Effective January 1st, 2018

"§ 90-106. Prescriptions and labeling.

(a3) Limitation on Prescriptions Upon Initial Consultation for Acute Pain.

A practitioner may not prescribe more than a five-day supply of any targeted controlled substance upon the initial consultation and treatment of a patient for acute pain, unless the prescription is for post-operative acute pain relief for use immediately following a surgical procedure. A practitioner shall not prescribe more than a seven-day supply of any targeted controlled substance for post-operative acute pain relief immediately following a surgical procedure. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription for a targeted controlled substance. This subsection does not apply to prescriptions for controlled substances issued by a practitioner who orders a controlled substance to be wholly administered in a hospital, nursing home licensed under Chapter 131E of the General Statutes, hospice facility, or residential care facility as defined in G.S. 14-32.2(c1).

(a4) Definitions. – As used in this subsection, the following terms have the following meanings:

1. Acute pain. – Pain, whether resulting from disease, accident, intentional trauma, or other cause, that the practitioner reasonably expects to last for three months or less. The term does not include chronic pain or pain being treated as part of cancer care, hospice care, palliative care, or medication-assisted treatment for substance use disorder.

2. Chronic pain. – Pain that typically lasts for longer than three months or that lasts beyond the time of normal tissue healing.

3. Surgical procedure. – A procedure that is performed for the purpose of structurally altering the human body by incision or destruction of tissues as part of the practice of medicine. This term includes the diagnostic or therapeutic treatment of conditions or disease processes by use of instruments such as lasers, ultrasound, ionizing radiation, scalpels, probes, or needles that cause localized alteration or transportation of live human tissue by cutting, burning, vaporizing, freezing, suturing, probing, or manipulating by closed reduction for major dislocations and fractures, or otherwise altering by any mechanical, thermal, light-based, electromagnetic, or chemical means.

Targeted Controlled Substances
Provisions of the STOP Act only apply to “targeted controlled substances” which includes all schedule II and III opioids as listed in listed in G.S. 90-90(1) & (2) and G.S. 90-91(d)
Important Contact Information for North Carolina Veterinarians
These sites will provide you with the most current rules and regulations that are required for your veterinary practice

Drug Enforcement Agency (DEA)
The mission of DEA's Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

https://www.deadiversion.usdoj.gov/index.html (Home web page)

Contact: (888) 869-9935

NC Department of Health and Human Services (Radiation Protection Service)
NC Radiation Protection Section expects individuals and organizations performing regulated activities to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities.

http://www.nrcradiation.net/regs.htm

Contact: 919-814-2250

NC Department of Environmental Quality (Medical Waste Management)
The North Carolina Medical Waste Rules cover all aspects of medical waste management including: packaging, storage, transportation, treatment and disposal. The medical waste management regulations are found in 15A NCAC 13B.


Contact: William.Patrakis@NCDENR.Gov (919-707-8290)
REGISTRANTS MOST FREQUENT VIOLATIONS

1. The facility Written Radiation Protection program was not available or not adequate.

2. Not maintaining the appropriate records (Notice of Registration (NOR), Plan Review, Report of Assembly (FDA 2579), Letter of Acknowledgement (LOA), Post room survey, and annual review of Written Safety program).

3. Personnel monitoring equipment has not been supplied and/or used by all occupationally exposed personnel.

4. The registrant failed to update the information contained in the application for registration or notice of registration no longer accurate.

5. The registrant failed to annually review the Written Radiation Protection program.

6. The registrant failed to have a copy of the "North Carolina Regulations For Protection Against Radiation" at the facility.

7. The registrant failed to provide a working technique chart for each diagnostic X-ray system.

8. There has not been an area radiation survey done within 30 days following initial operation of equipment.

9. Service Provider failed to submit records showing receipt, transfer, and/or disposal of radiation sources.

10. Annual registration fees not submitted.
DOSE LIMITS

Rule .0104 (10) "ALARA" (acronym for "as low as reasonably achievable")
Making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

Since the mid-1950s, radiation safety standards have included provisions for incorporating the philosophy of As Low As Reasonably Achievable into safety programs.

Rule .0104 (65) "Limits" or "dose limits"
The permissible upper bounds of radiation dose are termed limits or dose limits. Dose limits represent an acceptable level of potential risk and do not represent a level that will necessarily be unsafe if exceeded.

Rule .1604 (a) Occupational Dose Limits for Adults

<table>
<thead>
<tr>
<th>Dose Limit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 rems (5000 mrem) (0.05Sv)</td>
<td>Total effective dose equivalent (TEDE)</td>
</tr>
<tr>
<td>50 rems (50,000 mrem) (.5 Sv)</td>
<td>Total Organ does equivalent (TODE)</td>
</tr>
<tr>
<td>15 rems (15,000 mrem) (.15 Sv)</td>
<td>Eye dose equivalent</td>
</tr>
<tr>
<td>50 rems (50,000 mrem) (.5 Sv)</td>
<td>Shallow dose equivalent (SDE)</td>
</tr>
</tbody>
</table>

The facility should set action limits for the eventuality for exposure.

Level I  Those persons with TEDE that are less than one-tenth the acceptable dose limit for occupational and non-occupational. No action is necessary.

Level II  The Radiation Safety Officer should report Level II exposures to the Radiation Safety Committee.

Level III  The RSO will investigate the cause of the high exposure, and any necessary preventive action. An incident report may be needed.

Rule .1641: Records of Dose to Individual Members of the Public
(a) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with dose limit for individual members of the public required by Rule .1611. These records may include such things as survey results, monitoring results, calculations and other documents pertaining to the determination of doses to individual members of the public.

(b) The licensee or registrant shall retain the records required by paragraph (a) of this rule until the agency terminates each pertinent license or registration requiring the record.
SECTION .1200 - MEDICAL WASTE MANAGEMENT
15A NCAC 13B .1201 DEFINITIONS
For the purpose of the Section, the following definitions apply:
(1) "Blood and body fluids" means liquid blood, serum, plasma, other blood products, emulsified human
tissue, spinal fluids, and pleural and peritoneal fluids. Dialysates are not blood or body fluids under
this definition.
(2) "Generating facility" means any facility where medical waste first becomes a waste, including but not
limited to any medical or dental facility, funeral home, laboratory, veterinary hospital and blood
bank.
(3) "Integrated medical facility" means one or more health service facilities as defined in G.S.
131E-176(9b) that are:
(a) located in a single county or two contiguous counties;
(b) affiliated with a university medical school or that are under common ownership and control;
and
(c) serve a single service area.
(4) "Medical waste" as defined in G.S. 130A-290(18).
(5) "Microbiological waste" means cultures and stocks of infectious agents, including but not limited to
specimens from medical, pathological, pharmaceutical, research, commercial, and industrial
laboratories.
(6) "Microwave treatment" means treatment by microwave energy for sufficient time to render waste
non-infectious.
(7) "Off-site" means any site which is not "on-site".
(8) "On-site" means the same or geographically contiguous property which may be divided by public or
private right-of-way.
(9) "Pathological waste" means human tissues, organs and body parts; and the carcasses and body parts
of all animals that were known to have been exposed to pathogens that are potentially dangerous to
humans during research, were used in the production of biologicals or in vivo testing of
pharmaceuticals, or that died with a known or suspected disease transmissible to humans.
(10) "Regulated Medical Waste" means blood and body fluids in individual containers in volumes greater
than 20 ml, microbiological waste, and pathological waste that have not been treated pursuant to Rule
.1207 of this Section.
(11) "Sharps" means and includes needles, syringes with attached needles, capillary tubes, slides and
cover slips, and scalpel blades.
(12) "Treatment" as defined in G.S. 130A-309.26(a)(2).
History Note: Authority G.S. 130A-309.26;
Eff. October 1, 1990;
Amended Eff. April 1, 1993.

15A NCAC 13B .1202 GENERAL REQUIREMENTS FOR MEDICAL WASTE
(a) Medical waste is subject to all applicable rules in 15A NCAC 13B.
(b) At the generating facility, sharps shall be placed in a container which is rigid, leak-proof when in an upright
position and puncture-resistant. Contained sharps shall not be compacted prior to off-site transportation. After leaving
the generating facility, the container and its contents shall be handled in a manner that avoids human contact with the
sharps.
(c) Blood and body fluids in individual containers of 20 ml or less which are not stored in a secured area restricted to
authorized personnel prior to off-site transportation shall be packaged in accordance with the regulated medical waste
packaging requirements as described in Rule .1204(a)(1) of this Section or in a container suitable for sharps.
Containers of blood and body fluids which are packaged in accordance with Rule .1204(a)(1) of this Section or in a container
suitable for sharps as required by this Rule shall not be compacted prior to off-site transportation.
(d) Regulated medical waste shall not be compacted.
History Note: Authority G.S. 130A-309.26;
Eff. October 1, 1990;
Disposal of Unwanted Medications

The Problems
While prescription and over-the-counter medications can help people and animals when used appropriately, the same medicines can be dangerous to people, animals, and the environment when used, stored, or disposed of improperly.

- Over-the-counter and prescription medications – for both humans and animals – are now a leading cause of poisonings in our pets. Visit 10 “poison pills” for pets to learn more.
- Neither septic tank systems nor municipal sewage and water treatment facilities can eliminate all pharmaceutical contamination poured down drains or flushed down toilets. By disposing of drugs into the water system, the problem is not solved, but transferred to water which we depend upon. A wide range of pharmaceuticals have been found in rivers, streams, groundwater, and drinking water nationwide. Visit The Environmental Protection Agency’s website, Pharmaceuticals and Personal Care Products (PPCPs) in Water, for more details.

How you can be part of the solution
- Use medications as directed.
- Never pour or flush pharmaceuticals down drains or toilets.
- Do not take unwanted or expired medications to your veterinarian for disposal unless he or she has state or federal authorization to collect pharmaceuticals for disposal.
- Dispose of unwanted or expired medications, including prescriptions for controlled substances, through authorized take-back events, mail-back programs, and collection receptacles.
- Learn more about drug disposal programs offered in your area:
  - Check with your veterinarian or local pharmacist.
  - Search online drug disposal locators (e.g., AWARxE, Dispose My Meds, and others by entering “find drug disposal location” or variation of that into your web browser) to find authorized pharmaceutical disposal sites near you.
  - Contact your local environmental authority, department of public health, or Drug Enforcement Administration (DEA).
    - If there is not an authorized pharmaceutical collection program available in your area, visit Unwantedmeds.org to learn how you can get one started.
- If you are instructed to dispose of the medications in trash (not an option for prescriptions of controlled substances)
  - Remove or blacken out all personal information.
  - Leave visible the drug information (drug name, concentration, dose, volume, pill count, etc.)
  - If a medication’s bottle is designed to be opened, remove the lid, add a safe and unpalatable substance (e.g., kitty litter or used coffee grounds) to the medication in the bottle, replace the lid, and then seal the bottle in a leak-proof bag or other container.

AVMA Activities
In May 2016, the AVMA renewed a memorandum of understanding (MOU) with the National Sea Grant Office (NSGO), Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce to combine efforts and develop a joint outreach and educational campaign for veterinary clients regarding proper pharmaceutical disposal. The Illinois-Indiana Sea Grant represents the NSGO for this project.
and has excellent relevant public resources at Unwantedmeds.org.

Goals of the MOU

- Tell as many people as possible not to flush medications, and share with them the reasons and alternatives.
- Share safety information on how to properly store medications out of reach of children and animals.
- Reinforce to animal owners the necessity of following veterinarian directions in giving medications to their animals as well as with disposing of any unneeded doses.
- Increase public awareness of pharmaceutical disposal options and rules.
- Enhance collaboration and communications between animal owners and veterinarians to establish optimal prescription quantities and potential refills to address the animal health needs on an individual basis and to minimize potential pharmaceutical waste.

Accomplishments

- MOU signed
- Public Service Announcement: 15-second video (no audio) running on the CBS Jumbotron Super Screen in New York City through March 31st about 18 times every day – or approximately every 80 minutes for 3 months; IISG’s video about the PSA
- JAVMA News: Partnership to promote proper vet drug disposal
- Collaboration with IISG to develop the brochure, “Prescription for Safety: How to Dispose of Unwanted Medicine.”

Relevant AVMA Policies

- Animal Agriculture Waste Management
- Aquatic Ecosystems
- Best Management Practices for Pharmaceutical Disposal
- Environmental Responsibility
- One Health
- Toxicoses

Additional Resources

- AVMA’s Tips on How to Dispose of Pharmaceutical Waste (AVMA video)
- Waste Disposal by Veterinary Practices: What Goes Where? (AVMA, partially public access and partially restricted to members only)

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Veterinary Practitioners' Guide to DEA Security Requirements

According to federal regulations, all Drug Enforcement Administration (DEA) applicants and registrants shall provide effective controls and procedures to guard against thefts and diversion of controlled substances.¹

Overall facility security
Practitioners should consider the following factors when evaluating their controlled substance security:¹

- The location of the facility;
- The type of building and office construction;
- The type of storage medium (safe, vault, or steel cabinet);
- Use of an effective alarm or detective system;
- Availability of police or security personnel;
- The quantity of the controlled substance handled;
- The number of employees, customers and/or patients who may have access to controlled substances; and
- Procedures for handling guests, visitors, and nonemployee service personnel.

Controlled substances must be stored in a securely locked, substantially constructed cabinet.² If your facility's controlled substance security is found on inspection to be inadequate, a DEA investigator can require additional security measures.³

- If a controlled substance is transferred/recategorized to another drug schedule; if a non-controlled substance becomes a controlled substance; or if there is a significant increase in the quantity of controlled substances in your possession during normal business operation, DEA rules require adjustment to your security measures accordingly.¹
- Practitioners approved to possess carfentanil, etorphine hydrochloride and diprenorphine must have a U.S. Government class V security container for storage.² (Class V security container standards require 30 man-minutes against covert entry, 20 man-hours against surreptitious entry, and 10 minutes forced entry requirements.)

Personnel security controls⁴
DEA-registered practitioners shall not employ an agent or employee who has access to controlled substances if the employee:
• Has been convicted of a felony offense relating to controlled substances;
• Has had an application for registration which the DEA denied;
• Has had their DEA registration revoked or have surrendered their DEA registration as a penalty for any federal/state, civil or criminal action resulting from an investigation involving the handling of controlled substances.

A waiver of this requirement can be requested in writing.  

Additional security measures
In addition to the required security controls, practitioners can utilize extra measures to ensure security. These include:

• Use tamper-resistant prescription pads;
• Keep all prescription blanks in a safe place where they cannot be stolen;
• Minimize the number of prescription pads in use;
• Use prescription blanks only for writing prescription orders and not for notes;
• Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order; for example, "ten (10);"
• Never sign prescription blanks in advance;
• Assist the pharmacist when they telephone to verify information about a prescription order (a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription);
• Contact the nearest DEA field office to obtain or to furnish information regarding suspicious prescription activities.

In case of theft or loss
Practitioners must notify the Field Division Office of the Administration in the area, upon discovery, of any thefts or significant losses of controlled substances and complete a DEA Form 106 regarding such theft or loss. (CFR Section 1301.76 b) Other security controls for practitioners)

For more information, see http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html.

References:

1. 21 CFR Section 1301.71
2. 21 CFR Section 1301.75
3. 21 CFR Section 1301.72
4. 21 CFR Section 1301.76
5. 21 CFR Section 1307.03

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Disposal of Controlled Substances

In North Carolina any disposal of controlled substances must be witnessed by a state or federal official that is authorized to enforce either state or federal controlled substance acts. Typically that is one of the Drug Control Unit inspectors. This is usually expired medications or anything that is unwanted for use any longer. The administrative code does allow for the destruction of accidentally contaminated drugs or the unused portion of an injectable in schedules II – V by the registrant or the practitioner. Although not addressed specifically in the Administrative Code, CS medications can also be disposed of by a Reverse Distributor as long as they are registered with the Federal DEA. This is completed by transferring the medications from one DEA registrant to another DEA registrant. I have listed below the Administrative Code where these items can be found. Please let me know if you have any other questions regarding this issue. Hopefully this is the information that you are looking for.

Tim

10A NCAC 26E .0407 DISPOSAL BY REGISTRANTS AND PRACTITIONERS: SCHEDULES II - V
The destruction of a controlled substance in Schedules II, III, IV and V by a registrant or practitioner or by his authorized agent shall be witnessed by the director or his designated representative or a state or federal official authorized to enforce the Federal Controlled Substances Act or the North Carolina Controlled Substances Act except when a dose/doses of any controlled substance is accidentally contaminated at a nursing station or adjacent area, the controlled substance may be destroyed at the pharmacy or nursing station by a practitioner, a registered nurse or a licensed practical nurse; provided a record of destruction is made on a controlled substance disposition record showing the date, time, quantity, manner of destruction, and type of controlled substance, and the initials or signatures of persons destroying and witnessing the destruction. The destruction shall be in accordance with the procedures outlined by the director and a record of this destruction shall be kept available by the registrant or practitioner for a minimum of two years.

History Note: Authority G.S. 90 100; 143B 147;
Eff. June 30, 1978;

10A NCAC 26E .0409 DISPOSAL OF UNUSED PORTIONS OF INJECTABLE: SCHEDULES II - V
Both the amount of the injectable Schedules II V controlled substance administered to the patient and the amount destroyed shall be recorded on the controlled substances disposition document or the patient's medical record with initials of individual administering and destroying the injectable controlled substance. Other procedures of documenting this information shall be submitted to the director for approval before implementation.

History Note: Authority G.S. 90 100; 143B 147;
Eff. June 30, 1978;

Tim Jones
Drug Inspector
DMH/DD/SAS, Drug Control Unit
North Carolina Department of Health and Human Services
# NC Approved Reverse Distributors

<table>
<thead>
<tr>
<th>Company</th>
<th>Approval Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCM Ventures, Ltd. dba RxNet Services</td>
<td>RD0337623</td>
</tr>
<tr>
<td>3012 South Elm – Eugene Street, Suite G Greensboro, North Carolina 27406</td>
<td></td>
</tr>
<tr>
<td>(336) 273-5112</td>
<td>Schedules 2, 2N, 3, 3N, 4, 5</td>
</tr>
<tr>
<td>Pharmaceutical Dimensions</td>
<td>RP0308519</td>
</tr>
<tr>
<td>4500 Green Point Drive, Suite 102 Greensboro, North Carolina 27410</td>
<td></td>
</tr>
<tr>
<td>(336) 664-5287</td>
<td>Schedules 2, 2N, 3, 3N, 4, 5</td>
</tr>
<tr>
<td>Universal Dynamic Returns Co.</td>
<td>RU0345339</td>
</tr>
<tr>
<td>4280 Piedmont Parkway, Suite 101 Greensboro, North Carolina 27410</td>
<td></td>
</tr>
<tr>
<td>(336) 510-4970</td>
<td>Schedules 3, 3N, 4, 5</td>
</tr>
</tbody>
</table>
Addiction doesn’t discriminate  It can affect anyone, at any time, no matter their occupation, education, or other demographic factors. In fact, people working in healthcare are at a greater risk for developing an addiction due to the stress of the job and ready access to pharmaceuticals.

The results of a survey published in the September 2015 issue of the Journal of the American Veterinary Medical Association found that
- 72% of respondents said they worked with someone that they suspected of having a drug problem
- More than 40% said they knew of two or more colleagues who may have a drug problem
- 68% said addiction is at least as big a problem in the veterinary profession as in the general population, if not bigger.

Signs, symptoms, and warning signs of an addiction:
- Drop in performance at work, tardiness, frequent absences
- Engaging in secretive or suspicious behaviors; isolating
- Unexplained change in personality – irritable, anxious, frustrated
- Lack of motivation and energy, appears lethargic or “spaced out”
- Tremors, slurred speech, or impaired coordination

The North Carolina Veterinary Health Program (NCVHP) works with the North Carolina Veterinary Medical Board (NCVMB) to screen for and assist people suffering with the disease of addiction.

NCVHP offers:
Confidential program participation  Free screening interviews*
Compassionate Support  Evidence-based Advocacy
Comprehensive Monitoring  * Free for licensees of the NCVMB

NCVHP is here to help you. If you or a colleague think you have a problem with drugs or alcohol, please contact us.

NCVHP helps veterinary professionals so they can help their patients!

www.NCVHP.org  220 Horizon Drive, Ste. 201, Raleigh, NC 27615  P (919) 870-4480
reduce the likelihood of malpractice allegations

Before treatment

1. Advise your client of the options, risks, and cost estimates.

2. Never make a statement to the client that can be misinterpreted as a guarantee or a warranty of results.

3. Make sure the owner fully understands the procedure that will be performed.

4. Secure owner’s written consent before performing any procedure. Examples include: surgery, anesthesia, diagnostics, euthanasia, and alternative medicine.

5. Do not refer to yourself as a specialist unless you are willing to be held to a higher standard of skill and competency.

6. Ask if the animal has been under the care of another veterinarian. Obtain pertinent records when necessary.

7. If you can't access equipment for a preferred diagnostic or treatment procedure, postpone or offer a referral. If circumstances require you to proceed, inform your client of the risk involved and secure your client’s written consent.

8. Use appropriate identification techniques to avoid treating the wrong animal.

9. Note the procedure that you are admitting the animal for into the medical record. Review them immediately before surgery to avoid performing the wrong procedure.

During treatment

1. Keep accurate and detailed records of treatment and exam findings of animals in your care.

2. Avoid owner assistance—especially with restraining animals.

3. Communicate regularly with the client about treatment progress, course of action, prognosis and cost.

After treatment

1. If treatment was unsuccessful, avoid questioning the original course of action. Present additional options when appropriate.

2. A necropsy should be performed when the cause of death is in question. Using a veterinary pathologist is recommended.

3. Continue communication as you see fit. Tell the truth and never speculate.

4. Always express compassion for the owner(s) and animal(s).

5. Unless required by law, do not release original records or radiographs. Provide copies if requested.

Potential claim

1. Never make a statement agreeing to the settlement of a malpractice charge.

2. Any fee adjustment should be presented as a goodwill gesture.

3. Call the PLIT office immediately if an event occurs that could result in a claim. A client’s expression of dissatisfaction is sufficient reason for notification.

4. Cooperate fully with your claim representatives.

5. Never discuss possible malpractice—your own or another veterinarian’s—with clients or their attorneys. If a client’s attorney contacts you, state that you will notify your insurance carrier to handle the matter.