

THE VETERINARY FEED DIRECTIVE RULES

Compliance, Liability Reduction, and Efficiency in Practice

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The Veterinary Feed Directive Rules

Today's Plan

- Let's go beyond the basics
- What are the real-life issues?
- Identify, manage, and reduce liability
- Become more efficient and compliant

Why is this happening?

- The FDA has determined that a veterinarian is needed to oversee the “judicious use of antibiotics”
- The concern is for antibiotic resistance affecting human health
- There have been multiple steps leading up to this rule

What's going to change?

- 3rd classification used for “Medically Important” Antibiotics
- Production indications are withdrawn from labels
 - Feed Efficiency
 - Enhance Growth
- Label claims must now be for “treatment” “control” or “prevention”
- Adding a layer of regulation for everyone

Veterinary Oversight

Veterinary Client Patient Relationship (VCPR)

- “A veterinarian has **assumed the responsibility** for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
 - There is **sufficient knowledge** of the animal(s) by the veterinarian to initiate at least a **general or preliminary diagnosis** of the medical condition of the animal(s); and”

21 CFR 530.3

Veterinary Oversight

Veterinary Client Patient Relationship (VCPR)

- “Readily available for followup...Such a relationship can exist only when the veterinarian has recently seen and is **personally acquainted** with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely **visits to the premises** where the animal(s) are kept.”

21 CFR 530.3

- Veterinarian = Licensed in state where animals are housed

Key Phrases to the VCPR

- “Assumed the Responsibility”
- “Sufficient Knowledge”
- “General or Preliminary Diagnosis”
- “Personally Acquainted”
- “Examination...or Timely Visits to the Facility”

Get it **all** in the medical record

- “Assumed the Responsibility”
- “Sufficient Knowledge”
- “General or Preliminary Diagnosis”
- “Personally Acquainted”
- “Examination...or Timely Visits to the Facility”
- “Available for followup”

Get it **all** in the medical record

- “Assumed the Responsibility” - *Mitigate Liability*
- “Sufficient Knowledge” - *Clinical Discretion*
- “General or Preliminary Diagnosis” - *Meet standard of care*
- “Personally Acquainted” - *Can’t send a tech*
- “Examination...or Timely Visits to the Facility” - *6 months*
- “Available for followup” *Warn for adverse events, failure*

Creating the Medical Record

- Write only what is needed on the VFD
- Identify the owner and caretaker, physical location
- Identify/name the animal(s)
- Get the preliminary diagnosis and how it was made
- Client communications/recommendations made

Writing the VFD

- Know the label, write to the label
- No off label use
- Physical Location of the animal(s)
- Generic or Legend drug
- Watch for combination therapy

Becoming efficient

- Use templates and a protocol
- Leverage paraprofessionals for the data entry
- Use technology
- Piggy-back trips and facility visits
- Develop relationships with the feed mills and producers

Adding value and profits

Deliver information and recommendations beyond antibiotics
to show the value of a veterinary degree

- Protocols
 - Vaccination, Weaning, Shipping, Receiving
- Husbandry, Welfare
- Handling
- Nutrition
- Environmental
- Biosecurity
- Management, record-keeping
- Keep the lines of communication open

Efficiency in transmission & storage

- Transmit to the feed distributor
- Communicate, transmit to the client
- Store for 2+ years
 - Electronic storage is OK
 - Don't forget about your state record retention statutes/rules
- Electronic Transmission difficult,
 - "enforcement discretion" is used

Summary

- Watch for the liability
 - Off-label use
 - Lack of medical records
 - State board actions
 - Standard of care for a preliminary diagnosis
- Add Value
 - Make recommendations, educate
- Make the process streamlined and efficient
- Play by the rules to avoid further regulation

On the horizon

- Notice and Comment on “Judicious Use”
 - Duration of Use
- www.regulations.gov type FDA-2016-D-2635 in the search box

Questions?

- National Agriculture Law Center
 - <http://nationalaglawcenter.org/>
- Educational Multimedia - Coming Soon
 - Continuing Education Credit
- lance@roasalaw.com