Veterinary Medical Board
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MEMORANDUM

DATE	January 17, 2023
TO	Veterinary Medical Board (Board)
FROM	Leah Shufelt, RVT, Chair Multidisciplinary Advisory Committee (MDC)
SUBJECT	**Agenda Item 6.B. Recommendation on Proposed Regulatory Amendments to California Code of Regulations (CCR), Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 Regarding Veterinary Drug Compounding**

Background

The Board's drug compounding regulations became effective on April 1, 2022. During the January 2022 meeting, the Board directed the MDC to create a guidance document to assist licensees and registrants in complying with the new regulations. Dr. Sullivan and Ms. Ussery formed the Subcommittee to draft the guidance, as well as a courtesy formula form for use by practitioners to comply with CCR, title 16, section 2092, subsection (b).

On April 19, 2022, the MDC reviewed and approved the Subcommittee's Guidance on Veterinary Drug Compounding (Guidance) and a courtesy formula form (Compounded Drug Preparation Formula Form). On July 20, 2022, the Board reviewed, revised, and approved the Guidance and Compounded Drug Preparation Formula Form.

During the development of the Guidance, the Subcommittee identified several gaps in the paper trail that is necessary to document the process of compounding a drug preparation for a client or for office stock. In addition, the MDC received comments from stakeholders at its April 19, 2022 meeting that raised concerns about the efficiency of the process and lack of registered veterinary technicians (RVTs) in the workforce. A second issue was the cumbersome documentation requirements for compounded intravenous (IV) fluids administered on a continuous basis to an animal patient.

During the July 19, 2022 MDC meeting, the Subcommittee presented two ways, a legislative proposal and a regulatory proposal, to resolve the gaps in the regulations and the practical inefficiencies. At that meeting, the MDC approved a recommendation to the Board to submit to the California State Legislature an amendment to Business and Professions Code section 4826.5 to authorize a veterinary assistant controlled substance permit (VACSP) holder to compound preparations under the direct supervision of a veterinarian. This amendment is intended to help resolve the bottleneck of the compounding process that has arisen from veterinary workforce issues, but still has the consumer protection of

requiring veterinarian supervision of a “licensed” person. The Board reviewed and approved that legislative proposal at its October 19-20, 2022 meeting.

With respect to the regulatory proposal, discussion and public comment during the July 19, 2022 MDC meeting revealed that additional changes to the medical recordkeeping requirements for compounding drug preparations were needed.

As described in more detail here, the Subcommittee presented multiple regulatory amendments and the rationale behind each amendment during the October 2022 MDC meeting. After significant discussion with the MDC and stakeholders, the MDC approved a motion to recommend to the Board the attached regulatory proposal. For ease of reference, the discussion and amendments made during the meeting are reflected in the attached draft minutes.

One issue left to resolve for presentation of the rulemaking to the Board was whether to keep the requirement in CCR, title 16, section 2094, subsection (b)(3) (office stock labels to contain lot number or control number assigned by the preparer). However, the Subcommittee was unable to find any reference to item (3) in the Practice Act. Therefore, the Subcommittee recommends striking CCR, title 16, section 2094, subsection (b)(3).

After reviewing the MDC October 18, 2022 Meeting Minutes, the Subcommittee notes there is duplication of record keeping in CCR, title 16, section 2094, subsection (b)(1), that can be resolved by using the compounded drug preparation’s name indicated in the master formula document. CCR, title 16, section 2092, subsection (b), establishes requirements for the documentation of compounded drug preparations for office stock on a master formula document, which must include the name, strength, and quantity of each active ingredient. CCR, title 16, section 2094, subsection (d), only applies to formula records for compounded drug preparations for specific animal patients. Since there is no specific animal patient for office stock, compounded drug preparations must be documented on a master formula document. Since compounded drug preparations for office stock must be documented on a master formula document, the Subcommittee recommends amending CCR, title 16, section 2094, subsection (b)(1), to remove and replace “, strength, and quantity of each ingredient” with “assigned to the compounded drug preparation pursuant to paragraph (7) of subsection (b) of section 2092.” Section 2092, subsection (b), would also be amended to add new paragraph (7), to require documentation of the name assigned to the compounded drug preparation. These proposed amendments would reduce the amount of information listed on office stock labels and streamline the labelling process.

Action Requested

Please review and discuss the attached regulatory proposal. If the Board agrees with the MDC’s recommendations, please entertain a motion to approve the proposed regulatory changes, direct the Executive Officer to take all steps necessary to initiate the rulemaking process, authorize the Executive Officer to make any technical or non-substantive changes to the rulemaking package, notice the proposed text for a 45-day comment period and, if no adverse comments are received during the 45-day comment period and no hearing is requested, adopt the proposed regulatory changes.

Attachment

1. Regulatory Proposal to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 Regarding Veterinary Drug Compounding
2. Draft October 18, 2022 MDC Minutes Related to the above Regulatory Proposal

VETERINARY MEDICAL BOARD
REGULATORY PROPOSAL TO AMEND
CALIFORNIA CODE OF REGULATIONS, TITLE 16,
SECTIONS 2036.5, 2090, 2091, 2092, AND 2094

Additions are indicated in single underline.

Deletions are indicated in ~~single strikethrough~~.

Amend section 2036.5 of article 4 and sections 2090, 2091, 2092, and 2094 of article 11 of division 20 of title 16 of the California Code of Regulations as follows:

Article 4. Practice

§ 2036.5. Animal Hospital Health Care Tasks for Permit Holders and Veterinary Assistants.

(a) Permit holders and veterinary assistants shall be prohibited from performing any of the functions or activities specified in subsections (a)~~,~~, (b)~~,~~ and (c) of Section 2036 of these regulations, except that a permit holder under the direct or indirect supervision of a licensed veterinarian may administer a controlled substance or perform drug compounding as specified in subsections (c) or (d).

(b) Subject to the provisions of subsection (a) of this section, permit holders and veterinary assistants in an animal hospital setting may perform auxiliary animal health care tasks under the direct or indirect supervision of a licensed veterinarian or the direct supervision of an R.V.T. The degree of supervision by a licensed veterinarian over a permit holder or veterinary assistant shall be higher than or equal to the degree of supervision required when an R.V.T. performs the same task and shall be consistent with standards of good veterinary medical practices.

(c) Permit holders in an animal hospital setting may perform drug compounding from bulk drug substances under the direct supervision of a licensed veterinarian.

(d) Permit holders in an animal hospital setting may perform drug compounding from non-bulk drug substances under the direct or indirect supervision of a licensed veterinarian or the direct supervision of an R.V.T.

Note: Authority cited: Sections 4808 and 4836, Business and Professions Code. Reference: Sections 4826.5, 4836 and 4840, Business and Professions Code.

Article 11. Compounding in a Veterinary Premises

§ 2090. Definitions.

(a) “Compounding” means any of the following activities performed in a registered veterinary premises by a licensed veterinarian, ~~that~~who has established the veterinarian-client-patient relationship for the animal patient(s), or an R.V.T. ~~registered veterinary technician~~ or a permit holder under the direct or indirect supervision of that veterinarian:

(1) Altering the dosage form or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a compounded drug preparation from chemicals.

(b) “Compounding” also means preparing a compounded drug preparation from bulk substances by a licensed veterinarian, who has established a veterinarian-client-patient relationship for the animal patient or prepares the compounded drug preparation for office stock, or by an R.V.T. or permit holder~~registered veterinary technician~~ under the direct supervision of that veterinarian.

(c) “Compounding” does not include:

(1) Reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration.

(2) The sole act of tablet splitting or crushing~~,~~ or capsule opening.

(3) Addition of flavoring agent(s) to enhance palatability.

(d) “Expiration date” means the date, or date and time, determined from the date the preparation is compounded, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored other than for quarantine purposes.

(e) “Immediate use” means administration of a sterile compounded drug preparation to an animal patient beginning within four hours from the time the drug preparation was compounded.

(f~~e~~) “Office stock” means a compounded drug prepared without a patient-specific prescription that may be used within the registered veterinary premises where the drug preparation was compounded, in mobile units and vehicles operated from the registered veterinary premises in accordance with section 4353 of the code, or dispensed only to a client, client's representative, or other veterinarian at the same veterinary premises.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2091. Veterinary Drug Compounding.

(a) A veterinarian shall ensure the safety and efficacy of a compounded drug preparation, through reliance on drug compounding standards in the profession and in accordance with section 2032.

(b) A veterinarian shall not perform or supervise the performance by an R.V.T. or permit holder of either sterile or non-sterile drug compounding when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.

(c) A veterinarian shall not perform or supervise the performance by an R.V.T. or permit holder of either sterile or non-sterile drug compounding unless there are no other human or animal drugs approved by the United States Food and Drug Administration (FDA) and available that satisfy the need for this preparation.

(d) Sterile drug compounding shall be for immediate use except in the following conditions:

(1) A dilution of the ingredients is essential for the safe administration of the preparation.

(2) There is historical documentation of the need, safety, and efficacy of the preparation.

(e) Only sterile drugs approved by the FDA shall be used as the ingredients in a sterile compounded drug preparation.

(f) For non-sterile compounded drug preparations, active pharmaceutical ingredients (APIs) shall be purchased from an FDA-registered facility, and all records of such purchases shall be maintained for three (3) years to prove the origin of the APIs.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2092. Policies and Procedures.

(a) A veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual, which shall include:

(1) A list of each of the requirements of subsections (b) and (e) and sections 2093 and 2094.

(2) Policies and procedures for the training of an R.V.T. ~~registered veterinary technician~~ or permit holder who may perform compounded drug preparations.

(3) Policies and procedures for a quality assurance program established pursuant to section 2095.

(b) ~~For each compounded drug preparation, a~~ Except as provided under subsections (d) and (e), a master formula document shall be maintained for each compounded drug preparation and include all of the following:

(1) Equipment to be used.

(~~1~~2) Name, strength, and quantity of each a~~A~~ctive ingredient~~s~~ to be used.

(3) Calculation of e~~E~~xpiration date of the compounded drug preparation.

(4) Name, strength, and quantity of each i~~I~~nactive ingredient~~s~~ to be used.

(5) Specific compounding steps to be used to prepare the compounded drug preparation.

(6) Instructions for storage, handling, and administration of the compounded drug preparation.

(7) Name assigned to the compounded drug preparation.

(c) The master formula document may be included in the policies and procedures manual maintained pursuant to subsection (a).

(d) If the compounded drug preparation is not routinely compounded and a master formula document is not otherwise maintained pursuant to subsection (b), a formula record for the compounded drug preparation ~~may~~ shall be kept in the medical record of the animal patient and shall include all information required in paragraphs (2) through (7) of subsection (b).

(e) Notwithstanding subsections (b) and (d), for intravenous (IV) compounded drug preparations for immediate use on an animal patient that contain a sterile solution that is not otherwise compounded at the veterinary premises, the name and quantity of the sterile solution and the name, strength, and quantity of the ingredient(s) added to the sterile solution shall be recorded in the animal patient's medical record.

(~~e~~f) For each compounded drug preparation prepared for an animal patient, the following information shall be recorded in the animal patient's medical record:

(1) Name or initials of the veterinarian who made or supervised the making of a compounded drug preparation and the name or initials of the R.V.T.~~registered veterinary technician~~ or permit holder, if any, who made the compounded drug preparation.
(2) Expiration date of the compounded drug preparation.
~~(3) Directions for its storage and administration.~~
(43) Name, amount, and strength of the compounded drug preparation.
(4~~5~~) Date the drug preparation was compounded.

(~~f~~g) The veterinarian performing or supervising the compounding of drug preparations is responsible for the following:

(1) Training and supervision of the R.V.T. ~~registered veterinary technician~~ or permit holder who is compounding the drug preparation.

(2) Proper storage of the drugs used in compounding and the compounded drug preparations.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

§ 2094. Labeling of Compounded Preparations.

(a) All labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(b) All office stock ~~other~~shall be labeled with the following information:

(1) Name assigned to the compounded drug preparation pursuant to paragraph (7) of subsection (b) of section 2092~~, strength, and quantity of each ingredient~~.

(2) Expiration date.

~~(3) Lot number or control number assigned by the preparer.~~

(34) Name or initials of the preparer.

(45) Date of drug preparation.

(c) If the label or packaging of a component or ingredient in the compounded drug preparation indicates refrigeration is required, the label of the compounded drug preparation shall state refrigeration is required.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

6. Update, Discussion, and Potential Recommendation to the Board on Proposed Regulatory Amendments to California Code of Regulations (CCR), Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 Regarding Veterinary Drug Compounding Subcommittee – *Richard Sullivan, DVM, and Marie Ussery, RVT*

Meeting Materials

Webcast: 00:33:50

Dr. Sullivan presented this item and described the regulatory proposal, included in the meeting materials, discussed further below.

Proposed Amendments to CCR, Title 16, Section 2036.5

Meeting Materials

Webcast: 00:37:15

Dr. Sullivan explained the purpose of adding subsections (c) and (d) to allow Veterinary Assistant Controlled Substance Permit holders, in an animal hospital setting, to perform drug compounding either in bulk or non-bulk under the supervision of a licensed veterinarian, or in the case of non-bulk under the direct supervision of an RVT.

Dr. Sullivan requested public comment on this item. There were no public comments made on this item.

Proposed Amendments to CCR, Title 16, Section 2090

Meeting Materials

Webcast: 00:39:18

Dr. Sullivan explained the proposed amendments, included in the meeting materials, and noted a change on page 8 under subsection (e) "Immediate use" to remove the word "on" and replace it with "to". The language will state:

> (e) "Immediate use" means administration of a sterile compounded drug preparation to an animal patient within four hours from the time the drug preparation was compounded.

Dr. Lazarcheff inquired where the four-hour limit [in subsection (e)] was from and whether it was a standard term.

Dr. Sullivan responded that the original term was referenced in California Board of Pharmacy regulations. However, the U.S. Pharmacopeia (USP) has used the term "immediate use" in their updated guidelines. The USP accommodated veterinarians a little bit with this term; previously, the term was phrased "within one hour of the

preparation," and they were asked to give veterinarians some more leeway. The USP is still in the process of defining it as "within four hours;" Dr. Sullivan did not believe the USP guidelines have been totally approved yet. Dr. Sullivan explained the regulatory proposal would be a way to circumvent some of the drug compounding paperwork requirements. Under the proposed term of immediate use, veterinarians would not have as strict of recordkeeping requirements.

Ms. Welch added that the point is efficiency and streamlining the documentation process so animals can get the care they need, and to address the lack of staff in veterinary premises. The proposed amendment is intended to help the veterinary staff get the required drug compounding documentation down in a faster manner. She noted the "immediate use" documentation requirements would be discussed in the next section.

Following discussion of proposed amendments to CCR, title 16, section 2092, subsections (f) and (h) in section 2090 on page 7 were struck.

Dr. Sullivan requested public comment on this item. There were no public comments made on this item.

Proposed Amendments to CCR, Title 16, Section 2091

Meeting Materials

Webcast: 00:44:16

Dr. Sullivan described the proposed amendments, included in the meeting materials.

Dr. Sullivan answered a question from Dr. Sequoia seeking clarification of "historical documentation" in subsection (d)(2).

Dr. Sullivan requested public comment on this item. There were no public comments made on this item.

Proposed Amendments to CCR, Title 16, Section 2092

Meeting Materials

Webcast: 00:49:02

Dr. Sullivan presented this item and explained the sample Master Formula Form prepared by Ms. Ussery that was not included in the meeting materials as it would not be provided to practitioners until the proposed regulatory amendments were made effective. Dr. Sullivan discussed the proposed amendments, included in the meeting materials, and Dr. Sullivan and Ms. Ussery responded to Committee member questions.

Dr. Sullivan requested public comment on this item. The following public comments were made on this item:

- Grant Miller, DVM, CVMA, stated that this language was much clearer than the previous version and was headed in the right direction. He appreciated Dr. Bradbury's comments because they demonstrated that every practitioner who reads the regulation may see it differently; therefore, he felt that the guidance document would be pivotal to the success of the implementation. He added the guidance document, which is in the next section, was very good. He noted that it would probably need to be updated to reflect some of the more recent changes in these proposed regulations, but overall, he thought the document was getting to a better place in making this something attainable. He appreciated the Board's proactivity in creating a Master Formula Form, but it was not necessary in this regulation. He stated the regulation could state a master formula document may be maintained to include the items listed. Then, if the Committee wished, the guidance could offer a form; but the Committee may want to consider whether or not there needed to be a "Master Formula Form" in regulations. He did not mind it being there, but it probably was not necessary. He agreed that the Unique Formula Code may be unnecessary, and when he thought about this whole process, he recalled the Committee was not actually creating something new here – the Committee was trying to get around something that was already happening every day, but that practices were not using a unique formula code. He stated [practitioners] are probably writing [the information] on the bottle. So, he thought the Committee could probably go back more towards that. Dr. Miller provided an example of how a practice may be practicing now, because no one has an unlabeled bottle; the veterinarians are writing something on the bottles. He noted that perhaps the Master Formula Code or the Unique Formula Code were not necessary. He added that the veterinarians can just write the name and ingredients on there and make that work, so maybe this will get discussed in the labeling section, but it was a huge improvement and much easier to understand.

Dr. Sullivan said the word "may" is there, which indicated [the Master Formula Form] was not mandatory.

Ms. Welch noted that under subsection (d), if there is not a Master Formula Form, then the compounded drug preparation must be documented in the animal patient medical record and include the required items from paragraphs (2) through (7). There would be some documentation required for the compounded drug preparation.

Dr. Sullivan stated that was not the intent of subsection (d), but that is where they wound up.

Dr. Bradbury believed the Unique Formula Code would be more confusing than helpful in the end.

- Nancy Ehrlich, RVT, CaRVTA, inquired that if there was no section (b) Master Formula Form maintained, the licensee would have to [document the information in paragraphs] (2) through (7) in the patient record. She questioned why paragraphs (3) and (6) needed to be in the record.

Dr. Sullivan stated that the word "may" is an example of something that they can use; but if they have some other way of having the recipe for these compounded products, then it does not have to be in the medical record. He stated the reason for subsection (d) was, for example, if a compounded preparation was made only once, the licensee would not have to go through all the steps of the Master Formula Form. The licensee could put it in the medical record.

Ms. Ehrlich noted that, as written, if the Master Formula Form was not used, then everything must be included in the patient record, including the equipment to be used.

Dr. Sullivan responded affirmatively if the formula was going to be used one time; there will need to be an explanation of how the preparation was compounded.

Ms. Ehrlich inquired if licensees were going to have to explain atropine is mixed in a syringe.

Dr. Sullivan noted this was a requirement of the USP. If the Board does not establish its own guidelines, then that is what would be required.

Ms. Ehrlich stated she was concerned on the impact it will have to veterinary medicine as it is costing a lot more and the clients are getting upset. She asserted that this is going to increase the cost of administering drugs and prescribing drugs astronomically, and she thought it was going to be a detriment to the veterinary profession and recommended striking requirements in [paragraphs] (3) and (6). She added the information is not necessary for the patient record as there is irrelevant information being required.

Dr. Bradbury stated the example was one specific example, and there are many that are being sent home and compounded. As Dr. Miller mentioned previously, this is a current requirement. She noted there is a recipe to follow that must be documented.

Ms. Ehrlich noted that the regulations require the equipment to be used and the specific compounding steps.

Dr. Bradbury noted those are important steps, as some items may need mixing in a specific order. She added those things need to be written instructions for the person doing the compounding.

Ms. Ehrlich opined that nobody is going to be doing this.

- Dr. Miller stated for clarification relating to drawing up two sedatives in a single syringe for a patient, there is a special consideration in subsection (e), which

the Committee had yet to discuss. He noted that subsection (e) stated that if something is done for immediate use of some sterile, injectable IV products, they can essentially do an abridged version in the record that states that the name, strength, and quantity of those solutions needs to be recorded, which the profession is already doing now. He reminded everyone that this effort by the Board is of great service to the veterinary profession because if it were up to other boards, this would not occur at all. He added that it took CVMA years to do a statutory change to get the right to compound within their veterinary practices, to meet their patients' needs, and this Board is following its mandate pursuant to that statute to create regulations to make that happen. He felt that these regulations have come a long way. He stated the regulations are difficult, but it is correct that a lot of the requirements were already being done by the licensees, and he would encourage the [Committee] to remember that it was not creating something new here, it was just trying to harness what it was already doing, and he thought the Board is getting really close. He believed the Unique Formula Code maybe is going to end up working against [practitioners] and creating more confusion. He believed that licensees could write on the vials; it would not be perfect, but he thought that was what is probably already going on in the practice, so he thought that deserved a little more consideration.

Ms. Welch, the Committee, and Ms. Sieferman discussed the items brought up by the public and revised portions of the regulation.

- Dr. Miller stated the reason the language is there is because the Board is trying to follow the spirit of the USP monographs. However, the issue was that veterinarians essentially do what is called simple compounding. The veterinarians are not using bulk ingredients, and they are not doing a lot of complicated work on this. He stated it was essentially taking two FDA approved products and putting them in one syringe or adding something to IV fluids, or taking two creams, and putting them together in one container. For that very simple compounding, equipment is really not necessary, but the language is an attempt to stick with the spirit of what compounding is in a general sense, so that the Board is not criticized for not playing by the rules created. He agreed and thought that for 90% of the time, licensees are using a syringe as their equipment. He did not think that practitioners are going to inherently understand what the equipment part means, but he thought a guidance document can really help to discern, especially the samples that are provided in the Master Formula Document. He thinks it can go a long way to help people understand that it really is not rocket science; it is writing down what is happening. He noted that it might be worth it to just keep it there just to try to stay in the spirit of what USP mentions as a best practice.

The Committee, Ms. Sieferman, and Ms. Welch discussed the items brought up by the public and revised portions of the regulation.

The Committee took a brief break and continued discussing the items brought up by the public, and revised portions of the regulation.

- Dr. Miller thought that when the Board is creating a Master Formula Form, it is binding itself to a legal responsibility that it does not need. He stated it was great to have [a master formula form] in the guidance, but immediately what is going to come up is OAL is going to review the form to determine if it is legally acceptable. He noted that the form did not match the definition, which states it is a list of all drug preparations that is not reflective on the form; the form is not a list. It is an individual document, so that would have to be addressed. He asserted that a Master Formula Form is not necessary. Dr. Miller suggested the Committee can just state "the licensee has to maintain a document that has the following information…" in the guidance. He stated it would be great if the Committee would like to provide them a sample. In addition, he stated if there is an item titled a Master Formula Form, in capital letters, people are going to assume that it is a paper document. He said that one of the first questions that will come up is can this be electronically maintained. He agreed with the line of thinking, and he did not think it was necessary to have a Master Formula Form as a specific item referenced in regulations. He thought it was great if the Committee wanted to do that as guidance, but it was not necessary here. He stated he had seen boards get into trouble with this in the past by creating specific forms that they reference in the regulations. Dr. Miller stated that this can create problems as the world changes while the regulations are bound and require a specific item.

Ms. Sieferman, the Committee, and Ms. Welch discussed the items brought up by the public and revised portions of the regulation.

After Committee discussion and public comment, the proposed regulatory amendments to section 2092 were revised as follows:

- In subsection (b), strike the phrase "For each compounded drug preparation," because it would have required a master formula document to be prepared for each compounded drug preparation, rather than making it an optional document, as intended in the proposed amendments.

- In subsection (b), after "maintained," delete "on a Master Formula Form," because the Committee determined that form is unnecessary, and insert the phrase "to identify drug preparations compounded at the veterinary premises" to clarify why a master formula document would be maintained for drug preparations that are compounded at the veterinary premises.

- In subsection (b), paragraph (1), strike "Unique Formula Code," because if it is not necessary for office stock, the requirement would be cumbersome and/or confusing, and move to paragraph (1) "Equipment to be used" from paragraph (3).

- In subsection (c), strike "Master Formula Form," add "master" and retain "formula document" for consistency with changes to subsection (b).

- In subsection (d), change “Master Formula Form” to “master formula document” for consistency with changes to subsection (b), add the phrase “pursuant to subsection (b)” for clarity, renumber the required information to be documented from subsection (b) as paragraphs (2) through (6) in accordance with revisions to subsection (b)(1) through (7), and remove the requirement to document in the animal patient’s medical record the equipment to be used because that documentation is unnecessary and irrelevant in the animal patient’s medical record.

- In subsection (e), before “ingredient(s),” insert “name, strength, and quantity of the” to clarify the documentation required for the ingredients added to the sterile solution.

- In subsection (f), retain existing paragraph (4).

- In subsection (f), strike proposed paragraph (4), as the name and strength are already required under existing paragraph (4), and the Unique Formula Code is being stricken from the proposal.

Dr. Sullivan requested public comment on the revisions made to section 2092. There were no public comments made on this item.

Proposed Amendments to CCR, Title 16, Section 2094

Meeting Materials

Webcast: 01:55:50

Dr. Sullivan explained the proposed revisions to the regulatory proposal, included in the meeting materials. Taking into account the revisions made by the Committee to section 2092, Dr. Sullivan proposed additional revisions to section 2094 to conform the sections, as follows:

- In subsection (b), paragraph (1), strike “Unique Formula Code,” and maintain the existing text in the current regulation.

The Committee discussed whether subsection (b)(3) should be deleted as shown in the meeting materials but taking into account the Committee’s determination to remove the Master Formula Form. Ms. Welch recommended maintaining the existing text in subsection (b)(3) and, before the proposal is presented to the Board, researching the rationale for including the lot number or control number assigned by the preparer on the label as described in the Initial Statement of Reasons for the current regulation. The proposed regulation was revised as follows:

- In subsection (b), paragraph (3), maintain the existing text in the current regulation.

Dr. Sullivan requested public comment on the revisions made to section 2094. There were no public comments made on this item.

- Motion: Dr. Bradbury moved and Dr. Sequoia seconded a motion to recommend to the Board the regulatory proposal to amend California Code of Regulations, title 16, sections 2036.5, 2090, 2091, 2092, and 2094 related to veterinary drug compounding and all of the changes approved during this meeting.

Dr. Sullivan requested public comment on the motion. There were no public comments made on the motion.

Dr. Sullivan called for the vote on the motion. Ms. Sieferman took a roll call vote on the motion.

- Vote: The motion carried 7-0.

7. Discussion and Potential Recommendation to the Board on Proposed Revisions to Guidance on Veterinary Drug Compounding Regarding Drug Consultation – *Richard Sullivan, DVM, and Marie Ussery, RVT*

Meeting Materials

Webcast: 02:21:50

Dr. Sullivan and Ms. Ussery presented this item and answered questions.

Dr. Sullivan requested public comment on the item. The Committee received the following public comment:

- Grant Miller CVMA inquired after looking at page four of the guidance document, under animal patient medical record documentation, and comparing it to [16 CCR] section 2092(f), if there would be reconciliation. He asked if the directions for storage and administration have been struck from [subsection] (f)(3) in [16 CCR] section 2092. He requested that due to the changes that were made at this meeting, to make sure those changes match and are reflected because he thinks the guidance document is very good.

Dr. Sullivan responded that the Committee will do that, and it will be reviewed by the Board.

Ms. Welch clarified that what is available under agenda item 6 are the proposed amendments to the existing regulations, which will have to go through the whole process and be enacted before the Committee will make any further changes to the Guidance Document to reflect the regulatory amendments. She added it will take time, but the Guidance Document reflects the existing regulations.

Dr. Sullivan called for the vote on the motion. Ms. Sieferman took a roll call vote on the motion.

- Vote: The motion carried 7-0.