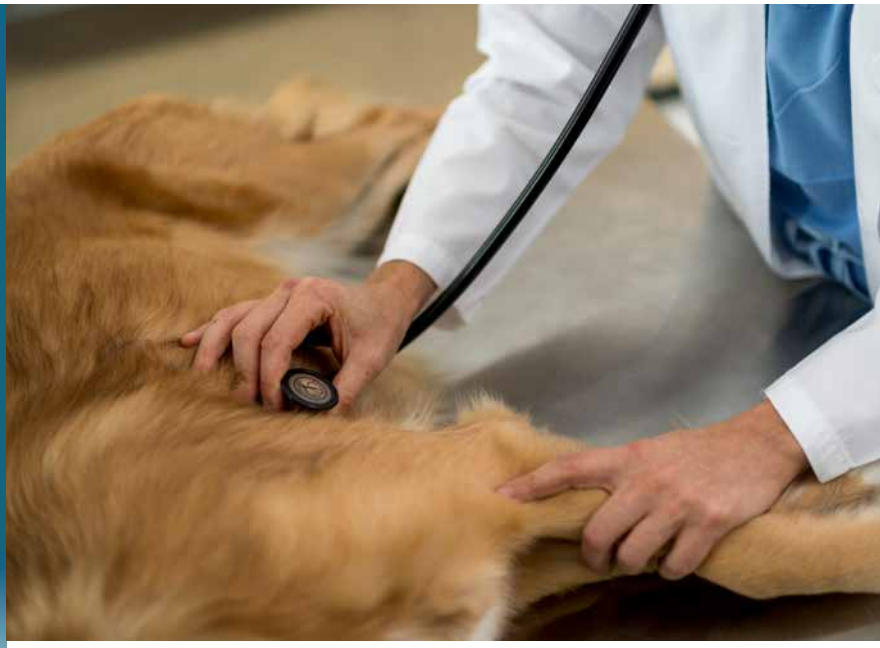
VISION

The world leader in veterinary assessments.

MISSION

Provide world-class examinations and other assessment tools to protect the public, and animal health and welfare.

Provide leadership and facilitate collaboration throughout veterinary medicine.



VALUES

Transparency
organizationally and in testing procedures, materials and content

Confidentiality
when collecting and reporting personal information, credit card data, and test scores

Reliability
in relevant test design, implementation, and scoring

Service
to candidates, licensing boards, and society at large

Respect, Civility & Collegiality
towards staff, stakeholders, board members, and across veterinary medicine

Integrity
In all actions and business relationships

Fiscal Responsibility
to ensure continuous improvements in our testing products and customer service, as well as a viable future for our organization

Diversity and Inclusion
treat everyone with fairness, respect and dignity, and purposefully act to attract and retain staff and Board members with a broad range of ideas, viewpoints, perspectives, expertise and experiences reflecting the diversity of the populations we serve. We respect and value these differences and encourage opportunities to learn from and be enriched by them as they challenge us to grow and think differently.

P060

Letter

Dr. Keith Poulsen

Dr. Heather Case

Letter from the Chair and CEO

We are pleased to report that test administrations are proceeding successfully during these rapidly-evolving times, maintaining the world-class standards of our examination process as we handle the increasing number of candidates worldwide taking ICVA's examinations.

8,915 candidates took the North American Veterinary Licensing Examination® (NAVLE®) during the 2023-2024 testing cycle, showing an **8.3% increase** from the 8,230 candidates who tested during the 2022-2023 cycle.

ICVA continues to invest in innovation in order to meet our commitment and vision of being a world leader in veterinary assessments. Over the last few years, we have increased our in-house assessment capabilities by adding a Chief Assessment Officer, a Senior Director of Assessment, and a Chief Operating Officer to our growing team. We have also expanded the number of team members working directly in program management, to keep pace with our expanding number of examinees and test administrations (more on that below).

Responding to the needs of the veterinary community, ICVA is moving from two to three annual NAVLE testing windows, beginning in mid-2025, to assist boards with individuals entering the licensure process. Beginning with the November-December 2024 administration, we have also introduced an approval option for NAVLE candidates who chose not to designate a specific licensing board to receive their test results, and have implemented a revised NAVLE retake policy to align with the best practices of assessment. Additionally, in January 2024 we streamlined the scheduling and score reporting for the Species Specific Examinations, to assist boards in verifying the competence of individuals who are already licensed.

We also continue to develop initiatives as part of our strategic priorities to provide the highest-quality assessments in a just and equitable manner to members of the veterinary community worldwide, such as our Diversity, Equity, and Inclusion Task Force, our International Activities Task Force, and our Communications Skills Assessment Task Force.

It's been a tremendous year at ICVA, and we're grateful for the hardworking volunteers, amazing staff, outstanding regulatory and academic colleagues, and candidates each doing their part to help fulfill our mission to provide world-class assessments that protect animals and humans alike.

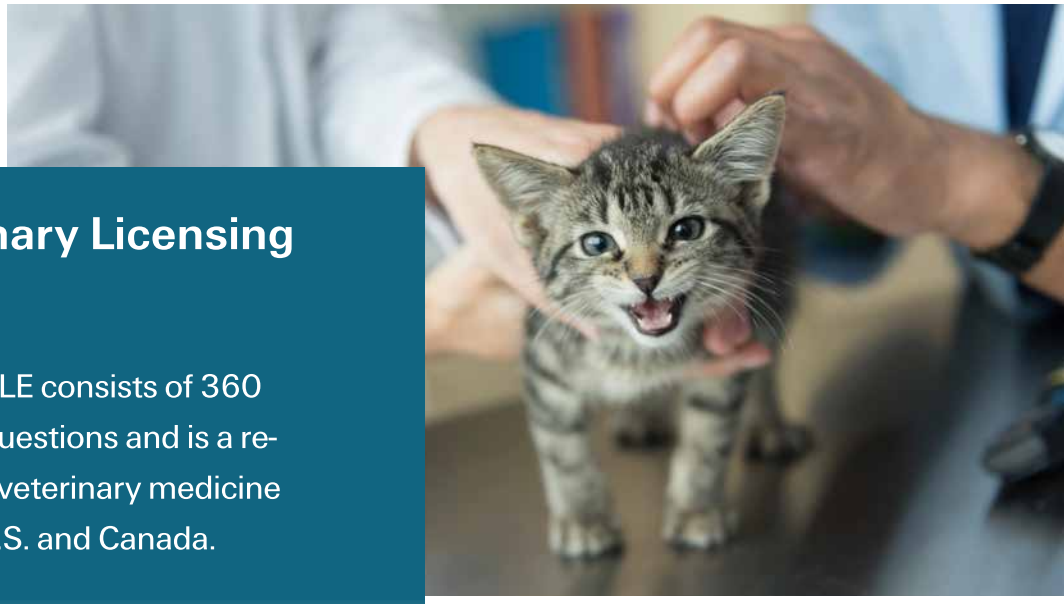
8,915

candidates took the North American Veterinary Licensing Examination® (NAVLE®) during the 2023-2024 testing cycle.

Keith Poulsen
DVM, PhD, DACVIM
ICVA Chair

Heather Case, DVM, MPH,
DACVPM, CAE
Chief Executive Officer

NAVLE®



North American Veterinary Licensing Examination (NAVLE)

Administered since 2000, the NAVLE consists of 360 clinically relevant multiple-choice questions and is a requirement for licensure to practice veterinary medicine in all licensing jurisdictions in the U.S. and Canada.

Cumulative Exam Completions by Candidates

8,915
candidates in the 2023-2024 testing cycle

101,372
total candidates have completed the exam to date

44.4%
increase in candidates in the past five years

NAVLE Fees

The 2023-2024 ICVA NAVLE application fee was $740 (USD) for candidates to take the test. For those who wanted to take the NAVLE at selected Prometric Testing Centers outside of the U.S. or Canada, there was an additional $355 (USD) international testing fee.

Ultimate Performance Passing Rate

for senior students from AVMA-accredited schools

2023-2024	2022-2023	2021-2022	2020-2021
88%	86%	90%	92%

NAVLE®

Extended Exam Window Options for Candidates

Prior to 2020, the NAVLE was typically offered twice a year – during a four- week window in November-December, and again during a two-week window in April. This provided most candidates two opportunities to pass the NAVLE before graduating from veterinary school.

Beginning with the COVID-19 pandemic, and continuing due to increasing candidate numbers, the Fall 2023 NAVLE window was expanded to over six weeks (spanning from November 1 - December 16) and the Spring 2024 NAVLE window was expanded to four weeks (from April 1 - April 26).

Performance on Fall 2023 NAVLE by Examinee Group

	Mean Scale Score	SD Scale Score	Number of Examinees Failing	Percent of Examinees Failing	Total Examinees
Criterion Group[1]	482	69	855	19.2%	4461
Non-Criterion Group[2]	427	65	534	47.1%	1133
Non-Accredited Group[3]	395	77	497	64.4%	772
Total Group	**462**	**76**	**1886**	**29.6%**	**6366**

Performance on Spring 2024 NAVLE by Examinee Group

	Mean Scale Score	SD Scale Score	Number of Examinees Failing	Percent of Examinees Failing	Total Examinees
Criterion Group[1]	448	66	119	33.8%	352
Non-Criterion Group[2]	423	53	684	48.4%	1412
Non-Accredited Group[3]	404	70	458	58.3%	785
Total Group	**420**	**62**	**1261**	**49.5%**	**2549**

Performance on Both Administrations by Examinee Group

	Mean Scale Score	SD Scale Score	Number of Examinees Failing	Percent of Examinees Failing	Total Examinees
Criterion Group[1]	480	69	974	20.2%	4813
Non-Criterion Group[2]	425	58	1218	47.9%	2545
Non-Accredited Group[3]	400	72	955	61.3%	1557
Total Group	**450**	**74**	**3147**	**35.3%**	**8915**

(1) Criterion Group: senior students of accredited veterinary schools who took the NAVLE for the first time under standard testing conditions;
(2) Non-Criterion Group: senior students of accredited veterinary schools who had previously taken the NAVLE or took the NAVLE with test accommodations or graduate veterinarians from accredited schools; and
(3) Non-Accredited Group: graduates or senior students of foreign veterinary schools that are not accredited by the American Veterinary Medical Association's Council on Education.

NAVLE®

NAVLE Communications

To handle the continued increase in inquiries from candidates, ICVA has revamped the FAQ section of the website, created an automatic reply to e-mails with helpful links with frequently-requested information, provided a NAVLE application checklist to all candidates, alerted candidates to the revised NAVLE retake policy, and successfully expanded the NAVLE dashboard to provide individualized information regarding applications.

NAVLE Approvals

The ICVA currently reviews and approves NAVLE candidates on behalf of 42 licensing boards. This service allows licensing boards to focus resources on licensing priorities.

Candidates pay an application fee to ICVA ($55 USD) and there is no cost to the licensing boards.

Beginning with the Fall 2024 NAVLE, an option is available for candidates to be approved without designating a specific licensing board to automatically receive their score report, and the revised NAVLE retake policy of five attempts has been implemented.

OUTREACH:
Dr. Elizabeth Johnson Million at Texas Tech University School of Veterinary Medicine.

Outreach to NAVLE Candidates – *The NAVLE: Why the Test Matters and What You Need to Know* Presentation

Dr. Elizabeth Johnson Million provided ICVA's *The NAVLE: Why the Test Matters and What You Need to Know* presentation at universities around the globe – including in-person presentations and discussions at Tuskegee University, Lincoln Memorial University, and the University of Tennessee, as well as presentations as an online webinar for the University of Pennsylvania, Ross University, the Ontario Veterinary College, the University of Wisconsin, Virginia Tech, The Ohio State University, Tufts University, Midwestern University, Auburn University, North Carolina State University, Oklahoma State University, Western University, Texas Tech University, Texas A&M University, Kansas State University, the University of Missouri, and the University of Minnesota.

Additionally, Dr. Million gave the presentation in-person at the SAVMA Symposium in Knoxville, Tennessee, and on three dates in March as an open online webinar with over 450 total participants from 33 countries. For each of the open webinars, time was also provided to give participants information from allied organizations of the ICVA, including one webinar with the American Veterinary Medical Association (AVMA) Educational Commission for Foreign Veterinary Graduates (ECFVG), a webinar with the Canadian National Examining Board (CNEB), and a webinar with the American Association of Veterinary State Boards (AAVSB).

Species Specific

Species Specific Examinations

In 2000, ICVA developed Species Specific examinations to evaluate veterinarians' knowledge of companion animals or equine medicine. Depending on the needs of the licensing board, veterinarians may take one or both of the examinations.

Exams assess a veterinarian's competency in disciplinary cases or provide verification of competency for a veterinarian who is licensed in another jurisdiction. The 100-item exam is only available to licensing boards, each in multiple forms that come with an ICVA-recommended passing standard.

ICVA most recently updated the Species Specific examinations through a standard setting process in 2019, implemented remote proctoring options in 2020 for easier administration, and increased flexibility for scheduling and score reporting in 2024.

State Board Examinations

Since 2016, the Wisconsin Veterinary Examination Board (VEB) has had ICVA handle the administration of their web-based Wisconsin State Laws and Rules Examination for veterinary licensure. The Wisconsin VEB provides ICVA with a list of eligible candidates, and ICVA then coordinates payment (a $50 fee), test administration, and score reporting to both the Licensing Board and to the examinee.

In 2024, ICVA implemented increased flexibility for scheduling and score reporting to assist the examinees and the board.

Volunteers

NAVLE Volunteer Opportunities

Licensing board members, academicians, current practitioners, and other subject matter experts are needed on an ongoing basis as part of ICVA's commitment to assessment quality.

Volunteer opportunities include the following:

NAVLE Item Writing: Writing items for the NAVLE in accordance with the current NAVLE blueprint.

Annual NAVLE Pool Reviews: Older NAVLE items are reviewed for accuracy and relevance.

Annual NAVLE Form Reviews: NAVLE forms are reviewed prior to use in the next testing cycle.

► LEARN MORE

If you are interested in learning more about volunteer opportunities with the ICVA, please contact our office by **clicking this link** or scanning the QR code.

"I see now the entire examination process for what it is and for all it can be. This is our opportunity as a profession to uphold the trust that veterinary consumers put in graduating professionals. I want to be a part of maintaining and adapting those standards so that community needs are met. I want to continue the torch of excellence in terms of item and form review, and developing opportunity areas for growth."

– Dr. Ryane E. Englar

"I've had, and still have, a great career as a poultry veterinarian and I wanted to give back to the veterinary community. I also served as an Associate Dean for Academic Affairs and was interested in assessments. I feel I can share these experiences to help enhance NAVLE while meeting other like-minded colleagues throughout North America."

– Dr. Teresa Y. Morishita

300+ volunteers

THANK YOU!

International Council for Veterinary Assessment

P.O. Box 1356 | Bismarck, ND 58502 USA | mail@icva.net

Outlook

Important Update on NAVLE® Retake Policy

From ICVA <mail@icva.net>
Date Tue 9/24/2024 12:59 PM
To Moss, Kelli G. (DHP) <kelli.moss@dhp.virginia.gov>

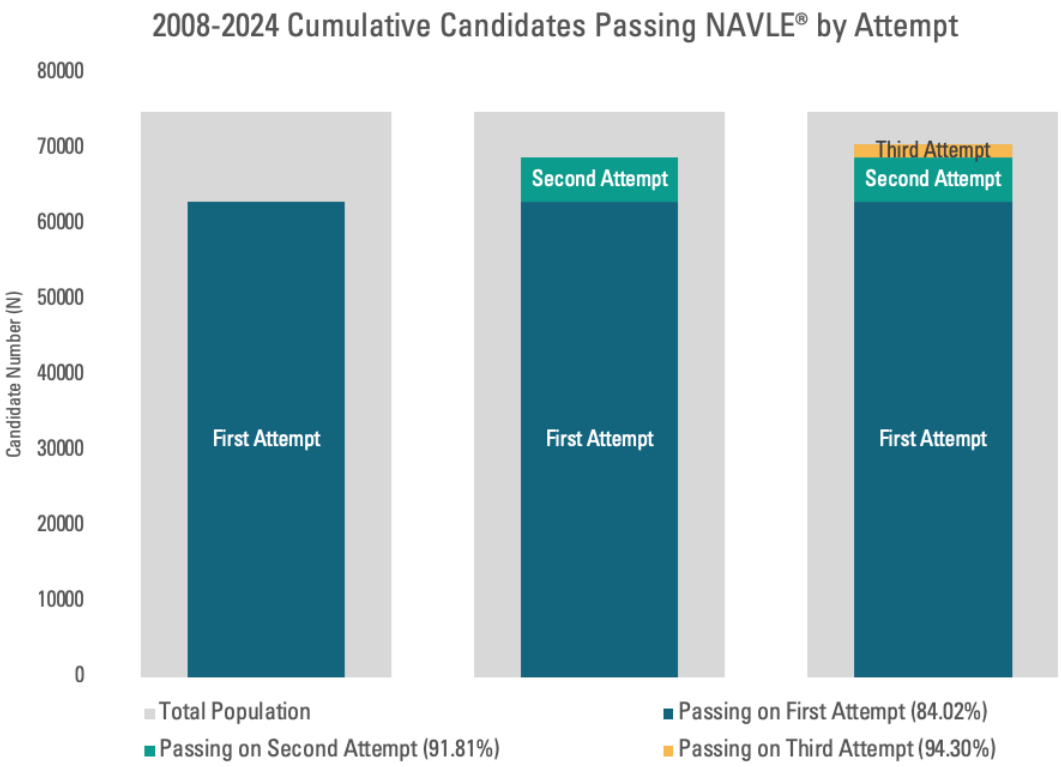
Recently, ICVA made important updates to the NAVLE® policy regarding the number of attempts candidates may take the exam.

Updated Retake Policy:

- Candidates will have the opportunity for up to **five attempts.**
- All attempts since the NAVLE® was implemented in 2000 will count toward the five-attempt limit.
- This policy applies to all candidates.
- Candidates who reach the five-attempt limit may file an appeal with the ICVA Board of Directors to request permission to take the NAVLE® beyond this limit.

Why Limit to Five Attempts?

- Aligns with best assessment practices.
- Provides ample opportunities for candidates to demonstrate their knowledge.



In the total studied population, approximately 1.5% of candidates passed after subsequent attempts not shown in the above graph

The NAVLE is designed to assist licensing boards by assessing minimal competency for initial licensure.

While ICVA supports allowing qualified candidates the opportunity to take the NAVLE, allowing unlimited retakes raises concerns. Permitting candidates to retake the NAVLE unlimited times raises concerns about whether the test score can be used to draw a valid inference of the candidate's knowledge, may cause threats to the security of the NAVLE, and may introduce potential risks related to animal welfare and public protection if the candidate were to be licensed to practice veterinary medicine.

If you have any questions or need further clarification regarding the updated policy, please don't hesitate to contact us at appeals@icva.net.

International Council for Veterinary Assessment

Our mailing address is:
P.O. Box 1356 | Bismarck, ND 58502 USA | 701.224.0332

www.icva.net

International Council for Veterinary Assessment

NAVLE

Retake Policy

Appeal Form

The only exception to the eligibility requirements will be at the explicit request through a United States or Canadian licensing/registration authority. ICVA will accept an appeal to the policy for a maximum of ONE additional attempt that includes an attestation of eligibility from a licensing/registration board on behalf of a candidate who is seeking licensure/registration in that jurisdiction.

CANDIDATE SECTION (Candidate must complete and then send to JURISDICTION for attempt limit appeals)			
Candidate Name:			
Current Email Address:			
If you have previously taken NAVLE under another name, enter that name here:			
ICVAID:		Date of Birth (MM/DD/YY):	
Veterinary School Name:		Graduation Year:	
Jurisdiction in which you intend to seek licensure/ registration:		Have you previously been approved to take NAVLE by this jurisdiction:	
Current Residence:			
How many times have you taken NAVLE?			
Dates and Scores for Previous NAVLE Attempts (attach additional documentation if necessary):	Date	Score	

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Reason for Appeal (attach additional documentation, if necessary):

Candidate Attestation:

I certify that the information provided on this form is true, accurate, and complete. I acknowledge that ICVA may verify the information included on this form and I understand that if I provide any false information, the jurisdiction may be notified, my appeal may be denied and I may be referred to the committee on irregular behavior.

Name: _____

Signature: _____ Date: _____

CANDIDATES APPEALING THE RETAKE POLICY – Contact the jurisdiction where you intend to seek licensure/registration to inquire as to the correct person to complete the attestation below.

JURISDICTION SECTION (To be completed by Administrator or Board Chair)	
Have you had any previous interactions with this candidate?	
Do you have any evidence that the candidate intends to practice in your jurisdiction?	
Does your jurisdiction have a remediation requirement after a specified number of attempts?	
Jurisdiction Position on ICVA's Retake Policy	
□	Jurisdiction has adopted ICVA's retake policy
□	Jurisdiction law requires an additional attempt be granted
	Citation:
□	Jurisdiction does not have a law related to attempts, but will permit an additional attempt
□	Jurisdiction has adopted a different retake policy or law (Describe and include citation, if applicable):

Licensing Authority/National Examining Board Attestation:

I have reviewed the individual's prior examination history. The candidate would be eligible for licensure/registration in this jurisdiction if they passed the NAVLE after more than five attempts and go on to meet all other licensure/registration requirements. I certify that I am authorized to provide this attestation on behalf of the veterinary licensing /registration authority.

Name: _____ Signature: _____

Title: _____ Date: _____

Jurisdiction: _____

JURISDICTIONS - PLEASE EMAIL THIS FORM TO appeals@icva.net at least 30 days prior to the close of the application widow.

- Appeals to ICVA will be reviewed within 30 days of submission.
- The candidate will then have 1 year from the date of the decision to apply to retake the NAVLE.
- Successful appeals will result in one additional attempt to pass the NAVLE.

Veterinary Medicine Monthly Snapshot for August 2024

Veterinary Medicine closed more cases in August than received. Veterinary Medicine closed 15 patient care cases and 11 non-patient care cases for a total of 26 cases.

Cases Closed	
Patient Care	15
Non-Patient Care	11
Total	**26**

Veterinary Medicine has received 15 patient care cases and 6 non-patient care cases for a total of 21 cases.

Cases Received	
Patient Care	15
Non-Patient Care	6
Total	**21**

As of August 31, 2024, there were 153 patient care cases open and 95 non-patient care cases open for a total of 248 cases.

Cases Open	
Patient Care	153
Non-Patient Care	95
Total	**248**

There are 9,459 Veterinary Medicine licensees as of August 31, 2024. The number of current licenses are broken down by profession in the following chart.

Current Licenses	
Equine Dental Technician	22
Veterinarian	5,146
Veterinary Establishment - Ambulatory	329
Veterinary Establishment - Stationary	1,004
Veterinary Faculty	116
Veterinary Intern/Resident	40
Veterinary Technician	2,802
Total for Veterinary Medicine	**9,459**

There are 81 licenses issued for Veterinary Medicine for the month of August. The number of current licenses are broken down by profession in the following chart.

Licenses Issued	
Equine Dental Technician	1
Veterinarian	24
Veterinary Establishment - Ambulatory	3
Veterinary Establishment - Stationary	4

Veterinary Faculty	1
Veterinary Intern/Resident	1
Veterinary Technician	47
Total for Veterinary Medicine	**81**

VIRGINIA BOARD OF VETERINARY MEDICINE
BYLAWS

Article I. Officers of the Board.

A. Election of officers.

1. The officers of the Board of Veterinary Medicine shall be a President, a Vice-President and a Secretary. At the last regularly scheduled meeting of the calendar year, the board shall elect its officers. Nominations for office shall be selected by open ballot, and election shall require a majority of the members present.

2. The term of office shall be one year from January 1 to December 31; a person may serve in the same office for one additional term.

3. A vacancy occurring in any office shall be filled during the next meeting of the board.

B. Duties of the officers

1. President.

The President shall preside at all meetings and formal administrative hearings in accordance with parliamentary rules and the Administrative Process Act, and requires adherence of it on the part of the board members. The President shall appoint all committees unless otherwise ordered by the board.

2. Vice-President.

The Vice-President shall, in the absence or incapacity of the President, perform pro tempore all of the duties of the President.

3. Secretary.

The Secretary shall perform generally all the duties necessary and usually pertaining to such office

4. In the absence of the President, Vice-President and Secretary, the President shall appoint another board member to preside at the meeting and/or formal administrative hearing.

5. The Executive Director shall be the custodian of all board records and all papers of value. The Executive Director shall preserve a correct list of all applicants and licensees. The

Executive Director shall manage the correspondence of the board and shall perform all such other duties as naturally pertain to this position.

Article II. Meetings.

A. Number and organization of meetings.

1. For purposes of these bylaws, the board shall schedule at least three full board meetings in each year, with the right to change the date or cancel any board meeting; with the exception that one meeting shall take place annually.

2. A majority of the members of the board shall constitute a quorum for the transaction of business. The current edition of Robert's Rules of Order, revised, shall apply unless overruled by these bylaws or when otherwise agreed.

B. Attendance of board members.

Members shall attend all scheduled meetings of the board and committee to which they serve, unless prevented by illness or similar unavoidable cause. In the event of two consecutive unexcused absences at any meeting of the board or its committees, the President shall make a recommendation about the board member's continued service to the Director of the Department of Health Professions for referral to the Secretary of Health and Human Resources and Secretary of the Commonwealth.

C. Order of business. The order of the business shall be as follows:

1. Call to order with statement made for the record of how many and which board members are present and that it constitutes a quorum.

2. Public comment.

3. Approval of minutes.

4. The Executive Director and the President shall collaborate on the remainder of the agenda.

Article III. Committees.

A. Standing Committees:

1. Special Conference Committee.

This committee shall consist of two board members who shall review information regarding alleged violations of the veterinary medicine laws and regulations and determine if probable cause exists to proceed with possible disciplinary action. The President shall also designate

another board member as an alternate on this committee in the event one of the standing committee members becomes ill or is unable to attend a scheduled conference date. Further, should the caseload increase to the level that additional special conference committees are needed, the President may appoint additional committees.

2. Regulatory/Legislative Committee.

The committee shall consist of at least three board members. The board delegates to the Regulatory/Legislative Committee to recommend actions to petitions for rulemaking. This committee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the drafting of board responses to public comment as required in conjunction with rulemaking; conducting the required review of all existing regulations as required by the board's Public Participation Guidelines and any Executive Order of the Governor, and other required tasks related to regulations. In accordance with the Administrative Process Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full board prior to publication. The board delegates the authority to develop proposals for legislative initiatives of the board. Any proposed draft legislation and response to public comment shall be reviewed and approved by the full board prior to publication.

3. Credentials Committee.

The committee shall consist of two board members. The members of the committee may review non-routine licensure applications to determine the credentials of the applicant and the applicability of the statutes and regulations when the Board President deems necessary. The committee shall not be required to meet collectively.

B. Ad hoc committees

There may be ad hoc committees, appointed as needed and shall consist of three or more persons appointed by the board who are knowledgeable in the particular area of practice or education under consideration by the board. The committee shall review matters as requested by the board and advise the board relative to the matters or make recommendations for consideration by the board.

Article IV. General Delegation of Authority.

A. The Board delegates to board staff the authority to issue and renew licenses and registrations for which statutory and regulatory qualifications have been met.

B. The Board delegates to the Executive Director the authority to reinstate a license or registration when the reinstatement is due to the lapse of the license or registration rather than a disciplinary action and there is no basis upon which the Board could refuse to reinstate.

C. The Board delegates to board staff the authority to develop, approve and update information on forms used in the daily operations of board business, to include, but not limited to, licensure

applications, renewal forms, inspection forms and documents used in the disciplinary process. The Executive Director shall consult with the board President prior to posting inspection form changes.

D. The Board delegates authority to the Executive Director to negotiate a Consent Order in consultation with the chair of a Special Conference Committee or formal hearing.

E. The Board delegates to the Executive Director the authority to sign as entered any Order or Consent Order resulting from the disciplinary process or other administrative proceeding.

F. The Board delegates to the Executive Director, who may consult with a special conference committee member, the authority to provide guidance to the agency's Enforcement Division in situations wherein a complaint is of questionable jurisdiction and an investigation may not be necessary.

G. The Board delegates to the Executive Director the authority to review information regarding alleged violations of law or regulations and, in consultation with a member of a special conference committee, make a determination as to whether probable cause exists to proceed with possible disciplinary action.

H. The Board delegates authority to the Executive Director to close non-jurisdictional cases and fee disputes cases without review by a board member.

I. The Board delegates authority to the Executive Director to grant an extension for good cause of up to one year for the completion of continuing education requirements upon written request from the licensee or registrant prior to the renewal date.

J. The Board delegates authority to the Executive Director to grant an exemption for all or part of the continuing education requirements due to circumstances beyond the control of the licensee or registrant, such as temporary disability, mandatory military service, or officially declared disasters.

K. The Board delegates authority to the Executive Director to issue an advisory letter, offer a confidential consent agreement or offer a Consent Order for action consistent with any board-approved guidance document.

L. The Board delegates to the President the authority to represent the board in instances where board "consultation" or "review" may be requested where a vote of the board is not required, and a meeting is not feasible.

M. The Board delegates to the Department of Health Professions' inspectors the authority to issue an Inspection Summary upon completion of an inspection, and the Board delegates to the Executive Director the authority to take action consistent with any board-approved guidance document related to inspection violations.

N. The Board delegates to the Executive Director the authority to grant an accommodation of additional testing time or other requests for accommodation to candidates for Board-required examinations pursuant to the Americans with Disabilities Act, provided the candidate provides documentation that supports such an accommodation.

O. The Board delegates authority to the Executive Director to issue an Advisory Letter to the person who is the subject of a complaint pursuant to Va. Code § 54.1-2400.2(F), when it is determined that a probable cause review indicates a disciplinary proceeding will not be instituted.

P. The Board delegates authority to the Executive Director to request and accept from a licensee or registrant, in lieu of disciplinary action, a Confidential Consent Agreement, pursuant to Va. Code § 54.1-2400(14), consistent with any guidance documents adopted by the Board.

Q. The Board delegates authority to the Executive Director or designee to make probable cause decisions for cases involving the following:

- Impairment;
- Diversion;
- Failure to maintain drugs in a secure manner;
- Inspections;
- Compliance with Board Orders;
- PMP reporting;
- Compliance with continuing education requirements;
- Unlicensed activity;
- Aiding and abetting unlicensed activity;
- Fraud;
- Unprofessional conduct for failure to release records; and
- Compliance with medical recordkeeping requirements.

R. The Board delegates authority to the Executive Director or designee to make investigation decisions for cases involving the following:

- Lack of evidence to proceed; and
- Reports of drug theft and loss

Article V. Amendments.

Proposed amendments to these bylaws shall be presented in writing to all Board members, the Executive Director of the Board, and the Board's legal counsel prior to any regularly scheduled Board meeting. Amendments to the bylaws shall become effective with a favorable vote of at least two-thirds of the board members present at that regular meeting.

BOARD OF VETERINARY MEDICINE

2025 CALENDAR

February 12, 2025 (Wednesday)	TR 2 HR 1 & 3 9:00 AM	INFORMAL CONFERENCES
MARCH 11, 2025 (Tuesday)	**BR 3** **9:00 AM**	**BOARD MEETING** **FORMAL HEARING, IF NEEDED**
April 17, 2025 (Thursday)	TR 1 HR 2 & 4 9:00 AM	INFORMAL CONFERENCES
June 19, 2025 (Thursday)	TR 1 HR 2 & 4 9:00 AM	INFORMAL CONFERENCES
JULY 29, 2025 (Tuesday)	**BR 4** **9:00 AM**	**BOARD MEETING** **FORMAL HEARING, IF NEEDED**
September 9, 2025 (Tuesday)	TR 2 HR 1 & 3 9:00 AM	INFORMAL CONFERENCES
OCTOBER 21, 2025 (Tuesday)	**BR 4** **9:00 AM**	**BOARD MEETING** **FORMAL HEARING, IF NEEDED**
NOVEMBER 4, 2025 (Tuesday)	BR 1 HR 2 & 4 9:00 AM	INFORMAL CONFERENCES
December 10, 2025 (Wednesday)	BR 1 HR 1 & 6 9:00 AM	INFORMAL CONFERENCES

CALENDAR_2025