

State of Wisconsin

Governor Tony Evers

Veterinary Examining Board

Dr. Robert Forbes, DVM, Chair

VETERINARY EXAMINING BOARD

2811 Agriculture Drive, Madison, Wisconsin Board Room (CR 106) Contact: Melissa Mace 608-224-4883 October 23, 2019

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.

AGENDA

I. 9:00 A.M. OPEN SESSION – CALL TO ORDER – ROLL CALL

- II. Introductions
- III. Approval of the Agenda
- IV. Approval of Board Meeting Minutes A. September 10, 2019

V. Public Comments

Each speaker is limited to five minutes or less, depending on the number of speakers. Each speaker must fill out and submit an appearance card to the Board clerk.

VI. American Association of Veterinary State Boards (AAVSB) Matters A. Updates from Annual Meeting

VII. Administrative Items

- A. Terms for Drs. Dommer and Nesson
- B. Guidance Documents
 - 1. Bull Semen Collection
 - 2. Cannabis Products
- C. Delegated Medical Services
- D. Staffing Update
- E. Outreach to WTCS CVT Program Professors

VIII. Licensing/Exam Inquiries

A. Renewing a veterinarian license after a greater than 5-year break in licensing

IX. Administrative Code Updates

A. VE 7 - Complementary, Alternative and Integrative Therapies

B. VE 1-11 - Reorganization

X. Legislative Update

A. Wis. Stat. Ch. 89 Legislation: Initial License Fees

XI. Future Meeting Dates and Times

A. Schedule 2020 Quarterly Board Meetings and Discuss Possibility of Alternate Locations

XII. CONVENE TO CLOSED SESSION

CONVENE TO CLOSED SESSION to discuss the Wis. Admin. Code ch. VE 11 update on the request for proposals where bargaining reasons require a closed session (§ 19.85 (1) (e), Stats.); to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.).

XIII. Wis. Admin. Code Ch. VE 11 Update on the Request for Proposals (RFP)

XIV. Deliberation on Licenses and Certificates

XV. Deliberation on Proposed Stipulations, Final Decisions and Orders

- A. 14 VET 020 PB
- B. 17 VET 037 RD
- C. 18 VET 055 JA
- D. 19 VET 001 SL
- E. 19 VET 019 BM
- F. 19 VET 042 LR

XVI. Review of Veterinary Examining Board Pending Cases Status Report

XVII. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

XVIII. Open Session Items Noticed Above not Completed in the Initial Open Session

XIX. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

XX. Ratification of Licenses and Certificates

To delegate ratification of examination results to DATCP staff and to ratify all licenses and certificates as issued.

XXI. ADJOURNMENT

The Board may break for lunch sometime during the meeting and reconvene shortly thereafter.



State of Wisconsin

Veterinary Examining Board

Dr. Robert Forbes, DVM, Chair

VETERINARY EXAMINING BOARD

MEETING MINUTES

Tuesday, September 10, 2019

PRESENT: Diane Dommer Martin, D.V.M.; Robert Forbes, D.V.M.; Kevin Kreier, D.V.M.; Hunter Lang, D.V.M.; Lyn Schuh; Lisa Weisensel Nesson, D.V.M.

STAFF: Department of Agriculture, Trade, and Consumer Protection (DATCP) Division of Animal Health: Melissa Mace, VEB Executive Director; Office of the Secretary: Cheryl Daniels and Liz Kennebeck, DATCP Attorney; Robert Van Lanen, Regulatory Specialist Senior; Angela Fisher, Program Policy Analyst; Karen Torvell, Program Assistant Supervisor; Introductions and Discussion.

Robert Forbes, Chair, called the meeting to order at 11:01AM. A quorum of six (6) members was confirmed.

I. 11:00 A.M. OPEN SESSION – CALL TO ORDER – ROLL CALL

II. Introductions

A. New Member: Lyn Schuh

III. Approval of the Agenda

MOTION: Lisa Weisensel Nesson moved, seconded by Kevin Kreier, to approve the agenda. Motion carried unanimously.

IV. Approval of Board Meeting Minutes

A. April 24, 2019B. July 24, 2019

MOTION: Hunter Lang moved, seconded by Kevin Kreier, to approve the minutes from the April 24, 2019, and July 24, 2019, meetings. Motion carried unanimously.

V. Public Comments

Each speaker is limited to five minutes or less, depending on the number of speakers. Each speaker must fill out and submit an appearance card to the Board clerk. No appearance cards were submitted.

VI. American Association of Veterinary State Boards (AAVSB) Matters

 A. Annual Meeting and Voting Diane Dommer Martin and Melissa Mace attending. Include follow-ups on the October 23rd VEB agenda.

- 1. Proposed AAVSB Bylaws Amendment 2019 Board members did not express any concerns with the delegate voting to approve at the annual meeting.
- Proposed Resolution 2019-1 Board members did not express any concerns with the delegate voting to approve at the annual meeting. (See section XIV below for an additional note)
- 3. Nominating Committee Report and Information on Nominees Board members did not express any concerns with letting the delegate choose who to vote for at the annual meeting.

VII. Administrative Items

- A. Appointments of Liaisons, Alternates, and Delegates (Where Dr. Johnson Served)
 - Continuing Education Use alternate for time being and hold topic for October 23rd meeting.
 - 2. Screening Panel Lyn Schuh
- **MOTION:** Lisa Weisensel Nesson moved, seconded by Hunter Lang, to affirm the Chair's appointment of Lyn Schuh to the Screening Panel effective immediately. Motion carried unanimously.
 - 3. Credentialing Committee Hunter Lang
- **MOTION:** Kevin Kreier moved, seconded by Diane Dommer Martin, to affirm the Chair's appointment of Hunter Lang to the Credentialing Committee effective immediately. Motion carried unanimously.

VIII. Future Meeting Dates and Times

A. October 23, 2019 (9:00AM)
Topics to consider: The board will determine the 2020 board meeting schedule. Include a discussion of the possibility of alternate locations. Include AAVSB report out Continuing Education liason appoint

IX. CONVENE TO CLOSED SESSION

MOTION: Lisa Weisensel Nesson moved, seconded by Kevin Kreier, to convene to closed session to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.). Robert Forbes read the language of the

motion. The vote of each member by was ascertained by voice vote. Roll Call Vote: Kevin Kreier – yes; Diane Dommer Martin – yes; Lisa Weisensel Nesson – yes; Hunter Lang – yes; Lyn Schuh – yes; Robert Forbes – yes; Motion carried unanimously.

X. Deliberation on Licenses and Certificates

- A. 19 TECH 001 LB
- B. DS

XI. Deliberation on Proposed Stipulations, Final Decisions and Orders

- A. 18 TECH 008 KC
- B. 17 VET 026 & 18 VET 015 JK
- C. 18 VET 032 LY
- D. 19 VET 012 RE
- E. 19 VET 020 PJ
- F. 19 VET 031 CW

XII. Review of Veterinary Examining Board Pending Cases Status Report

XIII. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Diane Dommer Martin moved, seconded by Kevin Kreier, to reconvene to open session. Motion carried unanimously. The Board reconvened at 12:10PM.

XIV. Open Session Items Noticed Above not Completed in the Initial Open Session For the AAVSB annual meeting, the VIVA definition of "discipline" includes warnings so the delegate would need to clarify that the Wisconsin VEB cannot provide information regarding administrative warnings per Wis. Stat. ch. 89.

XV. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

- **MOTION:** Hunter Lang moved, seconded by Lisa Weisensel Nesson, to issue administrative warnings in the cases of 18 TECH 008 KC, 19 VET 012 RE, 19 VET 020 PJ, and 19 VET 031 CW. Motion carried unanimously.
- **MOTION:** Kevin Kreier moved, seconded by Hunter Lang, to issue an order granting full license in the case of 17 VET 026 & 18 VET 015 and to issue a final decision order and an order granting full license in the case of 18 VET 032 LY. Motion carried unanimously.

XVI. Ratification of Licenses and Certificates

MOTION: Diane Dommer Martin moved, seconded by Hunter Lang, to delegate ratification of examination results to DATCP staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

XVII. ADJOURNMENT

MOTION: Lisa Weisensel Nesson moved, seconded by Hunter Lang, to adjourn. Motion carried unanimously.

The meeting adjourned at 12:16PM.

1) Name and Title of Person Submitting the Request:		t: 2) Date When Requ	2) Date When Request Submitted:				
Melissa Mace		Items will be conside date.	Items will be considered late if submitted after 12:00 p.m. on the deadline date.				
3) Name of Board, Comr	nittee, Council, Sections:						
Veterinary Examining Board							
4) Meeting Date: Oct 23, 2019	5) Attachments: Yes No	6) How should the item be titled on the agenda page? Updates from annual meeting					
7) Place Item in: Open Session Closed Session	8) Is an appearan scheduled?	ice before the Board being Board Appearance Request)	9) Name of Case Advisor(s), if required:				
Melissa Mace (Executive Director) and Dr. Dommer (VEB member and secretary) attended the annual AAVSB meeting. They will provide a summary of relevant information they took away for the meeting.							
11)	A	Authorization					
Signature of person mal	king this request		Date				
Supervisor (if required)			Date				
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date							
 Directions for including supporting documents: This form should be attached to any documents submitted to the agenda. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 							

AGENDA REQUEST FORM

Handoot Agunda Itom VI. Updotes from Annual Meeting



2019 AAVSB® Annual Meeting & Conference Highlights

This is a highlights summary document of the 2019 AAVSB Annual Meeting & Conference that was held in St. Louis, Missouri from September 26-28, 2019. Please add this packet to your next Board/Council meeting as a reference of the actions taken at the meeting.

BUSINESS SESSIONS OVERVIEW

The 53 Delegates participated in business sessions on Friday and Saturday including:

- Hearing the Treasurer's Report with 2018 Financials
- Nominations from the floor during which a nomination was presented and deemed eligible
- Voting on elected positions including a contested election for the Director positions
- Voting on a Bylaws amendment
- Voting on an update to the Practice Act Model for a new definition of the Veterinary-Client 8 Patient-Relationship (VCPR)
- Considering a resolution requesting certain licensee data for the AAVSB database

Results from this participation include:

- Electing Dr. Chris Runde from Maryland as President-Elect
- Reelecting Dr. Tim Kolb from Ohio to a second term as Director
- Electing new Directors Ms. Amy Haywood, LVT (Washington, D.C.) and Dr. Mark Logan ۰ (New Jersey)
- Reelecting Dr. Bruce Louderback (Colorado) to a third term as an AAVSB Representative to the International Council for Veterinary Assessment (ICVA)
- Electing new Nominating Committee members Dr. Mark Olson (Kansas) and Dr. Steven Wills (Kentucky)
- Approving the Bylaws change which updated the Conference Committee role
- Approving **Resolution 2019-01** which outlines the data points Member Boards are encouraged to provide in their licensee updates to the AAVSB's VIVA® database. This is important as the specific licensee information increases the accuracy and completeness of the licensee records maintained by the AAVSB.
- Approving the VCPR change in the AAVSB's Practice Act Model
- Providing feedback to both the AAVSB and ICVA (the entity that administers the NAVLE®) on programs and services which would be beneficial

The Board of Directors submitted four **Proclamations** to the Delegates who approved all four. The Proclamations acknowledged the Missouri Veterinary Medical Board for hosting the meeting, Dr. TC Branch for chairing the Conference Committee, Dr. Mark Olson for service to the AAVSB committees and the Board of Directors, and to past and present staff members of the AAVSB for their contributions over the years.

In addition to the 53 Delegates, 40 Alternate Delegates were in attendance. And this year was the highest ever attending meeting with 240 total attendees.



2

EARLY EDUCATIONAL SESSION OUTCOMES

Executive Directors & Registrars received training on strategic planning to assist with board effectiveness. They also learned about the newest AAVSB services for Member Boards.

Early attendees heard from the ICVA on how the **NAVLE®** is developed and were able to provide feedback regarding using the exam for licensing.

The members of our Member Board participated in an afternoon workshop facilitated by the AAVSB Parliamentarian. They learned how to have effective and efficient meetings using **Robert's Rules of Order.** This interactive session also focused on special procedures for small boards.

GENERAL SESSION EDUCATION OUTCOMES

Two sessions focused on handling unique **complaints** and, as small groups, diving into the **discipline** process from three Member Boards.

The importance of having a regulatory **Mission Statement** and how to develop an elevator speech was shared.

The **top legal cases** session examined recent court cases involving veterinary regulation as well as regulation of other professions. Standards of Care, unlicensed practice, and unprofessional conduct were among the cases covered.

An attorney for veterinary organizations and a corporate veterinary clinic owner shared their insight on how regulators are perceived from the perspective of **corporate practices**.

The last afternoon was dedicated to the **future of veterinary medicine**. Representatives from an artificial intelligence organization based in the United Kingdom presented how they are entering the veterinary medicine market with telemedicine. Two educators provided information regarding the use of blockchain in veterinary education. The entire group was joined by an Executive Director and a Registrar to bridge ideas on innovation and regulation.

Resources for Your Board

The AAVSB Bylaws can be found at https://www.aavsb.org/about-us/governance

The AAVSB Practice Act Model (PAM) can be found at: <u>https://www.aavsb.org/board-services/member-board-resources/practice-act-model/</u>

Resolution 2019-01 can be accessed here: <u>https://bit.ly/2ppaAqN</u>

2019 AAVSB Annual Meeting & Conference Highlights

1) Name and Title of Person Submitting the Request:			2) Date When Request Submitted: August 6, 2019				
Melissa Mace			Items will be considered late if submitted after 12:00 p.m. on the deadline date.				
3) Name of Board, Committee, Council, Sections:							
Veterinary Examining Board							
			should the item be tit	led on the agenda page?			
October 23,	│	Terms	for Drs. Dommer and Nesson				
2019							
7) Place Item in:			e the Board being	9) Name of Case Advisor(s), if required:			
Open Session	scheduled						
Closed Session		-ill out Board Ap	pearance Request)				
	No 🗌 No						
Drs. Dommer and Nesson were appointed to serve and additional 4 year term from July 1, 2019. This does not account for the time served since the expiration of their initial appointments. This creates concerns for the board:							
1. As there ter	ms arguably should	expire as follows	S:				
• Dr. Dommer Martin: 7/01/2021							
•	Dr. Nesson 7/01/	2022					
Could their service to the board be called in question in a case where a Veterinarian license suspension or revocation case is reviewed they may not have legal standing to serve, and therefore vote.							
2. The VEB will have 4 member that all expire on 7/01/2023, this could create a significant issue for the board as 5 members are needed for a basic quorum and 6 for action on licenses such as suspension/revocation/reinstatement. If there were a delay in appointments being made and 2 or more chose to not continue in service the Board would not have quorum.							
11) Authorization							
,							
Signature of person making this request Date							
Supervisor (if required)			Date				
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date							
 Directions for including supporting documents: This form should be attached to any documents submitted to the agenda. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 							

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:				2) Date When Request Submitted: 10/14/19				
Angela Fisher, Program and Policy Analyst				Items will be considered late if submitted after 12:00 p.m. on the deadline date.				
3) Name of Board, Committee, Council, Sections:								
Veterinary Examining Board								
4) Meeting Date:				should the item be titled on the agenda page?				
Oct 23, 2019		⊠ Yes □ No Guida		nce Documents				
7) Place Item in:		8) Is an appearanc	e before	e the Board being	9) Name of Case Advisor(s), if required:			
Open Session		scheduled?		Deres ()				
Closed Session		│	oard Ap	pearance Request)				
Guidance Documents: - Bull Semen Collection: Updated draft for final approval by the Board - Cannabis Products: First draft for discussion by the Board								
11)		Α	uthoriza	tion				
Signature of person mak	Date							
Supervisor (if required)					Date			
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date								
Directions for including supporting documents:								
 This form should be attached to any documents submitted to the agenda. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 								
	3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a							
meeting.								

AGENDA REQUEST FORM

State of Wisconsin



Veterinary Examining Board

2811 Agriculture Drive • PO Box 8911 • Madison, WI 53708-8911 • Wisconsin.gov

Guidance Document VEB-GD-001 DRAFT Bull Semen Collection (Electro-Ejaculation)

Wis. Stat. § 89.03 (1) Wis. Admin. Code § VE 7.02 7/15/19 DRAFT

<u>Topic</u>

This guidance document clarifies which procedures involving electro-ejaculation bull semen collection, as listed below, a licensed veterinarian must perform, which procedures may be delegated to a certified veterinary technician, and which procedures may be delegated to an unlicensed assistant.

- 1. Insert the probe
- 2. Ejaculate the bull
- 3. Collect the semen sample
- 4. Evaluate the semen for concentration, motility, and morphology
- 5. Measure scrotal circumference
- 6. Based on the evaluation parameters listed in 4 and 5, give a rating as to semen quality

Relevant Statutes and Administrative Code

Wis. Stat. § 89.02 (6) defines the practice of veterinary medicine as to examine into the fact or cause of animal health, disease or physical condition, or to treat, operate, prescribe or advise for the same, or to under-take, offer, advertise, announce, or hold out in any manner to do any of said acts, for compensation, direct or indirect, or in the expectation thereof.

Wis. Stat. § 89.03 (1) authorizes the board to promulgate rules to establish the scope of the practice permitted for veterinarians and veterinary technicians, within the limits of the definition under Wis. Stat. § 89.02 (6).

Wis. Admin. Code § VE 1.01 (5) defines "direct supervision" as immediate availability to continually coordinate, direct and inspect personally the practice of another.

Wis. Admin. Code § VE 7.02 (1) (a) limits the diagnosis and prognosis of animal diseases and conditions to veterinarians and prohibits the delegation of such acts to veterinary technicians or other persons not holding such license or permit.

Wis. Admin. Code § VE 7.02 (3) (b) allows veterinarians to delegate to certified veterinary technicians, while under the direct supervision of the veterinarian, the provision of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis, including nonsurgical specimen collection.

Wis. Admin. Code § VE 7.02 (5) (a) allows veterinarians to delegate to unlicensed assistants, while under the direct supervision of the veterinarian, the provision of basic diagnostic studies, including nonsurgical specimen collection.

Wis. Admin. Code § VE 7.02 (6) (b) allows veterinarians to delegate to unlicensed assistants, while under the direct supervision of the veterinarian when the veterinarian is personally present on the premises where the services are provided, the provision of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis.

Wis. Admin. Code § VE 7.02 (8) (c) requires that, when the veterinarian is not required to be personally present on the premises where the delegated services are performed, the veterinarian must be available at all times for consultation either in person or within 15 minutes of contact by telephone, by video conference, or by electronic communication device.

Board Position

The Board determined that steps 1 (insert the probe), 2 (ejaculate the bull), and 3 (collect the semen sample) are acts of nonsurgical specimen collection. As such, a veterinarian may delegate steps 1 through 3 to a certified veterinary technician under the direct supervision of the veterinarian (VE 7.02 (3) (b), Wis. Admin. Code) and/or to an unlicensed assistant under the direct supervision of the veterinarian (VE 7.02 (5) (a), Wis. Admin. Code).

The Board determined that step 4 (evaluate the semen for concentration, motility, and morphology) is within the scope of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis. As such, a veterinarian may delegate step 4 to a certified veterinary technician under the direct supervision of the veterinarian (VE 7.02 (3) (b), Wis. Admin. Code) and/or to an unlicensed assistant under the direct supervision of the veterinarian while the veterinarian is personally present on the premises where the services are provided (VE 7.02 (6) (b), Wis. Admin Code).

The Board determined that step 5 (measure scrotal circumference) on its own would not be the practice of veterinary medicine. However, the process of bull semen collection is the practice of veterinary medicine. As such, all steps of the process of bull semen collection must either be performed by a veterinarian or be delegated by the veterinarian to a certified veterinary technician or an unlicensed assistant. A layperson could potentially measure scrotal circumference if the act is not a part of the process of bull semen collection and not a part of any other process that is the practice of veterinary medicine.

The Board determined that step 6 (based on the evaluation parameters listed in 4 and 5, give a rating as to semen quality) is a diagnosis. As such, step 6 is limited to veterinarians and may not be delegated to or performed by veterinary technicians or other persons not holding such a license or permit (VE 7.02 (1) (a), Wis. Admin. Code).



State of Wisconsin

Veterinary Examining Board

2811 Agriculture Drive • PO Box 8911 • Madison, WI 53708-8911 • Wisconsin.gov

Guidance Document VEB-GD-002 DRAFT Cannabis

Wis. Stat. § 89.03 (1) Wis. Admin. Code § VE 7.06 7/15/19 DRAFT

<u>Topic</u>

This guidance document clarifies what a veterinarian may and may not do with regards to cannabis products.

Definitions

Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. Federal law divides cannabis into two categories: hemp and marijuana.

Hemp is defined by the 7 USC 1639o(1) as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." The 2018 Farm Bill removed hemp from Schedule I of the Controlled Substances Act.

Marijuana/Marihuana is defined by 21 USC 802(16) as "all parts of the plant Cannabis sativa L., whether grown or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivate, mixture, or preparation of such plant, its seeds or resin," except for "hemp, as defined in section 16390 of title 7; or 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." Marijuana/Marihuana is listed in Schedule I of the Controlled Substances Act.

THC is an abbreviation of delta-9-tetrahydrocannabinol, a compound of the cannabis plant. Hemp plants contain no more than 0.3 percent THC on a dry weight basis, and marijuana plants contain more than 0.3 percent THC on a dry weight basis.

CBD is an abbreviation of cannabidiol, a compound of the cannabis plant. Hemp plants and marijuana plants both contain CBD.

Hemp Seeds are the seeds of the Cannabis sativa plant. The seeds of the plant do not naturally contain THC or CBD. The seeds may pick up trace amounts of TCH and/or CBD during the harvesting and processing when they are in contact with other parts of the plant.

Relevant Statutes and Administrative Code

Wis. Stat. § 89.02 (6) defines the practice of veterinary medicine as to examine into the fact or cause of animal health, disease or physical condition, or to treat, operate, prescribe or advise for the same, or to under-take, offer, advertise, announce, or hold out in any manner to do any of said acts, for compensation, direct or indirect, or in the expectation thereof.

Wis. Stat. § 89.03 (1) authorizes the board to promulgate rules to establish the scope of the practice permitted for veterinarians and veterinary technicians, within the limits of the definition under Wis. Stat. § 89.02 (6).

Wis. Stat. § 89.068 (1) (a) prohibits making extra-label use of a drug on an animal without a prescription or in any manner not authorized by that prescription.

Wis. Stat. § 89.068 (1) (c) 3. prohibits a veterinarian from prescribing a drug to a client for extra-label use on a patient unless all of the following apply:

- a. A veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian has made a careful medical diagnosis of the condition of the patient within the context of that veterinary-client-patient relationship.
- b. The veterinarian determines that there is no drug that is marketed specifically to treat the patient's diagnosed condition, or determines that all of the drugs that are marketed for that purpose are clinically ineffective.
- c. The veterinarian recommends procedures for the client to follow to ensure that the identity of the patient will be maintained.
- d. If the patient is a food-producing animal, the veterinarian prescribes a sufficient time period for drug withdrawal before the food from the patient may be marketed.

Wis. Stat. § 89.07 (1) (b) classifies violating any federal or state statute or rule that substantially relates to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

Wis. Admin. Code § VE 7.06 (4) classifies violating or aiding and abetting the violation of any law or administrative rule or regulation substantially related to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

Federal Law and Regulation

The 2018 Farm Bill removed hemp from the Controlled Substance Act 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 the authority of the United States Food and Drug Administration (FDA) to regulate products containing cannabis or cannabis-derived compounds under the Food, Drug and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. It is illegal to market or sell cannabis products in interstate commerce for animal use unless the FDA approves the product for animal use. To date, the FDA has not approved any cannabis product for animal use.

Drugs: Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure of the body of humans or animals, is a drug. To date, the FDA has not approved any cannabis-containing, cannabis-derived, or cannabis-related drugs for animal use. The FDA has approved one cannabis-derived (Epidiolex) and three cannabis-related (Marinol, Syndros, and Cesamet) prescription drugs for human use. The Animal Medicinal Drug Use Clarification Act (AMDUCA)

permits veterinarians to prescribe extra-label uses of FDA approved human and animal drugs for animals under certain conditions. Among other limitations, extra-label use of a drug is only allowed in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

Foods: All food ingredients must be approved by the FDA as either a food additive or as Generally Recognized as Safe (GRAS). The FDA also recognizes ingredients listed in the Official Publication of the Association of American Feed Control Officials (AAFCO). To date, neither the FDA nor AAFCO have approved any cannabis-containing or cannabis-derived foods for animal use. The FDA has approved three cannabis products as GRAS for human use only: hulled hemp seed, hemp seed protein powder, and hemp seed oil.

Supplements: The definition of dietary supplement only applies to human products. All products for animal use are classified as either foods or drugs and must be FDA approved. CBD and THC are the active ingredients in FDA approved human prescription drugs, so all products containing CBD or THC are classified as drugs.

See the attached FDA documents for additional information: "Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds," dated May 31, 2019, and "FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers," dated April 2, 2019. See the FDA website at www.fda.gov for the latest information regarding FDA regulation of cannabis-containing and cannabis-derived products.

Board Position

This is a draft document. The topic is on the agenda for the July 24th board meeting.

Administering, prescribing, or dispensing drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Stat. § 89.07 (b) and Wis. Admin. Code § VE 7.06 (4)).

Referring or recommending drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Admin. Code § VE 7.06 (4)).

Questions for the Board:

Are there times when a veterinarian can or should discuss cannabis products with their clients? If so, are there any guidelines for these types of discussions?

- For example:
 - If the client has already given the patient an unapproved product?
 - If the client expresses an intention to give the patient an unapproved product?
 - If the veterinarian's discussion is focused on avoiding negative consequences for the patient and does not make a referral or recommendation to use unapproved products?
 - If a client is giving the patient unapproved products, or expresses an intention to give the patient an unapproved product, and the veterinarian refuses to discuss or does not discuss concerns (such as FDA status), would there be a concern for the veterinarian's license?

V

IN THIS SECTION

←

SPEECH

Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

MAY 31, 2019

Speech by

Norman E. "Ned" Sharpless, MD Acting Commissioner of Food and Drugs - Food and Drug Administration

White Oak, MD

(Remarks as prepared for delivery)

Thank you for joining FDA today for this public hearing titled "Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds".

I am pleased to see that there is such interest in this topic. 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.

We encourage all stakeholders – presenters, attendees, and those unable to participate in today's hearing – to submit comments to our docket on this topic, which is open until July 2, 2019.

Docket comments will help inform FDA as we consider the important policy options related to the regulation of products containing cannabis or cannabis-derived compounds.

It is important to note that the FDA's role in the regulation of products containing cannabis or cannabis-derived compounds is not new.

Cannabis contains more than 80 biologically active chemical compounds, including the two 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. As I said, this is nothing new for FDA.

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."

Marihuana is included in Schedule I of the CSA – the most restrictive schedule – due to its potential for abuse, largely attributable to the psychoactive effects of THC, and the absence of a currently accepted medical use in the United States.

Late 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.

As these laws have changed, FDA's authorities have become more relevant.

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.

FDA treats substances derived from cannabis just like we do any other substances, and they are subject to the same authorities as any other substance.

Under FDA's authorities, the relevant legal requirements vary depending on which type of product we're talking about.

For example, 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.

FDA has approved several drug products that contain compounds found in cannabis.

These include EPIDIOLEX, which contains CBD, for the treatment of specific types of seizures in certain pediatric patients, and MARINOL and SYNDROS, which contains dronabinol, a synthetic THC, for uses including the treatment of anorexia in patients with AIDS.

These drugs have important therapeutic value, and it is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis.

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

We know that American consumers depend on FDA to help make sure that the food they eat, and that they serve to their families, is safe. We do this through a number of requirements.

For example, while we don't generally require foods to be approved by FDA before coming to market, 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.

I will note that several cannabis-derived substances have already come to market through the GRAS pathway.

In December, FDA announced that we completed our evaluation of GRAS notices for three hemp seed ingredients and had no objection to their being marketed in human foods for certain uses without approval, provided they comply with all other requirements.

As I mentioned earlier, however, 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.

Although the law says that FDA can issue regulations to create new exceptions to these statutory provisions, FDA has never issued a regulation like that for any substance.

So, if we were thinking about doing that for a substance like CBD, it would be new terrain for the FDA.

There are important reasons to generally prohibit putting drugs in the food supply. When FDA approves a drug, we carefully evaluate the risks and benefits of a specific formulation, dosage form, and strength for a particular population.

Often, we conclude that to be safely used, it requires a prescription or other medical supervision to help protect against potentially dangerous misuse.

THC and CBD are no exception.

There are real risks associated with both those substances and critical questions remain about the safety of their widespread use in foods and dietary supplements, as well as other consumer products – including cosmetics, which are subject to a separate regulatory framework.

And 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 cannabisfocused 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.

For example, how much CBD is safe to consume in a day? What if someone applies a topical CBD lotion, consumes a CBD beverage or candy, and also consumes some CBD oil? How much is too much? How will it interact with other drugs the person might be taking? What if she's pregnant? What if children access CBD products like gummy edibles? What happens when someone chronically uses CBD for prolonged periods?

These and many other questions represent important and significant gaps in our knowledge.

To help us evaluate these questions, as well as potential pathways for CBD products, FDA has formed an internal working group to address these data gaps specifically. You'll be hearing more from this group in the months to come.

FDA is aware that some companies appear to be marketing products containing cannabis and cannabis-derived compounds in ways that violate the law.

FDA has issued warning letters to companies selling unapproved CBD products.

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.

Selling unapproved drug products with unsubstantiated therapeutic claims is a violation of the law, and puts patients at risk.

Patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

That being said, the agency does not have a policy of enforcement discretion with respect to any CBD products.

There are lots of questions we will need to answer to ensure that FDA is taking an appropriate, well-informed, and science-based approach to the regulation of cannabis and cannabis derivatives, including CBD.

We hope that this meeting, and the comments submitted to our public docket, will help us as we try to approach this issue in an informed way. This hearing is an important step in our continued evaluation of cannabis and cannabis-derived compounds in FDA-regulated products.

I thank you all for taking the time to join us today and your contributions toward this important topic. We have a full agenda....

G More Speeches by FDA Officials (/news-events/speeches-fda-officials)

FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers

Over the past decade, there has been a growing interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.

Latest News

In order to inform the regulatory path forward, FDA is holding a **<u>public hearing</u>** (/NewsEvents/MeetingsConferencesWorkshops/ucm634550.htm) on May 31, 2019, for stakeholders to share their experiences and challenges with products containing cannabis and cannabis-derived compounds, including information and views related to the safety of such products, as well as to solicit input relevant to the agency's regulatory strategy related to existing products. As part of that hearing, FDA is opening a docket for the public to submit comments.

Below are a number of frequently asked questions and answers on this topic.

- 1. What are cannabis and marijuana?
- 2. <u>How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?</u>
- 3. <u>Has FDA approved any medical products containing cannabis or cannabis-derived</u> <u>compounds such as CBD?</u>
- 4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?
- 5. <u>Why hasn't FDA approved more products containing cannabis or cannabis-derived</u> <u>compounds for medical uses?</u>
- 6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?
- 7. <u>Has the agency received any adverse event reports associated with cannabis use for</u> <u>medical conditions?</u>

- 8. Is it legal for me to sell CBD products?
- 9. Can THC or CBD products be sold as dietary supplements?
- 10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?
- 11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?
- 12. <u>Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?</u>
- 13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?
- 14. <u>Will FDA take action against cannabis or cannabis-related products that are in violation</u> of the FD&C Act?
- 15. Can I import or export cannabis-containing or cannabis-derived products?
- 16. <u>What is FDA's role when it comes to the investigation of cannabis and cannabis-</u> <u>derived products for medical use?</u>
- 17. Does the FDA object to the clinical investigation of cannabis for medical use?
- 18. <u>How can patients gain access to cannabis or cannabis-derived products for medical</u> <u>use through expanded access?</u>
- 19. <u>Can patients gain access to cannabis or cannabis-derived products for medical use</u> <u>through Right to Try?</u>
- 20. Does the FDA have concerns about administering a cannabis product to children?
- 21. <u>Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?</u>
- 22. What does the FDA think about making CBD available to children with epilepsy?
- 23. What should I do if my child eats something containing cannabis?
- 24. I've seen cannabis products being marketed for pets. Are they safe?
- 25. Can hemp be added to animal food?
- 26. <u>Can approved human drugs containing CBD or synthetic THC be used extralabel in ani-</u><u>mals?</u>

1. What are cannabis and marijuana?

A. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

A. At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?

A. To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

FDA has approved Epidiolex, which contains a purified form of the drug substance CBD for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means FDA has concluded that this particular drug product is safe and effective for its intended use.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of cannabis. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

A. No. There are no other FDA-approved drug products that contain CBD. We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses , and we have issued several <u>warning letters (/NewsEvents/PublicHealthFocus/ucm484109.htm)</u> to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular

drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.

FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

The agency has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved. At the same time, FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA continues to believe that the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process (see Question #16).

5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?

A. FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products (see Question #2).

FDA relies on applicants and scientific investigators to conduct research. The agency's role, as laid out in the FD&C Act, is to review data submitted to the FDA in an application for approval to ensure that the drug product meets the statutory standards for approval.

The study of cannabis and cannabis-derived compounds in clinical trial settings is needed to assess the safety and effectiveness of these substances for the treatment of any disease or condition. FDA's December 2016 <u>Guidance for Industry: Botanical Drug Development</u> (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM458484.pdf)

provides specific recommendations on submitting INDs for botanical drug products, such as those derived from cannabis, in support of future marketing applications for these products. The FDA will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of cannabis. Additional information concerning research on the medical use of cannabis is available from the National Institutes of Health, particularly the <u>National Cancer Institute</u> (<u>https://www.cancer.gov/)</u> (NCI) and <u>National Institute on Drug Abuse (https://www.dru-gabuse.gov/drugs-abuse/marijuana/nih-research-marijuana-cannabinoids)</u> (NIDA).

6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?

A. The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of cannabis and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of cannabis products through adequate and well-controlled clinical trials. We welcome the opportunity to talk with states who are considering support for medical research of cannabis and its derivatives, so that we can provide information on Federal and scientific standards.

7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?

A. The agency has received reports of adverse events in patients using cannabis or cannabisderived products to treat medical conditions. The FDA reviews such reports and will continue to monitor adverse event reports for any safety signals, with a focus on serious adverse effects.

Information from adverse event reports regarding cannabis use is extremely limited; FDA primarily receives adverse event reports for approved products. General information on the potential adverse effects of using cannabis and its constituents can come from clinical trials that have been published, as well as from spontaneously reported adverse events sent to the FDA. Additional information about the safety and effectiveness of cannabis and its constituents is needed. Clinical trials of cannabis conducted under an IND application could collect this important information as a part of the drug development process.

8. Is it legal for me to sell CBD products?

A. It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

9. Can THC or CBD products be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (i.e., dietary ingredients that were not marketed in the United States in a dietary supplement before October 15, 1994) generally must notify FDA about these ingredients (see section 413(d) of the FD&C Act [21 U.S.C. § 350b(d)]). Generally, the notification must include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury (see section 402(f)(1)(B) of the FD&C Act [21 U.S.C. 342(f)(1)(B)]).

Numerous other legal requirements apply to dietary supplement products, including requirements relating to <u>Current Good Manufacturing Practices (CGMPs) (/Food/GuidanceRegula-</u><u>tion/CGMP/ucm079496.htm)</u> and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website.

10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to

which THC or CBD has been added?

A. No. Under section 301(II) of the FD&C Act [21 U.S.C. § 331(II)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When this statutory prohibition applies to a substance, it prohibits the introduction into interstate commerce of any food to which the substance has been added unless FDA, in the agency's discretion, has issued a regulation approving the use of the substance in the food (section 301(II) (2) of the FD&C Act [21 U.S.C. § 331(II)(2)]). To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of 301(II), and therefore might be able to be added to food. For example, as discussed in Question #12, certain hemp seed ingredients can be legally marketed in human food. However, all food ingredients must comply with all applicable laws and regulations. For example, by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive (sections 201(s) and 409 of the FD&C Act [21 U.S.C. §§ 321(s) and 348]). Aside from the three hemp seed ingredients mentioned in Question #12, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Food companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS processes.

11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

A. THC (dronabinol) is the active ingredient in the approved drug products, Marinol capsules (and generics) and Syndros oral solution. CBD is the active ingredient in the approved drug product, Epidiolex.

The existence of substantial clinical investigations regarding THC and CBD have been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex. (See <u>Sativex Commences US Phase II/III Clinical Trial in Cancer Pain (https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain) @ (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Dis-claimers/default.htm))</u>

12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?

A. In December 2018, FDA <u>completed its evaluation (/Food/NewsEvents/Constituen-</u> <u>tUpdates/ucm628910.htm</u>) of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. These GRAS notices related only to the use of these ingredients in human food. To date, FDA has not received any GRAS notices for the use of hemp-derived ingredients in animal food (see Question #25).

Hemp seeds are the seeds of the *Cannabis sativa* plant. The seeds of the plant do not naturally contain THC or CBD. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high."

The GRAS conclusions can apply to ingredients for human food marketed by other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food.

13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

A. A cosmetic is defined in 201(i) as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."

Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be

used in a cosmetic if it causes the product to be adulterated or misbranded in any way. A cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)]).

If a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. (See Question #3 for more information about drugs.)

FDA can take action if it has information that an ingredient or cosmetic product is unsafe to consumers. Consumers can report adverse events associated with cosmetic products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088, or by contacting your nearest FDA district office consumer complaint coordinator. For more information, please see the FDA's webpage on how to <u>report a cosmetic-related complaint (/Cosmetics/ComplianceEnforcement/AdverseEventReporting/default.htm)</u>.

14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?

A. The FDA has sent <u>warning letters (/NewsEvents/PublicHealthFocus/ucm484109.htm</u>) in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

15. Can I import or export cannabis-containing or cannabis-derived products?

A. <u>General information about the import/export of drug products regulated by FDA</u> (/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm) can be found online here. The <u>Drug Enforcement Administration</u> (https://www.dea.gov/) (DEA) is the federal agency responsible for enforcing the controlled substance laws and regulations in the U.S. and, as such, should be consulted with respect to any regulations/requirements they may have regarding the import or export of products containing cannabis. Please see here for <u>information about importing or exporting food ingredients</u> (/Food/GuidanceRegulation/ImportsExports/default.htm).

Regarding imports, if it appears that an article is adulterated, misbranded, in violation of section 505 of the FD&C Act, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(II) of the FD&C Act, such article will be refused admission (see section 801(a)(3) of the FD&C Act [21 U.S.C. § 381(a)(3)]).

Research and Expanded Access

16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?

A. To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with the FDA and submit an IND application to the Center for Drug Evaluation and Research (CDER). The IND application process gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. For research for use as an animal drug product, researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

As discussed above (see Question #2), the 2018 Farm Bill removed hemp from the CSA. This change may streamline the process for researchers to study cannabis and its derivatives, including CBD, that fall under the definition of hemp, which could speed the development of new drugs.

Conducting clinical research using cannabis-related substances that are scheduled by the DEA often involves interactions with several federal agencies. This includes: a registration administered by the DEA; obtaining the cannabis for research from NIDA, within the National Institutes of Health, or another DEA-registered source; and review by the FDA of IND of INAD application and research protocol. Additionally:

- For a Schedule I controlled substance under the CSA, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site cannabis will be studied.
- NIDA provides research-grade cannabis for scientific study. The agency is responsible for overseeing the cultivation of cannabis for medical research and has contracted with the University of Mississippi to grow cannabis for research at a secure facility. Cannabis of varying potencies and compositions is available. DEA also <u>may allow additional growers</u> (https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-be-come-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to) to register with the DEA to produce and distribute cannabis for research purposes.
- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs in CDER depending on the therapeutic indication. Based on the results obtained in studies conducted at the IND stage, sponsors may submit a marketing application for formal approval of the drug.

17. Does the FDA object to the clinical investigation of cannabis for medical use?

A. No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from cannabis. The FDA supports the conduct of that research by:

- 1. Providing information on the process needed to conduct clinical research using cannabis.
- Providing information on the specific requirements needed to develop a drug that is derived from a plant such as cannabis. In December 2016, the FDA updated its <u>Guidance for Industry: Botanical Drug Development (/downloads/Drugs/GuidanceComplianceRegulatory-Information/Guidances/UCM458484.pdf)</u>, which provides sponsors with guidance on submitting IND applications for botanical drug products.
- 3. Providing specific support for investigators interested in conducting clinical research using cannabis and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.

 Providing general support to investigators to help them understand and follow the procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research's <u>Small Business and Industry Assistance group (/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm)</u>.

18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?

A. Expanded access (/NewsEvents/PublicHealthFocus/ExpandedAccessCompassion-

ateUse/default.htm) is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies available. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?

A. <u>Information for patients on Right to Try (/ForPatients/Other/ucm625115.htm)</u> (RTT) is available on our website. RTT is designed to facilitate access to certain investigational drugs through direct interactions between patients, their physicians and drug sponsors – FDA is not involved in these decisions. Sponsors developing drugs for life-threatening conditions are responsible for determining whether to make their products available to patients who qualify for access under RTT. If you are interested in RTT, you should discuss this pathway with your licensed physician. Companies who develop drugs and biologics, also known as sponsors, can provide information about whether their drug/biologic is considered an eligible investigational drug under RTT and if they are able to provide the drug/biologic under the RTT Act.

Children and Pregnant/Lactating Women

20. Does the FDA have concerns about administering a cannabis product to children?

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products containing cannabis or cannabis-derived compounds, and will continue to work with companies interested in bringing safe, effective, and quality products to market. With the exception of Epidiolex, Marinol, and Syndros, no product containing cannabis or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population, whether pediatric or adult.

21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?

A. The FDA is aware that there are potential adverse health effects with use of cannabis products containing THC in pregnant or lactating women. Published scientific literature reports potential adverse effects of cannabis use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and

stillbirth. [<u>1</u>, <u>2</u>, <u>3</u>] Based on published animal research, there are also concerns that use of cannabis during pregnancy may negatively impact fetal brain development. [<u>4</u>, <u>5</u>, <u>6</u>] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue cannabis use. In addition, ACOG notes that there are insufficient data to evaluate the effects of cannabis use on breastfed infants; therefore, cannabis use is discouraged when breastfeeding. [<u>7</u>] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of cannabis use.

22. What does the FDA think about making CBD available to children with epilepsy?

A. The FDA has approved Epidiolex, which contains a purified form of the drug substance CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended use. Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring cannabis-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, and the assurance of manufacturing quality standards, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

23. What should I do if my child eats something containing cannabis?

A. With the exception of products such as the hemp seed ingredients discussed in Question #12, which have been evaluated for safety, it is important to protect children from accidental ingestion of cannabis and cannabis-containing products. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion. If the parent or caregiver has a reasonable suspicion that the child accidentally ingested products containing cannabis, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

Pets and other Animals

24. I've seen cannabis products being marketed for pets. Are they safe?

A. FDA is aware of some cannabis products being marketed as animal health products. We want to stress that FDA has not approved cannabis for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

While the agency is aware of reports of pets consuming various forms of cannabis, to date, FDA has not directly received any reports of adverse events associated with animals given cannabis products. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting cannabis, we encourage you to report the adverse event to the FDA. Please visit **Reporting Information about Animal Drugs and De-vices (/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm#Drugs and Devic-es)** to learn more about how to report an adverse event related to an animal drug or for how to report an adverse event or problem with a pet food.

25. Can hemp be added to animal food?

A. All ingredients in animal food must be the subject of an approved food additive petition or generally recognized as safe (GRAS) for their intended use in the intended species. If an animal food contains an ingredient that is not the subject of an approved food additive petition or GRAS for its intended use in the intended species, that animal food would be adulterated under section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)]. In coordination with state feed control officials, CVM also recognizes ingredients listed in the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) as being acceptable for use in animal food. At this time, there are no approved food additive petitions or ingredient definitions listed in the AAFCO OP for any substances derived from hemp, and we are unaware of any GRAS conclusions regarding the use of any substances derived from hemp in animal food. Learn more about animal food ingredient submissions (/AnimalVeterinary/SafetyHealth/AnimalFeed-SafetySystemAFSS/default.htm) here.

With respect to products labeled to contain "hemp" that may also contain THC or CBD, as mentioned above it is a prohibited act under section 301(II) of the FD&C Act to introduce or deliver for introduction into interstate commerce any animal food to which THC or CBD has been added.

26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

A. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), permits veterinarians to prescribe extralabel uses of approved human and animal drugs for animals under certain conditions. Extralabel use must comply with all the provisions of AMDUCA and its implementing regulation at 21 CFR § 530. Among other limitations, these provisions allow extralabel use of a drug only on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship and only in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

In addition, under 21 CFR 530.20, extralabel use of an approved human drug in a food-producing animal is not permitted if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the use. In addition, under 21 CFR 530.20(b)(2), if scientific information on the human food safety aspect of the use of the approved human drug in food-producing animals is not available, the veterinarian must take appropriate measures to ensure that the animal and its food products will not enter the human food supply.

For more information on extralabel use of FDA approved drugs in animals, see <u>Extralabel Use of</u> <u>FDA Approved Drugs In Animals (/AnimalVeterinary/GuidanceComplianceEnforce-</u> <u>ment/ActsRulesRegulations/ucm085377.htm#extralabel)</u>. [1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. Clinical Chemistry. 2010; 56(9): 1442-1450.

[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ Open. 2016; 6:e009986.

[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. Pediatric Research. 2012; 71 (2): 215-219.

[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. Neurotoxicol and Teratol 2012; 34(1): 63-71.

[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. Psychopharmacology (Berl) 2008; 198(4): 529-537.

[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. Addict Biol 2007; 12(3-4): 485–495.

[7] <u>ACOG Committee Opinion: Marijuana Use During Pregnancy and Lactation</u> (https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committeeon-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation) @ (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

Related Information

- FDA and Marijuana (/NewsEvents/PublicHealthFocus/ucm421163.htm)
- Marijuana Research with Human Subjects (/NewsEvents/PublicHealthFocus/ucm421173.htm)

More in <u>Public Health Focus</u> (/NewsEvents/PublicHealthFocus/default.htm)

Expanded Access (Compassionate Use) (/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm)

1) Name and Title of Per	son Submitting the Request		2) Date When Request Submitted: October 10, 2019						
Melissa Mace			Items will be considered late if submitted after 12:00 p.m. on the deadline						
		date.							
3) Name of Board, Comr	nittee, Council, Sections:								
Veterinary Examining Be	oard								
4) Meeting Date:	5) Attachments:	6) How should the item be tit	tled on the agenda page?						
Oct 23, 2019	No	Delegated Medical Services							
7) Place Item in:		ce before the Board being	9) Name of Case Advisor(s), if required:						
 ☑ Open Session ☑ Closed Session 	scheduled?	Board Appearance Request)							
	No	,							
specific medica These changes specifically spe able to (or have on the premise performed by (have received know why this these commen This delegation medical service	al services that could be dele s, and the resulting education elled out to be a medical serve e been prior to this rule) dele es. Specifically the concern in CVT under the direct supervi a couple comments that this can't be done by an unlicens ts is in the attached emails.)	egated to other by the license n on these changes brought t vices that can be delegated to egate to unlicensed techniciar is over the placement of an IV ision of a licensed veterinarian s has been being done by an u sed assistant with veterinarian to be performed prior to this n	at was surgery, and in that process defined ad veterinarian. o light some medical practices that are now o a CVT, that many veterinarians want to be ns under the direct supervision of a veterinarian 'C, which was added to items that could be n if the veterinarian is on the premises. We inlicensed assistant, and they would like to n supervision (a good example of the flavor of rule change either as it was not defined as a CVT. However the added clarity in rule has						
11)	Α	Authorization							
Signature of person mal	king this request		Date						
Supervisor (if required)	Supervisor (if required) Date								
Executive Director signa	ature (indicates approval to a	add post agenda deadline iten	n to agenda) Date						
2. Post Agenda Deadlin	attached to any documents s e items must be authorized l	by a Supervisor and the Exect	utive Director. e to the Bureau Assistant prior to the start of a						

Handout VII. Administrative Items; C. Delegated Medical Services

General Response to VE 7 rule regarding delegated medical service:

As discussed here is the summary of changes that were recently effective in medical services that can be delegated to a CVT or an unlicensed CVT. The rule now actually allows more broadly for the administration of injections to be delegated to a CVT, however it does not restrict what was previously allowed to be delegated to CVTs or unlicensed technicians. So it allows injections that that were not previously addressed by rule as a medical service that could be delegated by a veterinarian, to be so delegated. It does not restrict the delegation of any medical services that were previously allowable under the law.

This rule change did not <u>limit</u> what veterinary services a veterinarian may delegate to a CVT or an unlicensed assistant with or without a veterinarian on the premises. It actually <u>expands</u> which services may be delegated to a CVT under the direct supervision of the veterinarian if the veterinarian is on the premises where the services are provided.

The substantive changes made in regards to what medical services may be delegated, were made to VE 7.02(4) which <u>was amended</u> to clarify <u>additional veterinary services</u> (additional activities that were added are in Bold) that maybe performed by a CVT under the direct supervision of a veterinarian, when the veterinarian is personally present on the premises where the services are provided:

7.02(4) Veterinarians may delegate to certified veterinary technicians the provision of the following veterinary medical services under the direct supervision of the veterinarian when the veterinarian is personally present on the premises where the services are provided:

(a) Administration of local or general anesthesia, including induction and monitoring.

(b) Performing diagnostic radiographic contrast studies.

(c) Dental prophylaxis and simple extractions that require minor manipulation and minimal elevation.

(d) Sample collection via a cystocentesis procedure.

(e) Placement of intravenous and arterial catheters.

(f) Suturing of tubes and catheters.

(g) Fine needle aspirate of a mass.

(h) Performing amniocentesis, embryo collection and transfer, follicular aspiration, and transvaginal oocyte collection and recovery on livestock.

Previously these acts would not have been eligible for delegation in any capacity to CVTs or unlicensed assistants and would have had to be performed by the licensed veterinarian.

VE 7.02(3), (5) and (6) were not changed and allow for delegation as described below:

VE 7.02(3) <u>was not amended</u> and its provisions continue to allow the following veterinary services to be delegated to certified veterinary technicians:

(3) Except as provided under s. <u>95.21 (2)</u>, Stats., veterinarians may delegate to certified veterinary technicians the provision of the following veterinary medical services under the direct supervision of the veterinarian:

Handout VII. Administrative Items; C. Delegated Medical Services

(a) Nonsurgical veterinary treatment of animal diseases and conditions, including administration of vaccines, including rabies vaccines.

(b) Observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis, including routine radiographs, nonsurgical specimen collection, drawing of blood for diagnostic purposes, and laboratory testing procedures.

(c) Administration of sedatives and presurgical medications.

(e) Nutritional evaluation and counseling

*under the direct supervision does not require the veterinarian to be on the premises. However the veterinarian must be available for consultation, as described in VE 7.02(8) (c).

VE 7.02(5) <u>was not amended</u> and its provisions continue to allow the following veterinary services to be delegated to unlicensed assistants:

(5) Veterinarians may delegate to unlicensed assistants the provision of the following veterinary medical services under the direct supervision of the veterinarian:

- (a) (a) Basic diagnostic studies, including routine radiographs, nonsurgical specimen collection, and laboratory testing procedures.
- (b) (b) Monitoring and reporting to the veterinarian changes in the condition of a hospitalized animal patient.
- (c) (c) Dispensing prescription drugs pursuant to the written order of the veterinarian. *under the direct supervision does not require the veterinarian to be on the premises. However the veterinarian must be available for consultation, as described in VE 7.02(8) (c)

VE 7.02(6) <u>was not amended</u> and continues to allow the following veterinary services_to be delegated to an unlicensed assistant:

(6) Except as provided under s. <u>95.21</u>, Stats., veterinarians may delegate to unlicensed assistants the provision of the following veterinary medical services under the direct supervision of the veterinarian when the veterinarian is personally present on the premises where the services are provided:

(a) Nonsurgical veterinary treatment of animal diseases and conditions, including administration of vaccines, and administration of sedatives and presurgical medications.

(b) Observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis, including the drawing of blood for diagnostic purposes.

(c) Dental prophylaxis.

(d) Nutritional evaluation and counseling.

The full rules regarding the delegation of veterinary medical acts are detailed in VE 7.02, which is available for review or downloanding here: https://docs.legis.wisconsin.gov/code/admin_code/ye/7

For all statutes and rules related to the VEB regulations can easily be accessed here: <u>https://docs.legis.wisconsin.gov/code/admin_code/ve</u>

From: Sent: To: Subject: DATCP VEB Tuesday, July 30, 2019 11:26 AM Mace, Melissa A - DATCP FW: new rules

Question for you.

Thank you,

Karen Torvell Program Assistant Supervisor Bureau of Animal Disease Control/Division of Animal Health Wisconsin Department of Agriculture, Trade and Consumer Protection Office: 608-224-4896 Fax: 608-224-4871 Karen.torvell@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Michel Peterson <chelpete@hotmail.com> Sent: Monday, July 29, 2019 5:32 PM To: DATCP VEB <datcpveb@wisconsin.gov> Subject: new rules

I received the email about the new rules for CVT's..... It states that only a CVT can administer injections, place IV catheters and perform cystocentesis. How would a Veterinary Technician student fall in this rule? Can they perform these procedures under supervision at a clinic? We have 2 students working at my clinic.

Thank you

Michel Peterson, CVT

From: Sent: To: Subject: DATCP VEB Tuesday, July 30, 2019 11:27 AM Mace, Melissa A - DATCP FW: Question about new rule

More coming

Karen Torvell Program Assistant Supervisor Bureau of Animal Disease Control/Division of Animal Health Wisconsin Department of Agriculture, Trade and Consumer Protection Office: 608-224-4896 Fax: 608-224-4871 <u>Karen.torvell@Wisconsin.gov</u>

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Kaitlin Young <kaitlinyoung@gmail.com>
Sent: Monday, July 29, 2019 5:45 PM
To: DATCP VEB <datcpveb@wisconsin.gov>
Subject: Question about new rule

Hi,

I have a question about the new definitions of surgery for veterinarians and CVTs. It mentions injections. I'm wondering about blood draws and non-rabies vaccinations. Are non-certified trained assistants allowed to do vaccines (other than rabies) that are given SQ and are they allowed to draw blood or is this limited to CVTs since it involves penetration of the skin?

Thanks for the clarification.

Kaitlin Young, DVM

From: Sent: To: Subject: DATCP VEB Tuesday, July 30, 2019 11:32 AM Mace, Melissa A - DATCP FW: Question regarding the "new rules for vetrinary medicaine effective July 1" e-mail received yesterday

Karen Torvell Program Assistant Supervisor Bureau of Animal Disease Control/Division of Animal Health Wisconsin Department of Agriculture, Trade and Consumer Protection Office: 608-224-4896 Fax: 608-224-4871 Karen.torvell@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: amym@wauwatosavet.com <amym@wauwatosavet.com>
Sent: Tuesday, July 30, 2019 9:11 AM
To: DATCP VEB <datcpveb@wisconsin.gov>
Subject: Question regarding the "new rules for vetrinary medicaine effective July 1" e-mail received yesterday

I am looking for a little clarification regarding the new rules for veterinary medicaine. The list of procedures that can be designated to a CVT only, states administration of injesctions, including local and general anestheia. Does this mean "injection" of any sort including but not limited to: vaccinations, subcutaneous fluids, administering of an antibiotic can only be administered by a CVT, and not a trained assistant?

We want to ensure we are following all regulations. I appreciate your time and response.

Thank you,

Amy Murphy CVT, CCRP

Director of Medical Services Wauwatosa Veterinary Clinic 414-475-5155

amym@wauwatosavet.com

From: Sent: To: Subject: DATCP VEB Tuesday, July 30, 2019 11:27 AM Mace, Melissa A - DATCP FW: Rules change

Karen Torvell Program Assistant Supervisor Bureau of Animal Disease Control/Division of Animal Health Wisconsin Department of Agriculture, Trade and Consumer Protection Office: 608-224-4896 Fax: 608-224-4871 Karen.torvell@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Robert Shampo <docbob94@gmail.com> Sent: Monday, July 29, 2019 5:52 PM To: DATCP VEB <datcpveb@wisconsin.gov> Subject: Rules change

I was just reading the email about the recent rules change and have some questions for clarification, specifically as they relate to the bullets below.

1. How does the administration of injections relate to administration of vaccinations other than rabies? Previously, other than rabies, other vaccinations may be administered but assistants under the supervision of a licensed veterinarian. And if assistants can no longer provide these vaccinations, then what will come of the OTC purchase of these vaccines in Wisconsin?

2. What about injection of antibiotics such as Convenia, polyflex and cefazolin? Or anti-nausea medications such as metoclopramide and Cerenia? In a hospital setting, these medications are often given by CVTs and assistants.

3. I've worked in many clinics over the course of my career and frequently IVCs are placed by assistants and CVTs alike, all under supervision of a licensed veterinarian. Am I reading this correctly that now they have to be placed by the Dr. or CVT only? Aren't we making that more restrictive than human medicine? I could be mistaken but I don't think placement if an IVC is restricted to only Dr. and RNs in human medicine.

Finally, it fascinates me that we are restricting injection of anesthetics and possibly antibiotics and anti-emetics as a veterinary medical procedure but yet use a pentobarbital (a schedule II narcotic) is not considered a veterinary medical procedure. Am I missing something here?

Thanks, Bob Shampo, DVM Cudahy Veterinary Clinic The procedures listed below are considered the practice of veterinary medicine. A licensed veterinarian may delegate the performance of them to a CVT only when under the direct supervision of a licensed veterinarian, when the veterinarian is personally present on the premises.

- Simple dental extractions that require minor manipulation and minimal elevation.
- Administration of injections, including local and general anesthesia.
- Sample collection via a cystocentesis procedure.
- Placement of intravenous and arterial catheters.

From: Sent: To: Subject: DATCP VEB Tuesday, July 30, 2019 11:32 AM Mace, Melissa A - DATCP FW: new Wisconsin rules for veterinary medicine

Karen Torvell Program Assistant Supervisor Bureau of Animal Disease Control/Division of Animal Health Wisconsin Department of Agriculture, Trade and Consumer Protection Office: 608-224-4896 Fax: 608-224-4871 Karen.torvell@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Tara Donovan <tdonovan@hanorusa.com>
Sent: Tuesday, July 30, 2019 9:41 AM
To: DATCP VEB <datcpveb@wisconsin.gov>
Subject: new Wisconsin rules for veterinary medicine

Hello,

I just read the new rules sent to me via email by the Wisc DATCP. In the section concerning injections: -Administration of injections, including local and general anesthesia.

on livestock farms, injections are given by farmers under the direction of the veterinarian but the veterinarian is not on premise.

Also, vaccinations which are injections.

is there any clarification for livestock farms? Thank you, Tara

Tara Donovan, DVM Vice-President of Health Management The HANOR Company of Wisconsin, LLC E4614 Hwy 14-60 Spring Green, WI 53588 Office: (608)588-9627 Cell: (608)588-5406 tdonovan@hanorusa.com www.hanorcompany.com

	son Submitting the Request	: 2) Date When Requ 10-11-2019	2) Date When Request Submitted: 10-11-2019					
Melissa Mace		Items will be consider date.	red late if submitted after 12:00 p.m. on the deadline					
3) Name of Board, Comr	nittee, Council, Sections:							
Veterinary Examining B	oard							
4) Meeting Date:	5) Attachments:	6) How should the item be tit	tled on the agenda page?					
Oct 23, 2019		Staffing Updates						
7) Place Item in: Open Session Closed Session	scheduled?	ce before the Board being Board Appearance Request)	9) Name of Case Advisor(s), if required:					
New State Vete	erinarian – Dr. Darlene Konkl	e						
No longer Acti	ng Executive Director – Meli	ssa Mace						
Request for a I	Permanent Inspector Position	n – At DOA						
	-	ive items, such as DSPS files ional LTE to assist legal. Fund	and transitioning them to CRM (DATCP ction in a paralegal aspect.					
11)	Δ	Authorization						
Signature of person mai	king this request		Date					
Supervisor (if required)	Supervisor (if required) Date							
Executive Director signation	ature (indicates approval to a	add post agenda deadline iten	n to agenda) Date					
 Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 								

	rson Submitting the Request	: 2) Date When Reque 10-11-2019	est Submitted:					
Melissa Mace		Items will be consider date.	red late if submitted after 12:00 p.m. on the deadline					
3) Name of Board, Com	mittee, Council, Sections:							
Veterinary Examining B	Veterinary Examining Board							
4) Meeting Date:	5) Attachments:	6) How should the item be tit	led on the agenda page?					
Oct 23, 2019	□ No	Outreach to WTCS – CV	/T program					
7) Place Item in: Open Session Closed Session								
	and Lyn Shuh will be present common barriers on Oct. 30,	• • •	am professor regarding requirements for					
11)	Α	Authorization						
Signature of person ma	king this request		Date					
Supervisor (if required)			Date					
Executive Director signa	ature (indicates approval to a	add post agenda deadline item	n to agenda) Date					
 This form should be Post Agenda Deadlin 	Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting							

1) Name and Title of Per	son Submitting the Request	t: 2) Date When Requ	est Submitted:				
Melissa Mace		Items will be consider date.	Items will be considered late if submitted after 12:00 p.m. on the deadline date.				
3) Name of Board, Comr	nittee, Council, Sections:						
Veterinary Examining B	oard						
4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?					
Oct 23, 2019	⊠ Yes □ No	Renewing a veterinarian lice licensing.	nse after a greater then 5year break in				
7) Place Item in: Open Session Closed Session	scheduled?	ice before the Board being Board Appearance Request)	9) Name of Case Advisor(s), if required:				

AGENDA REQUEST FORM

Melissa Mace received a contact from a veterinarian that was last licensed in 2009. The license was not renewed in the intervening years, and now the individual is inquiring regarding the process to renew their veterinarian license.

VE 7.055, below, speaks to this type of renewal but has some lack of detail as to what is acutally required for:

1. Continuing education, less than 5 years clearly states 30 hours (7.055(1)), greater than 5 years refers to VE 10 which does not directly address this issue.

2. What does the requirement for the board to inquire as to whether the applicant is competent to practice as a veterinarian in this state look like, what is the process?

VE 7.055 Renewal of license. A license expires if not renewed by January 1 of even-numbered years. A licensee who allows the license to expire may apply to the board for renewal of the license as follows:

(1) If the licensee applies for renewal of the license less than 5 years after its expiration, the license shall be renewed upon payment of the renewal fee and fulfillment of the 30 hours of continuing education required under ch. <u>VE 10</u>.

(2) If the licensee applies for renewal of the license 5 or more years after its expiration, in addition to requiring the licensee to pay the renewal fees required under s. 440.08, Stats., and to fulfill the continuing education hours required under ch. VE 10, the board shall inquire as to whether the applicant is competent to practice as a veterinarian in this state and shall impose any reasonable conditions on reinstatement of the license, including reexamination, as the board deems appropriate. An applicant under this subsection is presumed to be competent to practice as a veterinarian in this state if at the time of application for renewal the applicant holds a full unexpired license issued by a similar licensing board of another state or territory of the United States or of a foreign country or province whose standards, in the opinion of the board, are equivalent to or higher than the requirements for licensure in this state. Notwithstanding any presumption of competency under this subsection, the board shall require each applicant under this subsection to pass the examination specified under s. VE 3.02 (4).

Email exchange between Melissa Mace VEB Exec Director, and Cheryl Daniels VEB attorney attached.

11)	Authorization	
Signature of perso	n making this request	Date
Supervisor (if requ	ired)	Date
Executive Director	signature (indicates approval to add post agend	a deadline item to agenda) Date
1. This form shoul 2. Post Agenda De	ding supporting documents: d be attached to any documents submitted to th adline items must be authorized by a Superviso ovide original documents needing Board Chairpo	

From:	Daniels, Cheryl F - DATCP
Sent:	Wednesday, October 9, 2019 4:39 PM
То:	Mace, Melissa A - DATCP
Cc:	Saynisch, Carrie L - DATCP
Subject:	RE: Applying for a license after a 10 year lapse

That's a good question, Melissa. I have no idea if the VEB ever really judged competency for someone who simply has been out of the practice for, in this case, about 10 years. With lawyers, if you make up the CLEs, and you don't have anything as a blemish on your personal record, you can get back into the practice. Now one interesting thing that we need to discuss. Lawyers have to make up ALL the CLEs they missed – so 30 hours for every 2 years they have been out of practice. That section of the administrative code could be read the same way, which would mean he would need to complete 150 hours of CEs, in which case I think the VEB would consider him competent enough to re-license. The thought is with lawyers, and same could be said for veterinarians, that things have changed enough in ten years, that you need that amount of CEs to get yourself up to speed in practice from where you left those years ago.

Given all that, the subject probably requires a discussion with the board.

Cheryl Furstace Daniels Legal Counsel – Office of the Secretary Board Counsel – Wisconsin Veterinary Examining Board Board Counsel – Wisconsin Livestock Facility Siting Review Board Wisconsin Department of Agriculture, Trade and Consumer Protection 608-224-5026 cheryl.daniels@wisconsin.gov



Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Mace, Melissa A - DATCP <Melissa.Mace@wisconsin.gov>
Sent: Wednesday, October 9, 2019 4:28 PM
To: Daniels, Cheryl F - DATCP <Cheryl.Daniels@wisconsin.gov>
Cc: Saynisch, Carrie L - DATCP <carrie.saynisch@wisconsin.gov>
Subject: Applying for a license after a 10 year lapse

Cheryl;

A Dr. David Cook has reached out with a question on how to relicense as a veterinarian. His prior veterinarian license expired in 2009, he did not continue to practice and followed a different opportunity. Now he is looking to see what he would need to do if wanted to re-license. There is no disciplinary issue. I am curious if you have any knowledge of how this has been handled previously.

Looking at statute and rule the rule, the only requirements I see for this is VE 7.055 Renewal of License sub (2):

VE 7.055(2) (2) If the licensee applies for renewal of the license 5 or more years after its expiration, in addition to requiring the licensee to pay the renewal fees required under s. 440.08, Stats., and to fulfill the continuing education hours required under ch. VE 10, the board shall inquire as to whether the applicant is competent to practice as a veterinarian in this state and shall impose any reasonable conditions on reinstatement of the license, including reexamination, as the board deems appropriate. An applicant under this subsection is presumed to be competent to practice as a veterinarian in this state if at the time of application for renewal the applicant holds a full unexpired license issued by a similar licensing board of another state or territory of the United States or of a foreign country or province whose standards, in the opinion of the board, are equivalent to or higher than the requirements for licensure in this state. Notwithstanding any presumption of competency under this subsection, the board shall require each applicant under this subsection to pass the examination specified under s. VE 3.02 (4).

So how I understand this:

Type: He will apply as a Cat 3, which will require that he submit everything like a new grad (so proof of degree, NAVLE score, declaration of discipline and convictions, and he will have to retake the State exam)
Fee: \$185.00
CE: Not sure here, I think that he will need to demonstrate 30 hours of CE for the 2018-2019 years.
Competency: How does the Board inquire as to whether the applicant is competent to practice as a veterinarian?

Melissa Mace

Director, Bureau of Field Services, Division of Animal Health Executive Director Veterinary Examining Board Wisconsin Department of Agriculture, Trade and Consumer Protection Phone: 608-224-4883 Cell: 608-279-3861 Fax: 608-224-4903 <u>Melissa.Mace@Wisconsin.gov</u>

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

1) Name and Title of Per	rson Submitting the Request	: 2) Date When Requi	2) Date When Request Submitted: 10-11-2019						
Melissa Mace		Items will be consider date.	red late if submitted after 12:00 p.m. on the deadline						
3) Name of Board, Com	3) Name of Board, Committee, Council, Sections:								
Veterinary Examining Board									
4) Meeting Date:	5) Attachments:	6) How should the item be tit	led on the agenda page?						
Oct 23, 2019	│ ⊠ Yes │	Administrative Code Up	odates						
00120, 2010									
7) Place Item in:		ce before the Board being	9) Name of Case Advisor(s), if required:						
Open Session	scheduled?	Board Appearance Request)							
Closed Session	No	obard Appearance Request							
VE 1-11 Scope	VE 7 CAITS – Approved by the Governor, timeline for finalization to be discussed VE 1-11 Scope for reorganization and minor modifications, status and timeline to be discussed.								
Signature of person ma	king this request		Date						
Supervisor (if required)			Date						
Executive Director signation	ature (indicates approval to a	add post agenda deadline item	n to agenda) Date						
 This form should be Post Agenda Deadlin 		by a Supervisor and the Execu	utive Director. e to the Bureau Assistant prior to the start of a						

DAH Rules Estimated Timelines

Future dates are estimates for the purposes of work planning. Board meeting dates for 2020 onwards are not yet scheduled. Last Updated: 10/14/19

								Sta	tement of Sc	ope							Hearing Drat	t							Fina	Draft						
										Board Approval Prelim.	Prelim.			Hearing Draft		Board		Clearing- house				Board		Governor		Final Draft	Committ.		JCRAR	Final	Deadline to Refer to	
					Begin		Governor	Scope	Materials	Hearing &	Hearing &	Materials	Board	Posted for	Materials	Approval	Clearing-	Comment		Hearing	Materials	Approval	Final Draft	Approval	Final Draft	Referred	Review	Final Draft	Review	Adopted	Legis.	Rule
			DATCP	Clearing-	Scope	Scope to	Approval	Published	in Board	Comment	Comment	to Office of	Approve	EIA	to Office of	of Hearing	house	Received	Hearing	Record	to Office of	of Final	to	of Final	Referred	to	Period	Referred	Period	Rule Sent	(Scope	Effective
`	Topic	Scope #	Docket #	house #	Process	Governor	of Scope	in Register	Agenda	Period	Period	Secretary	Scope	Comment	Secretary	Draft	Referral	by DATCP	Dates	Open Until	Secretary	Draft	Governor	Draft	to Legis.	Committ.	Ends	to JCRAR	Ends	to LRB	Expires)	Date
VE 7	CAITs	SS 025-16	16-VER-7	CR 17-084	x	3/16/16	4/15/16	4/18/16	x	x	x	x	4/27/16	x	x	10/25/17	11/30/17	12/19/17	1/10/18, 1/11/18, 1/12/18, 1/9/18	1/31/18	x	2/13/18	3/2/18	10/3/19	10/25/19	11/4/19	1/3/20	1/13/20	3/13/20	3/19/20	2/4/20	5/1/20
VE 1-10	Reorg	SS 100-18			x	6/4/18	8/22/18	8/23/18	x	x	x	x	DATCP 9/20/18, VEB 11/7/18	In process of revising scope																	2/27/21	
VE 1-11	ReorgRevise	2			5/17/19	11/1/19	12/31/19	1/14/20	3/23/20	4/13/20	5/13/20	5/22/20	6/12/20	9/10/20	11/18/20	12/9/20	12/16/20	1/5/21	1/12/21	1/26/21	4/5/21	4/26/21	5/3/21	7/2/21	7/16/21	7/26/21	9/24/21	10/4/21	12/3/21	12/17/21	7/14/22	2/1/22
			Rule P	rocess Step:	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Step 11	Step 12	Step 13	Step 14	Step 15	Step 16	Step 17	Step 18	Step 19	Step 20	Step 21	Step 22	Step 23	Step 24	Step 25	Sten 26	Expiration	Step 2
		General	Projection A		•	90	60	14	21	90	30	21	30	90	21	90	7	20	7	14	21	90	7	60	14	10	60	10	60	14	30	1-2
			cific projectio	•	-	days	days	days	days	days	days	days	days	days	days	days	davs	days	days	days	days	days	days	days	days	days	days	days	days	days	months	month
		(-1			drafting	after	after	after	before	after	after	before	after	after	before	after	after	after	after	after	before	after	after	after	after	after	after	after	after	after	after	after
					scope	Step 1	Step 2	Step 3	Step 6	Step 4	Step 6	Step 9	Step 7	Step 9	Step 12	Step 10	Step 12	Step 13	Step 14	Step 15	Step 18	Step 16	Step 18	Step 19	Step 20	Step 21	Step 21	Step 22	Step 24	Step 25	Step 4	Step 26
				Notes:					7 days OS +			7 days OS +	· · ·		· ·	14, 30, or					7 days OS +	•					30 days,		30 days,			1st of
									14 days			14 days	after Step 4		14 days	60 days					14 days						can be		can be			month
									Board			Board	if no			comments					Board						extended		extended			after 1 fu
													prelim.			+ 30 days											to 60 days		to 60 days			month
													hearing			revisions											,.		,.			

I	Key
White	Estimated date
Blue	Actual date
Red	Projection exceeds deadline for adoption
Yellow	Date requires revision

	son Submitting the Request	: 2) Date When Require 10-14-2019	2) Date When Request Submitted: 10-14-2019					
Angela Fisher		Items will be consider date.	red late if submitted after 12:00 p.m. on the deadline					
3) Name of Board, Com	mittee, Council, Sections:							
Veterinary Examining Board								
4) Meeting Date: 5) Attachments: 6) How should the item be titled on the agenda page?								
Oct 23, 2019	□ No	Legislative Update						
7) Place Item in: Open Session Closed Session	scheduled?	ce before the Board being Board Appearance Request)	9) Name of Case Advisor(s), if required:					
Informational I Ch. 89 – Initial	∟egislative Update: License Fees							
11)	A	Authorization						
Signature of person ma	king this request		Date					
Supervisor (if required)			Date					
Executive Director signation	Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date							
 Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 								

DAH Relevent Statutes Current Status

2019-2020 Legislative Session Last Updated: 10/14/19

Agency	Ch.	Citation	Торіс	Description	LRB #	Bill #	Status Notes
DATCP	89	89.063	Initial Fees	Would remove initial license fees for veterinarians and veterinary	2457/1,	AB-130,	7/18/19 Fiscal estimate received.
				technicians.	1925/1	SB-140	3/28/19 Referred to committee.

	rson Submitting the Request	: 2) Date When Requ 10-14-2019	est Submitted:					
Angela Fisher		Items will be consider date.	Items will be considered late if submitted after 12:00 p.m. on the deadline date.					
3) Name of Board, Com	mittee, Council, Sections:							
Veterinary Examining B	Veterinary Examining Board							
4) Meeting Date:	5) Attachments:	6) How should the item be tit	led on the agenda page?					
Oct 23 2010		Future Meeting Dates a	nd Timee					
Oct 23, 2019	No No	Future Meeting Dates a	na Times					
7) Place Item in:	8) Is an appearan	ce before the Board being	9) Name of Case Advisor(s), if required:					
Open Session	scheduled?	-						
Closed Session		Board Appearance Request)						
	No No							
Schedule 2020	Schedule 2020 quarterly board meetings and discuss the possibility of alternate locations							
11)								
11)	F	Authorization						
Signature of person ma	king this request		Date					
Supervisor (if required)			Date					
Executive Director signation	ature (indicates approval to a	add post agenda deadline iterr	n to agenda) Date					
 This form should be Post Agenda Deadlin 	Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting							

2019 meeting Dates:

Routine aiming for the 3rd Wednesday of the first month of the quarter:

Jan. 30

April 24

July 24

Oct 23

Proposed dates for 2020

Jan. 22

April 22

July 22

Oct 21