VIRGINIA BOARD OF VETERINARY MEDICINE
Regulatory Advisory Panel on Opioid Prescribing
Wednesday, January 18, 2017
Department of Health Professions
Perimeter Center
9960 Mayland Drive, 2nd Floor Conference Center
Henrico, Virginia

TIME

1:00 p.m. **CALL TO ORDER** – Ellen Hillyer, D.V.M., Chair

EMERGENCY EGRESS INSTRUCTIONS – Leslie Knachel

ORDERING OF AGENDA – Dr. Hillyer

INTRODUCTIONS – Dr. Hillyer

CALL FOR PUBLIC COMMENT – Dr. Hillyer
The Board will receive all public comment related to agenda items at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending or closed complaint or disciplinary matter.

CHARGE OF THE PANEL – Dr. Hillyer
The Commissioner of the Virginia Department of Health has declared a public health crisis related to opioid abuse. The Board of Veterinary Medicine appointed a Regulatory Advisory Panel to develop emergency regulations for veterinarians related to opioid prescribing for the Board's consideration at a future meeting.

DISCUSSION – Elaine Yeatts
- Review of proposed regulations related to drug security and storage
- Review of Board of Medicine draft regulations for pain management
- Considerations for prescribing buprenorphine

ADJOURNMENT – Dr. Hillyer

Excerpt from Proposed Regulations Related to Drug Security and Storage

18VAC150-20-190

18VAC150-20-190. Requirements for drug storage, dispensing, destruction, and records for all establishments~~, full-service and restricted~~.

A. All drugs shall be maintained, administered, dispensed, prescribed and destroyed in compliance with state and federal laws, which include § 54.1-3303 of the Code of Virginia, the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia), applicable parts of the federal Food, Drug, and Cosmetic Control Act (21 USC § 301 et seq.), the Prescription Drug Marketing Act (21 USC § 301 et seq.), and the Controlled Substances Act (21 USC § 801 et seq.), as well as applicable portions of Title 21 of the Code of Federal Regulations.

B. All repackaged tablets and capsules dispensed for companion animals shall be in approved safety closure containers, except safety caps shall not be required when any person who requests that the medication not have a safety cap, or in such cases in which the medication is of such form or size that it cannot be reasonably dispensed in such containers (e.g., topical medications, ophthalmic, or otic). ~~A client~~ An owner request for non-safety packaging shall be documented in the patient record.

C. All drugs dispensed for companion animals shall be labeled with the following:

1. Name and address of the facility;

2. ~~Name~~ First and last name of ~~client~~ owner;

3. Animal identification and species;

4. Date dispensed;

5. Directions for use;

6. Name, strength (if more than one dosage form exists), and quantity of the drug; and

7. Name of the prescribing veterinarian.

D. All ~~drugs shall be maintained~~ veterinary establishments shall maintain drugs in a ~~secured~~ secure manner with precaution taken to prevent theft or diversion. Only the veterinarian or licensed veterinary technician shall have access to Schedule II through V drugs.

1. ~~All Schedule II through V drugs shall be maintained under lock at all times, with access to the veterinarian or veterinary technician only, but not to any unlicensed personnel~~ In a stationary establishment, the general stock of Schedule II through V drugs shall be stored in a securely locked cabinet or safe that is not easily movable.

2. The establishment may also have a working stock of Schedule II through V drugs that shall be kept in (i) a securely locked container, cabinet, or safe when not in use or (ii) direct possession of a veterinarian or veterinary technician. A working stock shall consist of only those drugs that are necessary for use during a normal business day or 24 hours, whichever is less.

3. Whenever the establishment is closed, all general and working stock of Schedule II through V drugs and any dispensed prescriptions that were not delivered during normal business hours shall be securely stored as required for the general stock.

4. Prescriptions that have been dispensed and prepared for delivery shall be maintained under lock or in an area that is not readily accessible to the public and may be delivered to an owner by an unlicensed person, as designated by the veterinarian.

~~2.~~ 5. Whenever ~~a veterinarian discovers~~ a theft or any unusual loss of Schedule II~~, III, IV, or~~ through V drugs is discovered, ~~he~~ the veterinarian-in-charge, or in his absence, his designee, shall immediately report such theft or loss to the Board of Veterinary Medicine and the Board of Pharmacy and to the ~~U.S. Drug Enforcement Administration~~ DEA. The report to the boards shall be in writing and sent electronically or by regular mail. The report to the DEA shall be in accordance with 21 CFR 1301.76(b). If the veterinarian-in-charge is unable to determine the exact kind and quantity of the drug loss, he shall immediately take a complete inventory of all Schedule II through V drugs.

E. Schedule II~~, III, IV and~~ through V drugs shall be destroyed by (i) transferring the drugs to another entity authorized to possess or provide for proper disposal of such drugs or (ii) destroying the drugs ~~by burning in an incinerator that is~~ in compliance with applicable local, state, and federal laws and regulations. If Schedule II through V drugs are to be destroyed, a DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the veterinarian practice site with other inventory records.

F. The drug storage area shall have appropriate provision for temperature control for all drugs and biologics~~, including~~. If drugs requiring refrigeration are maintained at the facility, they shall be kept in a refrigerator with the interior thermometer maintained between 36°F and 46°F. If a refrigerated drug is in Schedule II through V, the drug shall be kept in a locked container secured to the refrigerator, or the refrigerator shall be locked. Drugs stored at room temperature shall be maintained between 59°F and 86°F.

G. The stock of drugs shall be reviewed frequently, and expired drugs shall be removed from the working stock of drugs at the expiration date and shall not be administered or dispensed.

~~G.~~ H. A distribution record shall be maintained in addition to the patient's record, in chronological order, for the administration and dispensing of all Schedule ~~II V~~ II through V drugs.

This record is to be maintained for a period of ~~two~~ three years from the date of transaction. This record shall include the following:

1. Date of transaction;

2. Drug name, strength, and the amount dispensed, administered, and wasted;

3. ~~Client~~ Owner and animal identification; and

4. Identification of the veterinarian authorizing the administration or dispensing of the drug.

~~H.~~ I. Original invoices for all Schedule II~~, III, IV and~~ through V drugs received shall be maintained in chronological order on the premises where the stock of drugs is held, and the actual date of receipt ~~is~~ shall be noted. ~~Invoices for Schedule II drugs shall be maintained separately from other records.~~ All drug records shall be maintained for a period of ~~two~~ three years from the date of transaction.

~~I.~~ J. A complete and accurate inventory of all Schedule II~~, III, IV and~~ through V drugs shall be taken, dated, and signed on any date that is within two years of the previous biennial inventory. Drug strength must be specified. This inventory shall indicate if it was made at the opening or closing of business and shall be maintained on the premises where the drugs are held for ~~two~~ three years from the date of taking the inventory.

K. Inventories and records, including original invoices, of Schedule II drugs shall be maintained separately from all other records, and the establishment shall maintain a continuous inventory of all Schedule II drugs received, administered, or dispensed, with reconciliation at least monthly. Reconciliation requires an explanation noted on the inventory for any difference between the actual physical count and the theoretical count indicated by the distribution record. A continuous inventory shall accurately indicate the physical count of each Schedule II drug in the general and working stocks at the time of performing the inventory.

~~J.~~ L. Veterinary establishments in which bulk reconstitution of injectable, bulk compounding, or the prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the ~~drug(s)~~ drugs used; strength, if any; date repackaged; quantity prepared; initials of the veterinarian verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

M. If a limited stationary or ambulatory practice uses the facilities of another veterinary establishment, the drug distribution log shall clearly reveal whose Schedule II through V drugs were used. If the establishment's drug stock is used, the distribution record shall show that the procedure was performed by a visiting veterinarian who has the patient record. If the visiting veterinarian uses his own stock of drugs, he shall make entries in his own distribution record and in the patient record and shall leave a copy of the patient record at the other establishment.

DRAFT Regulations for Pain Management
Board of Medicine

18VAC85-20-95. Treatment of pain with controlled substances

A. Definitions. For purposes of this section, the following words and terms shall have the following meanings:

"Acute pain" shall mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.

"Chronic pain" shall mean non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" for the purpose of this regulation shall mean drugs listed in The Drug Control Act of the Code of Virginia in Schedules II through IV.

"Prescription Monitoring Program" shall mean the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

B. Management of acute pain

1. Evaluation of the patient.

Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days. (CDC#1,2)

Prior to initiating treatment with a controlled substance for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in the Code of Virginia and conduct an assessment of the patient's history and risk of substance abuse as a part of the initial evaluation.

Initiation of opioid treatment for opioid naïve patients shall be with short-acting opioids. (CDC#5)

Initiation of opioid treatment for all patients shall include the following:

The practitioner shall carefully consider and document the reasons to exceed 50 MME/day. (CDC#6)

Prior to exceeding 120 MME/day, the practitioner shall refer or consult with a pain management specialist. (CDC #7)

Naloxone shall be prescribed for any patient when risk factors of peior overdose, substance abuse, 120 MME/day, or concomitant benzodiazepine are present. (practitioners are encouraged... - see Jennifer) (CDC#9)

The practitioner shall document the rational to continue opioid therapy every 3 months. (CDC#8)

Due to a higher rise of fatal overdose when buprenorphine is given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document a tapering plan if these medications are used.

2. Medical records.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication prescribed (including date, type, dosage and quantity prescribed).

C. Management of chronic pain

1. Evaluation of the patient

Prior to initiating management of chronic pain with a controlled substance, a medical history and physical examination to include a mental status examination and shall be performed and documented in the medical record, including: a) the nature and intensity of the pain; b) current and past treatments for pain; c) underlying or coexisting diseases or conditions; d) the effect of the pain on physical and psychological function, quality of life and activities of daily living; e) psychiatric, addiction and substance abuse history of the patient and his family; f) a urine drug screen; and g) query the Prescription Monitoring Program as set forth in the Code of Virginia and conduct an assessment of the patient's history and risk of substance abuse as a part of the initial evaluation; h) a request for prior applicable records.

Prior to initiating opioid analgesia for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

2. Treatment

Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

Initiation of opioid treatment for opioid naïve patients shall be with short-acting opioids.

Initiation of opioid treatment for all patients shall include the following:

The practitioner shall carefully consider and document the reasons to exceed 50 MME/day. (CDC#6)

Prior to exceeding 120 MME/day, the practitioner shall refer or consult with a pain management specialist. (CDC #7)

Naloxone shall be prescribed for any patient when risk factors of peior overdose, substance abuse, 120 MME/day, or concomitant benzodiazepine are present. (practitioners are encouraged... - see Jennifer) (CDC#9)

The practitioner shall document the rational to continue opioid therapy every 3 months. (CDC#8)

Due to a higher rise of fatal overdose when buprenorphine is given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document a tapering plan if these medications are used.

The practitioner shall regularly screen for opioid use disorder and shall initiate or refer the patient for evaluation for treatment if indicated. (CDC #12)

3. Treatment Plan

The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function, quality of life and daily activities. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The prescriber shall record in the patient records the presence or absence of any indicators for medication misuse, abuse or diversion and take appropriate action.

4. Informed consent and agreement for treatment.

The prescriber shall document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain. There shall be a written treatment agreement in the medical record that addresses the parameters of treatment, including those behaviors which will result in a cessation of treatment or dismissal from care. The treatment agreement shall include, but not be limited to permission for the practitioner to: a) obtain urine/serum medication levels,

when requested; b) query and receive reports from the Prescription Monitoring Program; and c) consult with other prescribers or dispensing pharmacists for the patient.

Established expected outcome and improvement in both pain relief and function or just pain relief as well as limitations

(This paragraph needs to be worked in detail incorporating modern treatment plans)

5. Periodic review.

The prescriber shall review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health at least every three months. Continuation of treatment with controlled substances shall be supported by documentation of continued benefit from the prescribing. If the patient's progress is unsatisfactory, the prescriber shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Practitioners shall check the Prescription Monitoring Program at the initiation of treatment with opioids that will extend beyond 14 days, and a least every three months thereafter. (CDC #10)

Practitioner shall order and review a urine drug screen at the initiation of chronic pain management at least every 3 months in the first year, and at least annually thereafter. (CDC#11)

CDC #12 – The practitioner shall regularly screen for opioid use disorder and shall initiate or refer the patient for evaluation for treatment if indicated.

6. Consultation.

When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

When a practitioner makes the diagnosis of opioid disorder, he shall initiate or refer the patient for evaluation treatment. (CDC #12)

7. Medical records.

The prescriber shall keep current, accurate and complete records in an accessible manner and readily available for review to include:

a. The medical history and physical examination;

b. Past medical history;

c. Applicable records from prior treatment providers and/or any documentation of attempts to obtain;

d. Diagnostic, therapeutic and laboratory results;

e. Evaluations and consultations;

f. Treatment goals;

g. Discussion of risks and benefits;

h. Informed consent and agreement for treatment;

i. Treatments;

j. Medications (including date, type, dosage and quantity prescribed and refills).

k. Patients' instructions; and

l. Periodic reviews.