

Veterinary Medical Board's Guidelines for the Discussion of Cannabis Use for Veterinary Patients

Effective January 1, 2020

PREAMBLE

Pursuant to Business and Professions Code (BPC) section 4884, subdivision (b), a California licensed veterinarian will not be disciplined by the Veterinary Medical Board (VMB) solely for discussing the use of cannabis on an animal for medicinal purposes. As required by statute, the Board has developed these guidelines for discussion of the use of cannabis in veterinary patients with clients. (BPC, § 4884, subd. (c).)

BACKGROUND

On September 27, 2018, California Governor Edmund G. Brown, Jr. signed into law AB 2215 (Kalra, Chapter 819, Statutes of 2018). AB 2215 became effective January 1, 2019. This bill amends section 4883 of, and adds section 4884 to, the Business and Professions Code, relating to veterinarians.

The bill prohibits the VMB from disciplining, or denying, revoking, or suspending the license of, a licensed veterinarian solely for discussing the use of cannabis on an animal for medicinal purposes, absent negligence or incompetence.

The bill prohibits the veterinarian from dispensing or administering cannabis or cannabis products, or accepting, soliciting, or offering any form of remuneration from or to a cannabis licensee (aka, Medicinal and Adult-Use Cannabis Regulation and Safety Act [MAUCRSA] licensee) if the veterinarian or his or her immediate family have a financial interest with the cannabis licensee. Under both the federal Controlled Substances Act (CSA) (21 USCA § 801 et seq.) and the California Uniform Controlled Substances Act (CUCSA) (Cal. Health & Saf. Code, § 11000 et seq.), cannabis is listed as a Schedule I drug, characterized as having a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. A veterinarian is prohibited from prescribing a Schedule I drug.

GUIDELINES

The VMB has adopted the following guidelines for the discussion with veterinary clients of cannabis use on animal patients for medical purposes.

Veterinarian-Client-Patient Relationship: The veterinarian-client-patient relationship (VCPR) is fundamental to the provision of acceptable veterinary medical care. The veterinarian should document that an appropriate VCPR is established prior to discussions of cannabis with the animal owner client. (See California Code of Regulations (CCR), title 16, section 2032.1, Veterinarian-Client-Patient Relationship.)

Patient Evaluation and Record Keeping: A documented physical examination and collection of relevant clinical history is required. This history should include both subjective and objective data and must be obtained prior to discussion of cannabis for a medical purpose. Medical records must meet the accepted minimum requirements for record keeping as defined by the Veterinary Medicine Practice Act. (See CCR, tit. 16, § 2032.3, Record Keeping; Records; Contents; Transfer.)

Documentation of discussions should include the indication and safety of the use of cannabis. The discussions should be evaluated in accordance with accepted standards of practice as they evolve over time. This documentation may include advice about potential risks of the medical use of cannabis, including, but not limited to, the following:

- The variability of quality, source, safety, and testing of cannabis products (pesticide contamination, potentially harmful co-ingredients, e.g., xylitol, chocolate, butter).
- No federal or state agency oversees standardization of animal cannabis product concentrations.
- Research to-date is lacking conclusions regarding dose, toxicity, and efficacy.
- The side effects and signs of overdose or toxicity (e.g., ataxia, depression, vomiting, urinary incontinence, bradycardia, hyperthermia, tremors, anorexia, adipsia, hypothermia, seizure, stupor, tachycardia, weakness).
- Safeguarding of cannabis products from other pets and human exposures.
- Use in service animals that may place human handler safety in jeopardy.
- Possible interactions with other treatments and prescribed medications.
- Reminder to the client that cannabis is not being recommended or prescribed by the veterinarian.
- The importance of periodic re-evaluation of the patient in accordance with good veterinary practice.

Veterinarian's Conflicts of Interest: The amendments to BPC section 4883 and the addition of BPC section 4884 are very clear in that there will be no financial relationships with any cannabis licensees, no advertising of cannabis products, no stocking, dispensing, or administration of cannabis products. A veterinarian cannot prescribe or recommend the use of cannabis, only enter into discussions with the veterinary client concerning appropriate medical use within the confines of a VCPR. A veterinarian cannot have a professional office located at a dispensary or cultivation center. A veterinarian cannot be a director, officer, member, principal, employee, or a retailer of cannabis products. A cannabis dispensary may not employ a veterinarian to discuss cannabis with clients. (See BPC, §§ 4883, subds. (p), (q), (r), and 4884.)

Industrial Hemp: Under federal and state law (21 USCA § 802(16) and Cal. Health & Saf. Code, § 11018.5), industrial hemp is not a controlled substance regulated under the Uniform Controlled Substance Acts and is not regulated under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) (BPC, § 26000 et seq.). Rather, industrial hemp is regulated by the federal Department of Agriculture and the California Department of Food and Agriculture (7 USCA § 1639o; Cal. Food & Agr. Code, § 81000). Thus, if a veterinarian prescribes, dispenses, furnishes, or recommends the use of industrial hemp on an animal patient, the veterinarian would not be subject to the statutory provisions regarding cannabis but would be subject to the provisions of the Veterinary Medicine Practice Act applicable to diagnosing, prescribing, or administering a drug, medicine, appliance, application, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of animals (Bus. & Prof. Code, § 4826, subds. (b), (c)).

Definitions, Abbreviations, Acronyms

California Uniform Controlled Substances Act (CUCSA) – regulates the manufacture, importation, possession, use, and distribution of certain substances (Cal. Health & Saf. Code, § 11000 et seq.).

Cannabis – Cannabis means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include either of the following:

(a) Industrial hemp, as defined in Section 11018.5.

(b) The weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink, or other product.

(Cal Health & Saf. Code, § 11018.)

CBD – abbreviation for Cannabidiol, which is one out of 60 naturally occurring compounds present in cannabis. It is the second most prevalent cannabinoid in both hemp and marijuana and is non-psychoactive. CBD oil is mostly extracted from hemp and not marijuana. When extracted from hemp, this type of extract has less than 0.03% of THC.

CSA – The federal Controlled Substances Act (21 USCA § 801 et seq.).

Dronabinol, Marinol, Nabilone – synthetic cannabinoids.

Epidiolex – CBD product approved in June 2018 by the U.S. Food and Drug Administration (FDA) for controlling seizures in people with difficult-to-treat childhood-onset epilepsy.

Industrial Hemp – (a) Industrial hemp means a crop that is limited to types of the plant *Cannabis sativa* L. having no more than three-tenths of 1 percent tetrahydrocannabinol (THC) contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin produced therefrom.

(b) Industrial hemp shall not be subject to the provisions of this division or of Division 10 (commencing with Section 26000) of the Business and Professions Code, but instead shall be regulated by the Department of Food and Agriculture in accordance with the provisions of Division 24 (commencing with Section 81000) of the Food and Agriculture Code, inclusive. (Cal Health & Saf. Code, § 11018.5.)

Marijuana – (A) Subject to subparagraph (B), the term “marijuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.

(B) The term “marihuana” does not include-

- (i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946 [7 USCS § 1639o]; or
- (ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. [21 USCS § 802]

Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) –

establishes a comprehensive system to control and regulate the cultivation, distribution, transport, storage, manufacturing, processing, and sale of both of the following:

- (1) Medicinal cannabis and medicinal cannabis products for patients with valid physician’s recommendations.
- (2) Adult-use cannabis and adult-use cannabis products for adults 21 years of age and over.

MAUCRSA also defines the power and duties of the state agencies responsible for controlling and regulating the commercial medicinal and adult-use cannabis industry (BPC §, 26000 et seq.).

Oils – Cannabis oil, whether CBD, THC, or both, is extracted from the flowers, leaves, and stalk mainly using different solvents. Hemp oil is made only from pressed seeds.

Terpenes – aromatic metabolites found in the oils of all plants (i.e., flavor or fragrance). Terpenes work together to modulate cannabinoids resulting in the so-called “entourage effect.” Terpenes have their own medical effects, for example, interacting with neurotransmitters.

THC – delta-9 tetrahydrocannabinol, the primary psychoactive ingredient in marijuana, is one of at least 113 cannabinoids identified in cannabis.

Veterinarian-Client-Patient Relationship (VCPR) – a fundamental provision to acceptable veterinary medical care. A veterinarian-client-patient relationship 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. (CCR § 2032.1.)

Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing

MAY 31, 2019

<https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds>

Date: May 31, 2019

Time: 08:00 AM EDT – 06:00 PM EDT

Location: White Oak Campus: The Great Room
10903 New Hampshire Ave
Bldg 31 Conference Center, The Great Room (Rm 1503)
Silver Spring, MD 20993
United States

Organized By: [Food and Drug Administration](#)

Background

The Food and Drug Administration held a public hearing to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. See the *Federal Register* [notice](#) for more information.

Opening Remarks

Dr. Sharpless' [opening remarks](#) are now available.

<https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-sharpless-fda-public-hearing-scientific-data-and-information-about-products-containing>

The hearing transcript and slides will be posted online within 30 days.

Webcast Recording:

A webcast recording is available in four distinct segments. Each segment is in order based on the agenda.

- [Opening until morning break](#)
- [After morning break until lunch](#)
- [After lunch until afternoon break](#)
- [After afternoon break until closing](#)

Submitting Comments:

FDA established a docket for public comment on this hearing. The docket number is [FDA-2019-N-1482](#). On June 20, 2019, the comment period was extended and the docket will now close on July 16, 2019. See the [*Federal Register* announcement](#) for more information. Submit either electronic or written comments on this public hearing by July 16, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 16, 2019. The [Regulations.gov](#) electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 16, 2019. Comments received by mail/ hand delivery/ courier (for written/ paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

The Food and Drug Administration's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds Part 15 Public Hearing May 31, 2019 7:00 AM – 6:00 PM

<https://www.fda.gov/media/126123/download>

The Food and Drug Administration's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds Part 15 Public Hearing May 31, 2019 7:00 AM – 6:00 PM

<https://www.fda.gov/media/126625/download>

The Food and Drug Administration's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds Part 15 Public Hearing May 31, 2019 7:00 AM – 6:00 PM

<https://www.fda.gov/media/126784/download>

Excerpts from: Remarks by Dr. Sharpless at the FDA Public Hearing
MAY 31, 2019

Norman E. "Ned" Sharpless, MD

Acting Commissioner of Food and Drugs - Food and Drug Administration

<https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-sharpless-fda-public-hearing-scientific-data-and-information-about-products-containing>

We have over 500 people registered to attend in person, over 800 people registered to join us remotely, and over 100 speakers on today's agenda presenting on this topic.

Cannabis contains more than 80 biologically active chemical compounds, including the best known compounds, delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

If one of these compounds, or the plant itself, is added to a food or cosmetic, marketed as a drug, or otherwise added to an FDA-regulated product in interstate commerce, then it falls within FDA's jurisdiction.

At the same time, some relevant laws have changed. First, some states have changed their laws to allow for "medical" use of marijuana or CBD, and others have begun allowing for recreational marijuana use, or decriminalized recreational marijuana possession.

Second, certain federal laws have changed as well. Parts of the Cannabis sativa plant have been controlled under the Federal Controlled Substances Act, or CSA, since 1970 under the drug class "Marihuana." Last year, the federal scheduling of cannabis changed. The Agriculture Improvement Act of 2018, or the Farm Bill, removed hemp – meaning cannabis or derivatives of cannabis with a very low THC content (below 0.3% by dry weight) – from the CSA's definition of marijuana. As a result, while marijuana remains a Schedule I drug, hemp is no longer a controlled substance under Federal law.

The 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds. In doing so, Congress recognized FDA's important public health role with respect to all the products it regulates – including when those products are or contain cannabis ingredients.

If a product is being marketed as a drug – meaning, for example, that it's intended to have a therapeutic effect such as treating a disease or affecting the body's structure or function – then it's regulated as a drug, and it generally cannot be sold without FDA approval.

Food, including dietary supplements, is regulated differently, but with the same overarching goal of protecting consumers.

For example, while we don't generally require foods to be approved by FDA, we do require that a new food additive be approved as safe by FDA before being put in the food supply, unless the substance is generally recognized as safe, or GRAS.

This requirement applies to cannabis-derived ingredients, just as it does to any other substance. Americans deserve to know that substances being added to their foods are safe, regardless of the source.

Some compounds found in cannabis – specifically, CBD and THC – have been studied and even approved as drugs. It's important to note that the Federal Food, Drug & Cosmetic Act prohibits adding drugs to human or animal food in interstate commerce.

That includes both substances that have been approved as drugs, as well as compounds for which substantial clinical investigations have been instituted. Similarly, the law excludes these products from the statutory definition of a dietary supplement.

Based on the information available to FDA, we have concluded that these provisions apply to CBD and THC. And while there is an exception when the substance was marketed as a food or dietary supplement before it was studied as a drug, we have concluded that that is not the case for CBD or THC. What that means is that, under current law, CBD and THC cannot lawfully be added to a food or marketed as a dietary supplement.

Given the new interest in marketing cannabis products across the range of areas FDA regulates, we will need to carefully evaluate how all these pieces fit together in terms of how consumers might access cannabis products.

Nowhere is this truer than with CBD. While we have seen an explosion of interest in products containing CBD, there is still much that we don't know.

Prior to the 2018 Farm Bill, population-based research mostly included cannabis-focused observations in aggregate, rather than specific to CBD.

When hemp was removed as a controlled substance, this lack of research, and therefore evidence, to support CBD's broader use in FDA-regulated products, including in foods and dietary supplements, has resulted in unique complexities for its regulation, including many unanswered questions related to its safety.

Our biggest concern is the marketing of products that put the health and safety of consumers at risk, such as those claiming to prevent, diagnose, mitigate, treat, or cure serious diseases, such as cancer, in the absence of requisite approvals.