



MEMORANDUM

DATE	October 1, 2024
TO	Members Veterinary Medical Board
FROM	Tara Welch Board Counsel, Attorney IV Legal Affairs Division, Department of Consumer Affairs
SUBJECT	Agenda Item 9. Update and Discussion on Telehealth and Federal Prescription Requirements

This memorandum is intended to provide an update and discussion regarding the recent statutory authority under the Veterinary Medicine Practice Act (VMPA) for use of telehealth in the practice of veterinary medicine and the impact of recent guidance issued by the U.S. Food and Drug Administration (FDA) regarding, among other things, veterinarian-client-patient relationship (VCPR) requirements to issue prescriptions for the use of extralabel drugs¹ and veterinary feed directives (VFDs)² for the use of VFD drugs³ in animals.

¹ An extralabel drug use is the use of an approved drug in a way that differs from what is listed on the drug's label. Examples of extralabel use are prescribing the drug in a different dosage, interval, route, indication (disease or other conditions), or species. Use of extralabel drugs is permitted in certain circumstances, such as when there is no approved animal drug for the intended use, when the approved drug is not clinically effective, and when the animal's health is threatened.

² A VFD is a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed. (Code of Federal Regulations, tit. 21 (21 CFR), Part [558.3\(b\)\(7\)](#).) This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client's animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the FDA. (*Ibid.*) Federal regulations prescribe the information required to be documented in a VFD issued by a veterinarian. ([21 CFR 558.6\(b\)\(3\)](#).)

³ A VFD drug is a drug intended for use in or on animal feed that is limited by an approved application to such use or intended use of such drug, a conditionally approved application, or an index listing under the federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian. ([21 CFR 558.3\(b\)\(6\)](#).) Use of an animal feed bearing or containing a VFD drug must be authorized by a lawful VFD. (*Ibid.*)

Background

Federal Law

In 1994, Congress passed the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA),⁴ which established conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of FDA-approved new animal drugs and approved new human drugs. ([21 CFR 530.2.](#)) AMDUCA applies to prescriptions for extralabel drug use in animals and VFDs for the use of VFD drugs in animals. Among other things, AMDUCA and its implementing regulations require a valid VCPR to be established prior to a licensed veterinarian issuing a prescription for an extralabel drug or VFD for a VFD drug.^{5 6}

Under federal law, a VCPR is valid when:

- (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
- (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
- (3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept. ([21 CFR 530.3\(i\).](#))

State Law

As discussed in the meeting materials presented at the [July 24-25, 2024 Board meeting](#), state law also prohibits the administration of medically important antimicrobial drugs, as defined, to livestock unless ordered by a licensed veterinarian through a prescription or VFD, pursuant to a VCPR that meets the requirements under state law, as specified. (See Food and Agricultural Code (FAC), § [14401.](#)) State law also provides for civil penalties for violations of those statutes but

⁴ [Pub. L. No. 103-396](#) (Oct. 22, 1994) 108 Stat. 4153; U.S. Code, tit. 21 (21 USC), § [360b](#).

⁵ AMDUCA and its implementing regulations contain a variety of federal extralabel drug requirements, such as labeling and prohibited drugs, not covered in this memo.

⁶ 21 USC § [360b](#)(a)(4)(A), (5)(A); 21 CFR [530.1](#), [558.6](#)(b)(1)(ii).

excluded veterinarians from those provisions and, instead, stated the veterinarian may be subject to disciplinary sanctions pursuant to the VMPA if the Board determines that a veterinarian is in violation of the VMPA. (FAC, § [14408](#), subds. (a), (c).)

State regulation, California Code of Regulations (CCR), title 16, section [2032.1](#), established the requirements of a VCPR to prescribe treatment of any kind to an animal patient. The regulation provided that a VCPR shall be established by the following:

- (1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,
- (2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and
- (3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance.

Operative on January 1, 2020, CCR, title 16, section [2032.1](#), subsection (f), provided for telemedicine practice conducted within an existing VCPR, with the exception for advice given in an “emergency” until that patient(s) can be seen by or transported to a veterinarian. “Telemedicine” was defined to mean the mode of delivering animal health care services via communication technologies to facilitate consultation, treatment, and care management of the patient. In addition, the regulation prohibited establishment of a VCPR solely by telephonic or electronic means. (CCR, tit. 16, § [2032.1](#), subs. (e).)

COVID-19 Impact on Federal and State Law

Due to the COVID-19 outbreak and state modification of requirements for veterinary telemedicine and the VCPR, in March 2020, the FDA issued [CVM GFI #269](#), which loosened the federal VCPR requirements as follows:

Given that the Federal VCPR definition requires animal examination and/or medically appropriate and timely visits to the premises where the animal(s) are kept, the Federal VCPR definition cannot be met solely through telemedicine. To

further facilitate veterinarians' ability to utilize telemedicine to address animal health needs during the COVID-19 outbreak, FDA intends to temporarily suspend enforcement of a portion of the Federal VCPR requirements. Specifically, FDA generally intends not to enforce the animal examination and premises visit VCPR requirements relevant to FDA regulations governing Extralabel Drug Use in Animals ([21 CFR part 530](#)) and Veterinary Feed Directive Drugs ([21 CFR 558.6](#)).⁷

Similarly, the Board's regulations were somewhat loosened during the State of Emergency declared in response to the COVID-19 pandemic. On March 30, 2020, Governor Newsom signed Executive Order [N-39-20](#), which established a process under the Department of Consumer Affairs (DCA) for licensing boards to request a waiver of professional licensing requirements, including requirements related to practice and permissible activities. In May 2020, the Board voted to request the DCA Director issue a temporary waiver of CCR, title 16, section 2032.1, subsection (b)(3), to the extent it required a veterinarian to have communicated with the client a course of treatment appropriate to the circumstance (condition specific requirement) to establish a VCPR. ([May 14, 2020 Meeting Minutes](#); [May 14, 2020 Meeting Memo](#).) The Board requested the waiver be effective for the duration of the State of Emergency, or until January 1, 2021, whichever date was earlier.

In addition, the Board voted to request a waiver of CCR, title 16, section 2032.1, subsection (c), to the extent it prohibited a veterinarian from prescribing a drug for a duration longer than one year from the date the veterinarian examined the animal and prescribed the drug. This temporary waiver was requested for issuance of prescriptions for a duration of no longer than 18 months from the date of last examination and prescription of the medication or until the Declaration of Emergency ends, whichever date was earlier. On June 4, 2020, the DCA Director issued an [Order](#) Waiving Restrictions on Telemedicine and Extending Time to Refill Prescriptions. A number of additional extensions of the waiver were subsequently issued, with the final order extending the waiver until October 31, 2021, at which time it was allowed to expire.

On December 21, 2022, the FDA issued a [notice](#) withdrawing its March 2020 guidance stating that the conditions that created the need for the temporary enforcement policy outlined in [CVM GFI #269](#) had evolved, and after careful review

⁷ FDA, CVM GFI #269 – Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak, Docket No. FDA-2020-D-1140 (Mar. 2020) <https://public4.pagefreezer.com/content/FDA/01-02-2023T10:30/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-269-enforcement-policy-regarding-federal-vcpr-requirements-facilitate-veterinary>, as of Sept. 23, 2024.

of current industry practices with regard to on-premises animal examination and comments submitted associated with the guidance, the policy was no longer needed.⁸

VCPR and Telehealth Legislation

The COVID-19 pandemic highlighted the critical issues regarding access to veterinary care. To resolve practitioner confusion regarding the electronic services that could be provided to animal patients, at the Board's July 2021 meeting, the Board voted to recommend a legislative proposal to the California State Legislature that would have clarified the use of telemedicine in veterinary medicine practice. ([July 22-23, 2021 Meeting Minutes](#); [July 2021 Meeting Memo](#).) At the Board's January 2023 meeting, the Board approved a legislative proposal to move the VCPR regulatory requirements, including the in-person examination requirement, into statute with the new telemedicine provisions to provide the most direct and timely manner to resolve issues regarding herd and equine practice and client agent designations. ([January 25-26, 2023 Meeting Minutes](#); [January 2023 Meeting Memo](#).) However, the Board was unsuccessful in getting the legislative proposal included in a bill.

In March of 2023, [Assembly Bill \(AB\) 1399](#) (Friedman, Chapter 475, Statutes of 2023), sponsored by the American Society for the Prevention of Cruelty to Animals (ASPCA) and San Diego Humane Society, was introduced and preempted CCR, title 16, section 2032.1 to allow for a greatly expanded use of veterinary telemedicine. AB 1399 established VCPR requirements in statute, expanded the definition of veterinary telemedicine, authorized the ability of a veterinarian to create the VCPR by examining the animal patient in person, examining by use of synchronous audio-video communication, or making medically appropriate and timely visits to the premises on which the animal patient is kept. [AB 1399](#) went into effect on January 1, 2024.

At the Board's April 2023 meeting, the Board voted to oppose a prior version of AB 1399 and authorized the Executive Committee and Executive Officer to engage with the bill author and stakeholders regarding numerous concerns, including a federal prohibition on prescribing controlled substances via telemedicine for all healthcare providers and federal prohibition on initiating a VCPR through

⁸ Enforcement Policy Regarding Federal Veterinarian-Client-Patient Relationship Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak; Withdrawal of Guidance, 87 Fed.Reg. 78111 (Dec. 21, 2022) <https://www.federalregister.gov/documents/2022/12/21/2022-27673/enforcement-policy-regarding-federal-veterinarian-client-patient-relationship-requirements-to#:~:text=When%20the%20COVID%2D19%20public,of%20this%20guidance%20as%20necessary,> as of Sept. 23, 2024.

telemedicine, raised at the April 20, 2023 Board meeting. ([April 19-20, 2023 Meeting Minutes.](#)) In May 2023 Board Executive Committee discussions with ASPCA, the Executive Committee raised concern with how the bill would interact with federal VCPR in-person examination requirements to prescribe drugs for use in animal patients. ASPCA responded that federal law requires a VCPR for the use of pharmaceuticals in veterinary medicine only if the prescription applies to extralabel drug use ([21 CFR 530.1](#)) and VFDs for the use of drugs used in or on animal feed ([21 CFR 558.6](#)).

ASPCA further confirmed that the federal regulations relating to extralabel drug use and VFDs stipulate that a valid VCPR “can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept,” citing to [21 CFR 530.3\(i\)\(3\)](#). ASPCA stated that in applying these definitions to its regulations, the FDA has been clear that it defers to state definitions of VCPR.

At the Board's July 19-20, 2023 meeting, the Board discussed additional concerns with AB 1399, including the lack of exemption from the VCPR requirement for wild animals and animals whose owner is unknown and telehealth prescribing of antimicrobial drugs. The Board voted to oppose the bill unless it was amended to resolve the issues raised during the meeting and also voted to support the bill if the Board's requested amendments were included in the bill. ([July 19-20, 2023 Meeting Minutes.](#)) AB 1399 was amended on September 1, 2023, and included the Board's requested amendments, and amended on September 6, 2023, to resolve premises registration issues with telemedicine practice; the Board issued a letter of support on September 11, 2023. ([October 18-19, 2023 Meeting Materials.](#))

Following enactment of AB 1399 and contrary to ASPCA's interpretation that the FDA defers to state definitions of VCPR, as discussed further below, recent FDA guidelines have made clear that the federal VCPR requirements are controlling as they relate to prescribing extralabel drugs and VFDs.

Discussion

Conflict Between State and Federal Law

At issue is the provision enacted by AB 1399, in BPC section [4826.6](#), subdivision (b)(2), regarding a veterinarian establishing a VCPR by examining the animal patient by use of synchronous audio-video communication to issue an extralabel drug prescription or VFD for a VFD drug. On September 4, 2024, the FDA issued its

[guidance](#) that federal law requires a licensed veterinarian to establish a VCPR to prescribe the extralabel use of approved animal or human drugs and to issue a VFD for a VFD drug. (21 CFR [530.3\(i\)\(3\)](#), [530.10](#), [530.20](#).) The FDA guidance also stated that:

The federal VCPR definition (21 CFR 530.3(i)) includes the following requirement: “The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s) and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.” Therefore, for the purposes of the federal definition, a valid VCPR cannot be established solely through telemedicine (e.g., photos, videos, or other electronic means that do not involve examination of the animal(s) or timely visits to the premises). However, once a VCPR is established, telemedicine can be a useful tool for maintaining the VCPR.⁹

The guidance also notes that states may have additional (but not fewer) extralabel prescription and VFD requirements, and federal law does not establish specific VCPR requirements related to the on-label use of approved animal drugs; state specific VCPR requirements would apply to on-label use of approved animal drugs.

Because BPC section [4826.6](#), subdivision (b)(2), allows a VCPR to be established through telehealth, it is less prescriptive than federal law, which only allows a VCPR to be established after the veterinarian has recently seen and is personally acquainted with the animal by virtue of examination and/or by medically appropriate and timely visits to the premises where the animal is kept. (21 CFR [530.3\(i\)\(3\)](#).) As such, it would appear state law conflicts with the requirements under federal law regarding prescribing extralabel drugs and issuing VFDs for VFD drugs. Given the differences in the VCPR requirements under federal and state law, the method of establishing the VCPR will impact the ability of the veterinarian to prescribe drugs and issue VFDs for VFD drugs.

Federal Law Controls

Although California law authorizes the use of telehealth, as specified, to establish a VCPR and prescribe, dispense, or administer a drug, federal law does not if the drug

⁹ U.S. FDA, *Veterinarian-Client-Patient Relationships, Prescribing/Dispensing Animal Drugs and Telemedicine* (Sep. 4, 2024) <https://www.fda.gov/animal-veterinary/product-safety-information/veterinarian-client-patient-relationships-prescribingdispensing-animal-drugs-and-telemedicine>, as of Sept. 23, 2024; emphasis added.

is prescribed for extralabel use or a VFD drug. Pursuant to the Supremacy Clause of the United States Constitution (U.S. Const., art. VI., § 2), federal law supersedes any state or local regulation or statute that conflicts with the federal law, and federal law preempts state law.

Federal law requires a valid VCPR to be established through an in-person exam or by medically appropriate and timely visits to the premises where the animal is kept to issue veterinary extralabel prescriptions. The FDA's guidance states that "a valid VCPR cannot be established solely through telemedicine (e.g., photos, videos, or other electronic means that do not involve examination of the animal(s) or timely visits to the premises). However, once a VCPR is established, telemedicine can be a useful tool for maintaining the VCPR."¹⁰

In addition, the FDA previously clarified VCPR requirements to issue a VFD for VFD drugs in its final action on 21 CFR parts 514 and 558 that stated:

In those States that do not define a VCPR that includes the key elements in the Federally defined VCPR, or in the States that define a VCPR but do not require it for the issuance of a VFD, the veterinarian is required to issue the VFD within the context of a valid VCPR as that term is defined by FDA at § 530.1(i).¹¹

According to the final action, if the state VCPR requirement is not as prescriptive as federal law, federal law would control. However, the FDA has noted that states may have additional or more specific VCPR requirements.¹²

Following enactment of AB 1399, BPC section [4826.6](#) established a VCPR exists if, among other conditions, the veterinarian possesses sufficient knowledge of the animal patient to initiate at least a general or preliminary diagnosis of the animal patient's medical condition. (BPC, § [4826.6](#), subd. (a)(2).) A veterinarian possesses

¹⁰ U.S. FDA, *Veterinarian-Client-Patient Relationships, Prescribing/Dispensing Animal Drugs and Telemedicine* (Sep. 4, 2024) <https://www.fda.gov/animal-veterinary/product-safety-information/veterinarian-client-patient-relationships-prescribingdispensing-animal-drugs-and-telemedicine>, as of Sept. 13, 2024.

¹¹ U.S. FDA, *Veterinary Feed Directive; Final Rule, 21 CFR Parts 514 and 558* 80 Fed.Reg. 31718 (June 3, 2015) <https://www.regulations.gov/document/FDA-2010-N-0155-0209>, as of Sept. 23, 2024; see also FDA, *Does the State or Federal VCPR Definition Apply to a Lawful VFD in my State?* (Jan. 3, 2024) <https://www.fda.gov/animal-veterinary/development-approval-process/does-state-or-federal-vcpr-definition-apply-lawful-vfd-my-state>, as of Sept. 23, 2024.

¹² U.S. FDA, *Veterinarian-Client-Patient Relationships, Prescribing/Dispensing Animal Drugs and Telemedicine* (Sep. 4, 2024) <https://www.fda.gov/animal-veterinary/product-safety-information/veterinarian-client-patient-relationships-prescribingdispensing-animal-drugs-and-telemedicine>, as of Sept. 23, 2024.

sufficient knowledge of the animal patient if the veterinarian has recently seen, or is personally acquainted with, the care of the animal patient by doing any of the following:

- (1) Examining the animal patient in person.
- (2) Examining the animal patient by use of synchronous audio-video communication.
- (3) Making medically appropriate and timely visits to the premises on which the animal patient is kept. (BPC, § [4826.6](#), subd. (b)(1)-(3).)

Since federal law does not allow examination of the animal patient through telehealth by use of synchronous audio-video communication to establish a VCPR to issue an extralabel drug prescription or VFD for a VFD drug, federal law is more prescriptive than state law and preempts state law. As such, pursuant to the federal VCPR requirements and FDA announcement clarifying that telemedicine cannot be used to establish a VCPR to prescribe an extralabel drug or issue a VFD for a VFD drug, in-person examination and/or medically appropriate and timely visits to the premises where the animal is kept is required prior to prescribing an extralabel drug or issuing a VFD for a VFD drug for use in an animal patient.

Notably, BPC section [4826.6](#), subdivision (i)(3), authorizes a veterinarian who practices veterinary medicine via telehealth to order, prescribe, or make available drugs, as defined in Health and Safety Code section [11014](#), in accordance with all relevant state and federal regulations. Thus, if a veterinarian establishes the VCPR by telehealth and prescribes on-label use of approved animal drugs, the veterinarian may follow state law VCPR requirements. However, to issue a prescription for an extralabel drug or VFD for a VFD drug, the veterinarian must follow the state VCPR requirements that are not in conflict with the federal VCPR requirements. In effect, a veterinarian prescribing extralabel use drugs or a VFD for VFD drugs cannot establish a VCPR via telehealth under BPC section [4826.6](#), subdivision (b)(2). As such, if a veterinarian establishes a VCPR through telehealth and issues a prescription or distributes an extralabel drug or issues a VFD for a VFD drug for use in an animal patient in violation of 21 CFR parts [530.3\(i\)\(3\)](#) and [530.10](#) or [530.20](#), as applicable, the veterinarian would be subject to enforcement action by the Board and the FDA. The veterinarian also may risk enforcement action against their Drug Enforcement Agency (DEA) registration.

Conclusion

The provision in BPC section [4826.6](#), subdivision (b)(2), authorizing examination by use of synchronous audio-video communication to establish a VCPR conflicts with

the federal law requirement for the veterinarian to have recently seen and be personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s) and/or by making medically appropriate and timely visits to the premises where the animal is kept to establish a VCPR to prescribe an extralabel drug or issue a VFD for a VFD drug. However, BPC section [4826.6](#) subdivision (i)(3), requires a veterinarian practicing via telehealth to comply with all relevant state and federal regulations to order, prescribe, or make available drugs. As such, a veterinarian who distributes or issues a prescription for an extralabel drug or issues a VFD for a VFD drug to treat an animal patient may maintain the VCPR via telehealth and issue an extralabel prescription or VFD drug in accordance with state and federal law but is prohibited under federal law from establishing the underlying VCPR via telehealth.

Potential Legislation

FAC section [14401](#) may need clarifying amendments to specify a medically important antimicrobial drug shall not be administered to livestock unless ordered by a licensed veterinarian through a prescription or VFD, pursuant to a VCPR that meets the requirements of federal and state law, rather than BPC section [4826.6](#). Such a legislative proposal should be coordinated with the California Department of Food and Agriculture.