

What are the Compliance Issues for Veterinarians?

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Veterinarians have unique compliance issues. Many of the rules and regulations these physicians follow are the same that govern medical practices that treat and care for humans. Still, there are also differences because animals are involved. Failure to comply with federal, state, and local laws as well as the ethical rules of conduct can result in the fines, penalties, and the forced closure of the business.

Experienced healthcare lawyers can explain which laws, regulations, and ethical rules apply to a veterinary practice. Skilled healthcare attorneys understand which drugs and dietary supplements are regulated by the FDA. They understand what solicitation and promotional marketing is acceptable and what advertising may lead to complaints and litigation.

It is advisable for veterinarians and veterinary practices to consult a skilled veterinary healthcare lawyer if they have not done so. It's often much easier to address problems before they occur, rather than waiting until you receive a warning letter or are told you have just days to respond to formal actions.

Telemedicine

Telemedicine, also called telehealth, involves remote consultations and reviews. During the current pandemic, many medical practices and veterinary practices are using telemedicine more and more to avoid physical contact. Veterinarians use telehealth to:

- Review medical records about any pet or any email
- Review medical images
- Consult with the owner of a dog, cat, bird, or other pet that isn't feeling well or with the owner of any livestock. These consultations may be face-to-face video. The consultations may also involve submitting questions by email or through a form and then waiting for a reply.

Veterinarians who wish to use telemedicine should work with IT professionals to ensure they have the right equipment for communicating with clients.

Veterinarians also need to understand the laws that apply to telemedicine. Traditionally, doctors in a broad array of specialties and practices consult with their patients in person so the veterinarians can see, touch, feel and speak to the humans and see, touch, and feel the animals the vets are taking care of. Telemedicine is a trade-off of convenience and, in the age of

COVID-19, safety – for the inability to be in direct contact with the animal and the animal's owner.

To ensure that veterinarians maximize this trade-off so the veterinarians can provide quality care, the American Veterinary Medical Association (AVMA) and other veterinary organizations have developed guidelines for when and how telemedicine should be used.

The starting point is that there should be an existing Veterinarian-Client-Patient Relationship (VCPR). Different organizations may define this term differently. Essentially it is the creation of a formal relationship in which the veterinarian agrees to provide medical care to the owner's animal in return for compensation.

According to the AVMA:

“Telemedicine, which is client-facing, includes the delivery of information specific to a particular patient and is allowable only within the context of an established VCPR; and non-client-facing models that involve delivery of general advice, telemarketing, and advertising.” In non-client-facing models, the veterinary may be able to give general advice but not advice that applies to a specific animal.

The participants in a veterinary telemedicine conference can include:

- The veterinarian
- The animal
- The client – generally, the owner of the animal
- A pharmacy or medicated feed distributor
- A specialist
- The healthcare team

Telehealth includes:

- Telemedicine
- Teleconsulting
- Telemonitoring
- Teleadvice
- Telerriage
- E-prescriptions
- Mobile health

The AVMA has guidelines for how to use telehealth/telemedicine. The guidelines are just advisory. Each state has its own veterinary licensing boards. For example, California has a [veterinary medical board](#). The board regulates:

- **Licenses to practice veterinary medicine.** Licensees need to understand their continuing education requirements, their duties regarding controlled substances, and animal shelter issues.
- **Enforcement issues.** For example, veterinarians need to know if animal shelters are practicing safe veterinary medicine.
- **Inspection issues.**

Some of the regulations of the California Veterinary Medical Board include:

- Telemedicine
- Animal Control and Humane Officer Training
- Fee schedules
- Consumer protection

If there is a valid VCPR, veterinarians, in general, can offer and charge for telemedicine services – provided the veterinarian provides competent medical care.

In most telemedicine consults, for animals and humans, it is helpful (and possibly mandatory) that the veterinarian/doctor have an initial in-person consultation with the pet/person.

Anti-referral laws – Stark Law and the Anti-Kickback Statute

Medical practices including veterinary practices are subject to the federal and state anti-referral laws. These laws are designed to ensure fair competition and to ensure that patients (including the owners of dogs, cats, cows, and other animals) are being advised based on what is in their best health interest and not on what is in the best interest of the physician.

Both Stark Law and the AKS regulate how and when referrals can be made – and what exceptions and safe harbors apply.

Stark Law

Stark law prohibits doctors who have a financial relationship in a designated health facility from referring patients to the facility if that facility then charges Medicare for the services or products that are provided. A common example of a designated health facility is an ambulatory surgery center.

A financial interest can be direct or indirect. Stark Law applies if the doctor or a member of the doctor's immediate family has a financial interest or investment in the designated health facility.

Stark Law provides for civil penalties in the form of reimbursement of any fees to Medicare, statutory penalties, and treble damages. Violations of the Stark Law are often also violations of the federal False Claims Act.

The Anti-Kickback Statute

This federal law forbids the use of any incentive to pressure or compel a physician to make a referral to the party providing the inducement. Common examples include the payment of cash or the creation of sham directorships by a drug company in order to induce physicians to suggest patients use the drug company's products instead of drugs manufactured or sold by other companies.

The AKS is a criminal statute that includes fines and possible imprisonment. Violations of the AKS may also be violations of the False Claims Act.

An experienced veterinary and healthcare compliance lawyer will review any referral arrangements the veterinary practice has with others. Some types of conduct and actions such as waving copayments, providing discounts, accepting reduced payments, and gifts raise red flags that the referral is not based on merit.

Exceptions and safe harbors

The lawyer can also explain which exceptions and safe harbors apply. Some of the exceptions to Stark Law include:

- **In-Office Ancillary Services Exception.** This exception allows a veterinary or other medical practice to make referrals for ancillary services such as laboratory services – if certain conditions are met.
- **Fair Market Compensation Exception.** This exception is useful if the arrangement for referrals is in writing, there's a specific timeframe, the compensation is based on fair market value, and the transactions are not based on the volume or amount of the referrals – and other conditions are met.

There are also Stark Law exceptions for the following, among others, if all the conditions are met:

- Physician services
- Referrals made to organizations that provide prepaid health services to enrollees such as HMOs and plans approved by Medicare
- Academic medical centers
- Preventive services
- Rental of office space
- Equipment rental
- Bona fide employee relationships
- Personal service arrangements
- Nonmonetary compensation up to \$3,000 a year – if the veterinarian didn't solicit the compensations and the compensation isn't based on the amount of referrals
- Physician recruitment
- Medical staff incidental benefits

There are AKS safe harbors which also offer protection. Many of the safe harbors are comparable to the Stark Law exceptions. An experienced veterinary healthcare compliance lawyer can explain the similarities, the differences, and the key requirements as far as Stark Law exceptions and AKS safe harbors are concerned.

Exceptions to the Stark Law Prohibition of Medical Referrals

The Stark Law governs what types of referrals doctors can make if they bill for Medicare and Medicaid. The presumption is that that referrals made by a doctor to a designated health service are [...]

California Medical Board

Veterinarians cannot abandon their patients. If the veterinarian leaves a medical practice or is fired from the practice, the physician must inform the owner of the pet, that the owner will need to hire a new veterinarian. Veterinarians should also make the medical records of the animal available to the owner in a timely manner.

FDA and FTC compliance

Veterinarians and vet practices must comply with the FD&C Act and the FTC Act.

These agencies will send out warning letters and file legal actions if any of the following are condoned by the veterinary practice.

- False, misleading, or deceptive statements are made on company websites, social media accounts, print advertising, and any other marketing. Examples of false statements and misbranding include claims that treatments or medications can provide relief, can cure diseases, can prevent diseases, or can reduce the severity of animal disorders – when the statements are not supported by scientific evidence and/or clinical studies.
- The veterinarian provides drugs or treatments that aren't medically approved.

The FDA works to “*assure that animal food is safe, made under sanitary conditions, and properly labeled, that animal drugs, animal devices, and animal food additives are safe and effective, and in cooperation with other agencies that no harmful residues in food-producing animals enter the human food supply.*”

Additional veterinary rules and regulations

Veterinarians are generally required to comply with the California laws that govern medical practices such as the:

- California Medical Practices Act,
- The Controlled Substances Utilization Review and Evaluation System (CURES)
- Various consumer protection laws
- The laws and principles of informed consent – where the owner of the pet should be notified of the risks and dangers of proposed medications, treatments, and medical procedures.
- The confidentiality of veterinary patient records

Additional legal services for veterinarians

Skilled healthcare lawyers also advise veterinarians on a range of other issues including:

- What type of business entity to use for the practice
- The use of managed service organizations
- Employment contracts
- Contract negotiation
- Non-solicitation and non-compete clauses
- Severance packages
- Billing and coding issues including issues of upcoding and of bundling of services
- Whether American Animal Hospital Association (AAHA) Accreditation is required

When Using a Management Services Organizations (MSO) Is the Right Choice for Your Medical Practice

Managed Services Organizations help physicians focus on practicing medicine by freeing doctors from many administrative tasks. Failure to consult with an MSO healthcare lawyer can cause civil and [...]

Veterinarians should consult with experienced healthcare attorneys before starting their medical practice and any time they expand their practice. A skilled lawyer will review the anti-referral laws, the telemedicine laws and guidelines, the federal and state laws and boards that regulate veterinary practice, and the practical and legal issues of complying with these laws.

Contact Cohen Healthcare Law Group for a review of the laws, regulations, ethics requirements, and other compliance issues that govern veterinary practices. Our experienced healthcare attorneys understand the compliance issues at stake and advise

clients on proactive strategies and on responding to complaints.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.