#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 723 Medical Treatment of Animals **SPONSOR(S):** Regulatory Reform Subcommittee, Buchanan

TIED BILLS: IDEN./SIM. BILLS: SB 448

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Regulatory Reform Subcommittee	17 Y, 0 N, As CS	Thompson	Anstead
2) Commerce Committee			

#### **SUMMARY ANALYSIS**

In Florida, the practice of "veterinary medicine" means the diagnosis of medical conditions of animals, and the prescribing or administering of medicine and treatment to animals for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease. Veterinarians are regulated by the Board of Veterinary Medicine (Board) in the Department of Business and Professional Regulation (DBPR) pursuant to ch. 474, F.S., relating to veterinary medical practice (practice act). The purpose of the practice act is to ensure that every veterinarian practicing in this state meets minimum requirements for safe practice to protect public health and safety.

Current law defines a "veterinarian/client/patient relationship" (VCPR) as one in which a veterinarian has assumed responsibility for making medical judgments about the health of an animal and its need for medical treatment. Veterinarians are permitted to prescribe drugs in the course of veterinary practice; however, the veterinarian must be either personally acquainted with the keeping and caring of the animal and have recently seen the animal, or have made medically appropriate and timely visits to the premises where the animal is kept before prescribing drugs in the course of practice.

The use of electronic communications to facilitate patient health care (telemedicine) is not addressed in the practice act and is not specifically prohibited or authorized in Florida. However, medical doctors may practice telemedicine in Florida and may establish a patient relationship with a patient evaluation via telemedicine under certain circumstances.

#### The bill:

- Establishes a framework for the practice of veterinary telemedicine.
- Limits a veterinarian's ability to prescribe controlled substances while practicing telemedicine to situations where:
  - The veterinarian has previously performed an in-person physical examination or made medically appropriate and timely visits to the premises where the animal is kept; or
  - The veterinarian is treating a terminal patient transferred to the veterinarian for hospice care by a veterinarian who previously performed an in-person physical examination of the patient and such veterinarian has reviewed the patient's medical records.
- Specifies that only Florida licensed veterinarians may practice veterinary telemedicine, and grants the Board jurisdiction over the practice of veterinary telemedicine.
- Allows an animal control authority under the "indirect supervision" of a veterinarian to administer rabies vaccinations.

The bill is not expected to have a fiscal impact on state or local government, and may have a positive fiscal impact on the private sector.

The bill provides an effective date of July 1, 2022.

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

## A. EFFECT OF PROPOSED CHANGES:

## **Current Situation**

## **Practice of Veterinary Medicine**

The Board of Veterinary Medicine (Board) in the Department of Business and Professional Regulation (DBPR) implements the provisions of ch. 474, F.S., relating to veterinary medical practice (practice act). The purpose of the practice act is to ensure that every veterinarian practicing in this state meets minimum requirements for safe practice to protect public health and safety.<sup>1</sup>

A "veterinarian" is a health care practitioner licensed by the Board to engage in the practice of veterinary medicine in Florida<sup>2</sup> and subject to disciplinary action from the Board for various violations of the practice act.<sup>3</sup>

The practice of "veterinary medicine" is the diagnosis of medical conditions of animals, and the prescribing or administering of medicine and treatment to animals for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease, or holding oneself out as performing any of these functions.<sup>4</sup>

Veterinary medicine includes, with respect to animals:5

- Surgery;
- Acupuncture;
- Obstetrics;
- Dentistry;
- Physical therapy;
- Radiology;
- Theriogenology (reproductive medicine);<sup>6</sup> and
- Other branches or specialties of veterinary medicine.

The practice act does not apply to the following categories of persons:

- Veterinary aides, nurses, laboratory technicians, preceptors,<sup>7</sup> or other employees of a licensed veterinarian, who administer medication or provide help or support under the responsible supervision<sup>8</sup> of a licensed veterinarian;
- Certain non-Florida licensed veterinarians who are consulting upon request of a Florida-licensed veterinarian on the treatment of a specific animal or on the treatment on a specific case of the animals of a single owner.
- Faculty veterinarians when they have assigned teaching duties at accredited<sup>9</sup> institutions;
- Certain graduated intern/resident veterinarians of accredited institutions;

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<sup>&</sup>lt;sup>1</sup> S. 474.201, F.S.

<sup>&</sup>lt;sup>2</sup> S. 474.202(11), F.S.

<sup>&</sup>lt;sup>3</sup> Ss. 474.213 & 474.214, F.S.

<sup>&</sup>lt;sup>4</sup> See s. 474.202(9), F.S. Also included is the determination of the health, fitness, or soundness of an animal, and the performance of any manual procedure for the diagnosis or treatment of pregnancy or fertility or infertility of animals.

<sup>&</sup>lt;sup>5</sup> See s. 474.202(13), F.S. Section 474.202(1), F.S., which defines "animal" as "any mammal other than a human being or any bird, amphibian, fish, or reptile, wild or domestic, living or dead."

<sup>&</sup>lt;sup>6</sup> The Society for Theriogenology, established in 1954, is composed of veterinarians dedicated to standards of excellence in animal reproduction. *See* <a href="https://www.therio.org/">https://www.therio.org/</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>7</sup> A preceptor is a skilled practitioner or faculty member who directs, teaches, supervises, and evaluates students in a clinical setting to allow practical experience with patients. *See also* <a href="https://www.merriam-webster.com/dictionary/preceptor#medicalDictionary">https://www.merriam-webster.com/dictionary/preceptor#medicalDictionary</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>8</sup> The term "responsible supervision" is defined in s. 474.202(10), F.S., as the "control, direction, and regulation by a licensed doctor of veterinary medicine of the duties involving veterinary services" delegated to unlicensed personnel.

<sup>&</sup>lt;sup>9</sup> Ss. 474.203(1) and (2), F.S., provide that accreditation of a school or college must be granted by the American Veterinary Medical Association (AVMA) Council on Education, or the AVMA Commission for Foreign Veterinary Graduates.

- Certain students in a school or college of veterinary medicine who perform assigned duties by an instructor or work as preceptors;
- Certain doctors of veterinary medicine employed by a state agency or the United States Government;
- Persons or their employees caring for the persons' own animals, as well as certain part-time or temporary employees, or independent contractors, who are hired by an owner to help with herd management and animal husbandry tasks; and
- Certain entities or persons<sup>10</sup> that conduct experiments and scientific research on animals as part
  of the development of pharmaceuticals, biologicals, serums, or treatment methods of treatment
  or techniques to diagnose or treatment of human ailments, or in the study and development of
  methods and techniques applicable to the practice of veterinary medicine.<sup>11</sup>

Any permanent or mobile establishment where a licensed veterinarian practices must have a premises permit issued by DBPR.<sup>12</sup> Each person to whom a veterinary license or premises permit is issued must conspicuously display such document in her or his office, place of business, or place of employment in a permanent or mobile veterinary establishment or clinic.<sup>13</sup>

By virtue of accepting a license to practice veterinary medicine in Florida, a veterinarian consents to:

- Render a handwriting sample to an agent of the department and, further, to have waived any
  objections to its use as evidence against her or him.
- Waive the confidentiality and authorize the preparation and release of medical reports
  pertaining to the mental or physical condition of the licensee when the department has reason
  to believe that a violation of this chapter has occurred and when the department issues an
  order, based on the need for additional information, to produce such medical reports for the time
  period relevant to the complaint.<sup>14</sup>

For Fiscal Year 2020-2021, there were 12,156 actively licensed veterinarians in Florida. DBPR received 472 complaints, which resulted in 17 disciplinary actions.<sup>15</sup>

# **Veterinarian/Client/Patient Relationship**

The practice act defines a "patient" as any animal for which the veterinarian practices veterinary medicine. 16

The practice act defines a "veterinarian/client/patient relationship" (VCPR) as one in which a veterinarian has assumed responsibility for making medical judgments about the health of an animal and its need for medical treatment.<sup>17</sup>

Veterinarians are permitted to prescribe drugs in the course of veterinary practice, but may be disciplined by the Board for certain related violations, including ordering, prescribing, or making available medicinal drugs or drugs<sup>18</sup> or controlled substances<sup>19</sup> for use other than for the specific treatment of animal patients for which there is a documented VCPR and without:

Having sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis
of the medical condition of the animal, which means that the veterinarian is personally

<sup>&</sup>lt;sup>10</sup> See s. 474.203(6), F.S., which states that the exemption applies to "[s]tate agencies, accredited schools, institutions, foundations, business corporations or associations, physicians licensed to practice medicine and surgery in all its branches, graduate doc tors of veterinary medicine, or persons under the direct supervision thereof. . . ."

<sup>&</sup>lt;sup>11</sup> See s. 474.203, F.S.

<sup>&</sup>lt;sup>12</sup> S. 474.215(1), F.S.

<sup>&</sup>lt;sup>13</sup> S. 474.216, F.S.

<sup>&</sup>lt;sup>14</sup> S. 474.2185, F.S.

<sup>&</sup>lt;sup>15</sup> Department of Business and Professional Regulation, *Division of Professions Annual Report Fiscal Year* 2020-2021, <a href="http://www.myfloridalicense.com/DBPR/os/documents/DivisionAnnualReport FY2021.pdf">http://www.myfloridalicense.com/DBPR/os/documents/DivisionAnnualReport FY2021.pdf</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>16</sup> S. 474.202(8), F.S.

<sup>&</sup>lt;sup>17</sup> S. 474.202(12), F.S.

<sup>&</sup>lt;sup>18</sup> S. 465.003(8), F.S.

<sup>&</sup>lt;sup>19</sup> S. 893.02(4), F.S.

- acquainted with the keeping and caring of the animal and has recently seen the animal or has made medically appropriate and timely visits to the premises where the animal is kept;
- Being available to provide for follow-up care and treatment in case of adverse reactions or failure of the regimen of therapy; and
- Maintaining records which document patient visits, diagnosis, treatment, and other relevant information required under the practice act.<sup>20</sup>

## **Veterinary Telemedicine**

The use of electronic communications to facilitate patient health care (telemedicine) is not addressed in the practice act and is not specifically prohibited or authorized for practitioners of veterinary medicine in Florida.<sup>21</sup>

# **Veterinary Telemedicine During the Pandemic**

On March 24, 2020, the U.S. Food and Drug Administration (FDA) announced that it would temporarily suspend enforcement of certain prescription limitations in order to allow veterinarians to better utilize telemedicine to address animal health needs during the COVID-19 pandemic. Specifically, the FDA has provided guidance related to suspending the enforcement of the animal examination and premises visit VCPR requirements relevant to FDA regulations governing **Extralabel Drug Use in Animals**<sup>22</sup> and **Veterinary Feed Directive Drugs**.<sup>23</sup> This allows veterinarians to prescribe or authorize the use of drugs without direct examination or making visits to patients, which will limit human-to-human interaction and potential spread of COVID-19 in the community.<sup>24</sup>

According to the FDA, veterinarians are licensed by their state veterinary licensing board and must meet the requirements of the licensing board to practice in that state. FDA regulates the devices and drugs that veterinarians use, and the conditions under which veterinarians may **prescribe drugs for extra-label uses**. When an approved drug is used in a manner other than what is stated on the label, it is an extra-label use. This is commonly called an "off-label" use because the drug is used in a way that is "off the label."

On March 27, 2020, DBPR issued emergency order EO 2020-04, which suspends any restriction of ch. 474, F.S., or ch. 61G-18, F.A.C., which would prohibit an active Florida-licensed veterinarian from practicing telemedicine on a patient. The order specifies that attending veterinarians must be comfortable assessing the patient remotely and feel able to exercise good clinical judgment to assist the patient.<sup>26</sup> The emergency order ended with the expiration of Florida's COVID-19 state of emergency (EO 20-52) on Saturday June 26, 2021.<sup>27</sup>

### **Veterinary Telemedicine in Other States**

The use of telemedicine by veterinarians varies by state. Some states allow telemedicine to be used at the veterinarian's discretion, others allow it after the establishment of a VCPR, some do not allow it at

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<sup>&</sup>lt;sup>20</sup> S. 474.214(1)(v)., F.S.

<sup>&</sup>lt;sup>21</sup> R. 64B8-9.0141, F.A.C. Currently, medical doctors may practice telemedicine in Florida in a patient relationship with a patient evaluation, under certain circumstances.

<sup>&</sup>lt;sup>22</sup> 21 C.F.R. part 530.

<sup>&</sup>lt;sup>23</sup> 21 C.F.R. § 558.6.

<sup>&</sup>lt;sup>24</sup> U.S. Food and Drug Administration, *Coronavirus* (*COVID-19*) *Update: FDA Helps Facilitate Veterinary Telemedicine During Pandemic*, <a href="https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-helps-facilitate-veterinary-telemedicine-during-pandemic">https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-helps-facilitate-veterinary-telemedicine-during-pandemic</a> (last visited Jan. 25, 2022).

<sup>&</sup>lt;sup>25</sup> .S. Food and Drug Administration, *What FDA Does and Does Not Regulate*, <a href="https://www.fda.gov/animal-veterinary/animal-health-literacy/what-fda-does-and-does-not-regulate#top">https://www.fda.gov/animal-veterinary/animal-health-literacy/what-fda-does-and-does-not-regulate#top</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>26</sup> Department of Business and Professional Regulation, *Emergency Order EO 2020-04*, Mar. 27, 2020, <a href="http://www.myfloridalicense.com/dbpr/os/documents/EO 2020-04.pdf">http://www.myfloridalicense.com/dbpr/os/documents/EO 2020-04.pdf</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>27</sup> On March 9, 2020, Governor DeSantis issued Executive Order 20-52 which declared a state of emergency for the entire state due to COVID-19. The Executive Order was extended several times. Executive Order 21-94 extended the state of emergency for sixty days from April 27, 2021. The sixtieth day was Saturday June 26, 2021, and the order was not renewed by the Governor.

all, and others limit telemedicine for purposes of prescribing medication or controlled substances.

Virginia allows veterinarians to practice telemedicine. In addition, it allows a veterinarian who performs or has performed an appropriate examination of a patient to prescribe certain controlled substances to a patient via the practice of telemedicine. The Virginia Board of Veterinary Medicine adopted guidance effective September 17, 2020, for telehealth in the practice of veterinary medicine, which indicates that:

"Using telehealth technologies in veterinary practice is considered a method of service delivery. The current, applicable regulations apply to all methods of service delivery, including telehealth. The licensee is responsible for using professional judgment to determine if the type of service can be delivered via telehealth at the same standard of care as in-person service." 28

The Idaho Board of Veterinary Medicine provides the following guidance on telehealth:

"The veterinarian must employ sound profession judgment to determine whether using Telehealth is appropriate in particular circumstances each and every time animal care is provided and only provide medical advice or treatment via Telehealth to the extent that it is possible without a hands on examination. A veterinarian using Telehealth must take appropriate steps to obtain Informed Consent, establish the VCPR and conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation. As such, some situations and patient presentations are appropriate for the utilization of Telehealth as a component of, or in lieu of, hands on medical care, while others are not."

The state of Oklahoma only allows a veterinarian to prescribe drugs via telemedicine under the following conditions:

"The veterinarian accepts that he or she cannot prescribe drugs when practicing via telehealth alone, unless the veterinarian has sufficient knowledge of the animal or group of animals by virtue of a history and inquiry, and either physical examination or medically appropriate and timely visits to the premises where the animal or group of animals is kept." 30

The state of Washington only allows telemedicine after a VCPR has been established:

"The veterinarian shall not establish a veterinary-client-patient relationship solely by telephonic or other electronic means. However, once established, a veterinary-client-patient relationship may be maintained between medically necessary examinations via telephone or other types of consultations." <sup>31</sup>

Michigan recently repealed the need for an **in-person** exam prior to practicing telemedicine. Effective April 15, 2021, a veterinarian providing a "telehealth service" is required to have sufficient knowledge of the animal patient by having recently examined the animal patient in person or obtained current knowledge of the animal patient through the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, or have conducted medically appropriate and timely visits to the premises where the group of animal patients is kept.<sup>32</sup>

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<sup>&</sup>lt;sup>28</sup> Virginia Board of Veterinary Medicine, *Guidance for Telehealth in the Practice of Veterinary Medicine, Guidance Document: 150-25*, https://www.dhp.virginia.gov/media/dhpweb/docs/vet/guidance/150-25.pdf (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>29</sup> Idaho Veterinary Medical Association, *State specific questions for Idaho – Essential services, taxes, telehealth, IDAHO BOARD OF VETERINARY MEDICINE – TELEMEDICINE STATEMENT*, <a href="https://www.ivma.org/2020/03/26/idaho-essential-services-extended-tax-filing-deadline/">https://www.ivma.org/2020/03/26/idaho-essential-services-extended-tax-filing-deadline/</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>30</sup> Oklahoma State Board of Veterinary Medical Examiners, Board Telemedicine/Telehealth Position Statement, <a href="https://www.okvetboard.com/veterinarian-faq/95-board-telemedicine-telehealth-position-statement">https://www.okvetboard.com/veterinarian-faq/95-board-telemedicine-telehealth-position-statement</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>31</sup> Wash. Rev. Code § 246-933-200(2).

<sup>&</sup>lt;sup>32</sup> Mich. Gen. R. 338.4901a.
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#### Florida Telehealth for Medical Doctors

Effective July 1, 2019,<sup>33</sup> Florida law authorizes Florida-licensed health care providers<sup>34</sup> to use "telehealth" to deliver health care services within their respective scopes of practice.<sup>35</sup> The law also authorizes out-of-state health care providers to use telehealth to deliver health care services to Florida patients if they register with the Department of Health (DOH) or the applicable board<sup>36</sup> and meet certain eligibility requirements.<sup>37</sup> A registered out-of-state telehealth provider may use telehealth, within the relevant scope of practice established by Florida law and rule, to provide health care services to Florida patients but is prohibited from opening an office in Florida and from providing in-person health care services to patients located in Florida.

On March 16, 2020, Surgeon General Scott Rivkees executed DOH Emergency Order 20-002 authorizing certain out-of-state physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses to provide telehealth in Florida without the need to register as a telehealth provider under s. 456.47(4), F.S.<sup>38</sup> This emergency order ended with the expiration of Florida's COVID-19 state of emergency (EO 20-52) on June 26, 2021.<sup>39</sup>

The Surgeon General also executed DOH Emergency Order 20-003<sup>40</sup> authorizing certain out-of-state clinical social workers, marriage and family therapists, mental health counselors, and psychologists to provide telehealth in Florida without the need to register as a telehealth provider under s. 456.47(4), F.S. This emergency order also ended on June 26, 2021.<sup>41</sup>

#### **Controlled Substances**

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. The scheduling of substances in Florida law is generally consistent with the federal scheduling of substances under 21 U.S.C. s. 812:

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples include heroin and lysergic acid diethylamide (LSD).
- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples include cocaine and morphine.
- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples include lysergic acid; ketamine; and some anabolic steroids.

<sup>35</sup> See also s. 394.453(3), F.S. The Florida Mental Health Act (popularly known as "The Baker Act," s. 394.451, F.S.), contains a legislative finding that "the use of telemedicine for patient evaluation, case management, and ongoing care will improve management of patient care and reduce costs of transportation."

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<sup>&</sup>lt;sup>33</sup> Chapter 2019-137, s. 6, Laws of Fla.

<sup>&</sup>lt;sup>34</sup> S. 456.47(1)(b), F.S.

<sup>&</sup>lt;sup>36</sup> Under s. 456.001(1), F.S., the term "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH's Division of Medical Quality Assurance.

<sup>&</sup>lt;sup>37</sup> Section 456.47(4), F.S.

<sup>&</sup>lt;sup>38</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-002* (Mar. 16, 2020) <a href="http://floridahealthcovid19.gov/wp-content/uploads/2020/03/filed-eo-doh-no.-20-002-medical-professionals-03.16.2020.pdf">http://floridahealthcovid19.gov/wp-content/uploads/2020/03/filed-eo-doh-no.-20-002-medical-professionals-03.16.2020.pdf</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>39</sup> On March 9, 2020, Governor DeSantis issued Executive Order 20-52 which declared a state of emergency for the entire state due to COVID-19. The Executive Order was extended several times. Executive Order 21-94 extended the state of emergency for sixty days from April 27, 2021. The sixtieth day was Saturday June 26, 2021, and the order was not renewed by the Governor.

<sup>&</sup>lt;sup>40</sup> Department of Health, State of Florida, *Emergency Order DOH No. 20-003* (Mar. 21, 2020) <a href="https://s33330.pcdn.co/wpcontent/uploads/2020/03/DOH-EO-20-003-3.21.2020.pdf">https://s33330.pcdn.co/wpcontent/uploads/2020/03/DOH-EO-20-003-3.21.2020.pdf</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>41</sup> On March 9, 2020, Governor DeSantis issued Executive Order 20-52 which declared a state of emergency for the entire state due to COVID-19. The Executive Order was extended several times. Executive Order 21-94 extended the state of emergency for sixty days from April 27, 2021. The sixtieth day was Saturday June 26, 2021, and the order was not renewed by the Governor.

- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples include alprazolam, diazepam, and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples include low dosage levels of codeine, certain stimulants, and certain narcotic compounds.

# **Prescription Drug Law for Medical Doctors**

Section 456.44, F.S., limits the authorization to prescribe only a three-day supply of a Schedule II opioid<sup>42</sup> or up to a seven-day supply if medically necessary. The prescribing limits on Schedule II opioids do not apply to prescriptions for acute pains related to: cancer, a terminal condition, pain treated with palliative care, or a traumatic injury with an Injury Severity Score of 9 or higher.<sup>43</sup> A prescriber and dispenser must also report to and review the Prescription Drug Monitoring Program database to review a patient's controlled substance dispensing history prior to prescribing or dispensing a Schedule II-IV controlled substance for patients 16 years older. 44 These limitations and requirements apply to practitioners providing services in-person and through telehealth.

Section 456.47(2)(c), F.S., prohibits telehealth providers from prescribing any controlled substance unless the controlled substance is prescribed for:

- The treatment of a psychiatric disorder:
- Inpatient treatment at a licensed hospital:
- The treatment of a patient receiving hospice services; or
- The treatment of a resident of a nursing home facility.

According to a study published by the University of Florida College of Pharmacy, 45 the "2018 Florida law restricting opioid prescriptions for acute pain has led to a drop in opioid use." Specifically, the study "found the number of new opioid users per month dropped 16 percent immediately after the law was implemented, and the number of new users continues to decrease each month. Additionally, the average days' supply fell from 5.4 days prior to the law to three days. The law was also associated with an immediate decrease in the use of hydrocodone, the most commonly used Schedule II opioid."46

### **Prescription Drug Law for Veterinarians**

In order to purchase, prescribe, administer or dispense controlled substances in Florida, veterinarians must obtain a license from the U.S. Drug Enforcement Administration (DEA). Florida does not require any additional licensure for veterinarians to purchase and prescribe controlled drugs.<sup>47</sup>

The DEA is a division within the U.S. Department of Justice and reports to the U.S. Attorney General. In consultation with the U.S. Secretary of the federal Department of Health and Human Services (HHS) and others, the Attorney General oversees the listing of substances on five schedules (Classes I, II, III, IV or V) of controlled agents as described in Title 21 United States Code (USC) of the Controlled

<sup>&</sup>lt;sup>42</sup> All opioids are controlled substances. Opioids range in classification between Schedule I and Schedule V.

<sup>&</sup>lt;sup>43</sup> S. 456.44(1)(a), F.S.

<sup>&</sup>lt;sup>44</sup> S. 893.055, F.S.

<sup>&</sup>lt;sup>45</sup> Juan M. Hincapie-Castillo, Changes in Opioid Use After Florida's Restriction Law for Acute Pain Prescriptions (Feb. 28, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2762015?utm\_source=For\_The\_Media&utm\_referral&utm\_c ampaign=ftm links&utm term=022820 (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>46</sup> Matthew Splett, UF College of Pharmacy, Department of Pharmaceutical Outcomes and Policy (Feb. 27, 2020), https://ufhealth.org/news/2020/new-florida-law-leads-decline-opioid-use-according-uf-study (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>47</sup> Thomas Vickory, PhD, DEA REGULATION OF CONTROLLED DRUGS, https://www.vetfolio.com/learn/article/florida-druglaws-update-2013 (last visited Jan. 5, 2022). STORAGE NAME: h0723a.RRS

Substances Act. The central mission of the DEA is to enforce controlled substances laws and regulations.48

With respect to veterinarians and other health professionals, the major focus of the DEA is to prevent illegal diversion of controlled prescription drugs for the purpose of illicit or non-medical uses. In order to legally purchase, dispense or prescribe controlled prescription drugs, a veterinarian must be licensed by the DEA. Prescription drugs that are regulated or controlled by the DEA include many important drugs that are used routinely by veterinarians. DEA-controlled drugs are tightly controlled at all aspects of manufacturing, distribution, ordering, storage, use and disposition.<sup>49</sup>

While veterinarians are allowed to write prescriptions for controlled drugs, they cannot order controlled drugs from their local pharmacy for "in-house" use nor for secondary re-sale. Like any other prescription, controlled drug prescriptions must be written for a specific patient and cannot be for general use. As a licensed DEA registrant, veterinarians are expected to create and maintain a system that provides strong safeguards against theft or diversion of controlled drugs in their practice.<sup>50</sup>

Two opioids are approved and marketed for use in animals, butorphanol and buprenorphine. Due to the limited number of approved and marketed veterinary opioids, veterinarians who need to use opioids to control pain in their patients generally use products approved for use in people.<sup>51</sup>

### Federal Controlled Substance Law<sup>52</sup>

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008<sup>53</sup> amended the federal Controlled Substances Act, to prohibit a practitioner from issuing a "valid prescription" for a controlled substance through the Internet without having first conducted at least one in-person medical evaluation, except in certain circumstances. Thereafter, the prescriber may prescribe controlled substances to that patient via Internet or a phone call. The Act offers seven exceptions to the in-person exam. One such exception occurs when the U.S. Secretary of HHS has declared a public health emergency.

# Florida DOH Emergency Order No. 20-002

The U.S. Secretary of HHS authorized qualified prescribers to prescribe Schedule II-V controlled substances, and Surgeon General Rivkees issued DOH Emergency Order No. 20-002.54 which suspended s. 456.47(2)(c), F.S., and authorized specified Florida-licensed prescribers<sup>55</sup> to issue a renewal prescription for a Schedule II-IV controlled substance only for an existing patient for the purpose of treating chronic nonmalignant pain without conducting another physical examination of the patient. This emergency order ended with the expiration of Florida's COVID-19 state of emergency (EO 20-52) on Saturday June 26, 2021.56

## Federal Prescription Guidance During the COVID-19 Public Health Emergency

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<sup>&</sup>lt;sup>48</sup> Thomas, *supra* note 46.

<sup>&</sup>lt;sup>49</sup> Thomas, *supra* note 46.

<sup>&</sup>lt;sup>50</sup> Thomas, *supra* note 46.

<sup>&</sup>lt;sup>51</sup> U.S. FDA, The Opioid Epidemic: What Veterinarians Need to Know, https://www.fda.gov/animal-veterinary/resources-you/opioidepidemic-what-veterinarians-need-know (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>52</sup> 21 U.S.C. s. 829.

<sup>&</sup>lt;sup>53</sup> Public Law No. 110-435 (2008).

<sup>&</sup>lt;sup>54</sup> Department of Health, State of Florida, Emergency Order DOH No. 20-002 (Mar. 16, 2020) http://floridahealth.covid19.gov/wpcontent/uploads/2020/03/filed-eo-doh-no.-20-002-medical-professionals-03.16.2020.pdf (last visited Feb. 14, 2021).

<sup>55</sup> Physicians, osteopathic physicians, physician assistants, or advanced practice registered nurses that have designated themselves as a controlled substance prescribing practitioner on their practitioner profiles pursuant to s. 456.44, F.S.

<sup>&</sup>lt;sup>56</sup> On March 9, 2020, Governor DeSantis issued Executive Order 20-52 which declared a state of emergency for the entire state due to COVID-19. The Executive Order was extended several times. Executive Order 21-94 extended the state of emergency for sixty days from April 27, 2021. The sixtieth day was Saturday June 26, 2021, and the order was not renewed by the Governor.

On January 31, 2020, the U.S. Secretary of HHS issued a public health emergency.<sup>57</sup> On March 16, 2020, the DEA published a COVID-19 Information page on the Diversion Control Division website, authorizing DEA-registered practitioners to issue prescriptions for all Schedule II-V controlled substances to patients without first conducting an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.
- The evaluation is conducted using an audio-visual, real-time, two-way interactive communication system.
- The practitioner is acting in accordance with applicable federal and state law.<sup>58</sup>

#### **Rabies Vaccinations**

All dogs, cats, and ferrets four months of age or older must be vaccinated **by a licensed veterinarian** against rabies with a vaccine that is licensed by the U.S. Department of Agriculture (USDA) for use in those species. The owner must have the animal revaccinated 12 months after the initial vaccination, and subsequent vaccinations must conform to the vaccine manufacturer's directions. The cost of vaccination must be borne by the animal's owner. Violations of this requirement are a civil infraction, punishable as provided in s. 828.27(2), F.S.<sup>59</sup>

Currently, Florida law does not appear to allow anyone other than the veterinarian to administer the rabies vaccine. The law allows certain vaccines, anesthesia and tranquilization to be administered by a veterinary aide, nurse, laboratory technician, intern, or other employee of a licensed veterinarian while under the "immediate supervision" of a licensed veterinarian. <sup>60</sup> In addition, the following tasks may be performed without the licensed veterinarian on the premises:

- The administration of medication and treatment, **excluding vaccinations**, as directed by the licensed veterinarian; and
- The obtaining of samples and the performance of those diagnostic tests, including radiographs, directed by the licensed veterinarian.<sup>61</sup>

The Board has recognized that the following diseases are communicable to humans and are of public health significance, and as a result, **only a veterinarian** is authorized to immunize or treat an animal for these diseases. The diseases include:

- Brucellosis.
- Tuberculosis.
- Rabies.
- Equine Encephalomyelitis.<sup>62</sup>

## **Effect of the Bill**

The bill allows licensed veterinarians to practice veterinary telemedicine, and indirectly supervise rabies vaccinations of impounded animals, as follows:

## **Veterinary Telemedicine**

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<sup>&</sup>lt;sup>57</sup> Determination that a Public Health Emergency Exists, Alex M. Azar II, Secretary of U.S. Department of Health and Human Services (January 31, 2020) <a href="https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx">https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>58</sup> Diversion Control Division, U.S. Department of Justice Drug Enforcement Administration, *COVID-19 Information Page*, <a href="https://www.deadiversion.usdoj.gov/coronavirus.html">https://www.deadiversion.usdoj.gov/coronavirus.html</a> (last visited Jan. 5, 2022). Letter from Thomas Prevoznik, Deputy Assistant Administrator, Diversion Control Division, U.S. Department of Justice Drug Enforcement Administration, to DEA Qualifying Practitioners and Other Practitioners, (Mar. 31, 2020) <a href="https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)% 20DEA% 20SAMHSA % 20buprenorphine % 20tele medicine % 20% 20(Final)% 20+Esign.pdf">https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)% 20DEA% 20SAMHSA % 20buprenorphine % 20tele medicine % 20% 20(Final)% 20+Esign.pdf</a> (last visited Jan. 5, 2022). <a href="https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)% 20DEA % 20SAMHSA % 20buprenorphine % 20tele medicine % 20% 20(Final) % 20+Esign.pdf</a> (last visited Jan. 5, 2022).

<sup>&</sup>lt;sup>60</sup> S. 474.202(5), F.S., defines "immediate supervision" or words of similar purport to mean a licensed doctor of veterinary medicine is on the premises whenever veterinary services are being provided.

<sup>61</sup> R. 61G18-17.005, F.A.C.

 $<sup>^{62}</sup>$  R. 61G18-17.006, F.A.C. **STORAGE NAME**: h0723a.RRS

- Defines "veterinary telemedicine" to means the use of synchronous telecommunication technology by a veterinarian who has access to and has reviewed the patient's relevant medical records to provide veterinary services, including, but not limited to, consultation, evaluation, diagnosis, and treatment of a patient; transfer of medical records; and exchange of information with a client.
- Requires a veterinarian practicing veterinary telemedicine to take appropriate steps to establish
  the VCPR, and provide quality of care, consistent with the prevailing professional standards of
  care for a veterinarian.
- Only allows a veterinarian practicing telemedicine to prescribe controlled substances if the veterinarian:
  - Has previously performed an in-person physical examination of the patient or made medically appropriate and timely visits to the premises where the animal is kept; or
  - For a terminal patient that is transferred to the veterinarian for hospice care by a veterinarian who has previously performed an in-person physical examination of the patient or made medically appropriate and timely visits to the premises where the animal is kept, has reviewed the patient's medical records.
- Revises the requirement that a veterinarian have "seen the animal" in order to prescribe
  medicinal drugs and controlled substances, to instead require the veterinarian to have recently
  performed an examination of the animal or group of animals:
  - Physically in person; or
  - By the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or made medically appropriate and timely visits to the premises where the animal is kept.
- Requires veterinarians to hold a current license to practice veterinary medicine in Florida in order to practice veterinary telemedicine.
- Specifies that the practice of veterinary medicine is deemed to occur at the premises where the
  patient is located at the time the veterinarian practices veterinary telemedicine.
- Grants the Board jurisdiction over a veterinarian practicing veterinary telemedicine in Florida, regardless of where the veterinarian's physical offices are located.
- Specifies that the practice of veterinary telemedicine is not a violation of the standard of care, and a veterinarian may not be disciplined solely for practicing veterinary telemedicine.

#### **Rabies Vaccinations**

- Allows an employee, agent, or contractor of an animal control authority acting under the indirect supervision of a veterinarian to administer rabies vaccinations to impounded animals that will be transferred, rescued, fostered, adopted, or reclaimed by the owner.
- Defines "indirect supervision," to mean the supervising veterinarian must be available for consultation through telecommunications but is not required to be on the premises during such consultation.
  - The supervising veterinarian assumes responsibility for the veterinary care given to the animal by any person working under or at his or her direction and supervision.
- Authorizes veterinarians who supervise an employee, agent, or contractor of an animal control
  authority administering the rabies vaccination to an animal to affix his or her signature stamp in
  lieu of an actual signature.

## B. SECTION DIRECTORY:

- Section 1: amends s. 474.202, F.S., providing a definition.
- Section 2: creates s. 474.2021, F.S., authorizing the use of veterinary telemedicine; requiring a veterinarian to establish a VCPR to practice veterinary telemedicine; authorizing a veterinarian to prescribe controlled substances under specified circumstances; providing licensure requirements to practice veterinary telemedicine; providing jurisdiction of the Board of Veterinary Medicine.
- Section 3: amends s. 474.203, F.S., providing an exception to who may immunize or treat an animal for certain diseases.

Section 4: amends s. 474.214, F.S., revising grounds for disciplinary action against a veterinarian.

Section 5: amends s. 828.30, F.S., authorizing certain employees, agents, or contractors to

administer rabies vaccinations under certain circumstances; defining the term "indirect supervision"; providing that a supervising veterinarian assumes responsibility for any

person working under or at his or her direction and supervision; authorizing a

veterinarian who indirectly supervises the administration of the rabies vaccination to affix

his or her signature stamp in lieu of an actual signature on the rabies vaccination

certificate.

Section 6: provides an effective date of July 1, 2022.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

#### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

#### 1. Revenues:

Indeterminate. Animal control authorities will be able to administer rabies vaccinations of impounded animals without a veterinarian having to be physically present. This may create a savings for local animal control authorities to the extent they are incurring extra veterinary costs associated with veterinarians being required to be onsite to administer rabies vaccinations.

### 2. Expenditures:

None.

#### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Licensed veterinarians will be permitted to practice veterinary telemedicine, including limited controlled substance prescription authority, thus giving them more flexibility in their practice. This will move them further toward equal footing with licensed health care providers in the state who are already allowed to practice telehealth.

Animal owners may have greater access to veterinarians and may feel more comfortable, especially during a state of emergency. Visitors and tourists with pets may be able to obtain veterinarian care while on vacation in Florida without the need for locating and transporting their animal to a veterinarian's office.

# D. FISCAL COMMENTS:

None.

#### III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

#### B. RULE-MAKING AUTHORITY:

The bill authorizes employees, agents, or contractors of animal control authorities to administer rabies vaccinations under "indirect supervision" of a veterinarian. According to DBPR, "an amendment to r. 61G18-17.006, F.A.C. will be required as the rule currently states that you must be a licensed veterinarian to provide rabies vaccinations." <sup>63</sup>

### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On January 12, 2021, the Regulatory Reform Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The committee substitute removed unclear language and instead cross-referenced the section that requires veterinarians to be in compliance with the controlled substance prescription limitations in the bill for veterinarians practicing telemedicine.

<sup>63</sup> Florida Department of Business and Professional Regulation, Agency Analysis of 2022 SB 448, p. 6 (Oct. 21, 2021). **STORAGE NAME**: h0723a.RRS