



State of Wisconsin  
Governor Scott Walker

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**Department of Agriculture, Trade and Consumer Protection**  
Ben Brancel, Secretary

## **VETERINARY EXAMINING BOARD**

**CR 106 Board Room, 2811 Agriculture Drive, Madison, Wisconsin**  
**Contact: Matt Tompach (608) 224-5024**  
**November 4, 2015**

*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**

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

- A. Introductions**
- B. Approval of the Agenda (1-3)**
- C. Approval of Board Meeting Minutes of July 29, 2015 (4-6)**
- D. APPEARANCE – Department of Agriculture, Trade, and Consumer Protection (DATCP) Office of the Secretary: Ben Brancel, Secretary, Sandy Chalmers, Assistant Deputy Secretary, Lauren Van Buren and Dennis Fay, DATCP Attorneys, Matt Tompach, Administrative Policy Advisor, Gretchen Mrozinski, Attorney, Department of Safety & Professional Services. Introductions and Discussion**
- E. 9:30 a.m. ADMINISTRATIVE RULES HEARING – Chapter VE 10, Continuing Veterinary Education for Veterinarians and Veterinary Technicians (7-16)**
  - 1) Summary of the Proposed Change to Chapter VE 10
  - 2) Review and Respond to Clearinghouse Report
  - 3) Public Comments
- F. Legislative/Administrative Rule Matters**
  - 1) Future Rulemaking Priorities
- G. American Association of Veterinary State Boards (AAVSB) Matters (17-310)**
  - 1) Annual Meeting of the AAVSB Report – September 22-24, 2015 – Milwaukee, WI
    - i. North Carolina Dental Board Case (**18-33**)
    - ii. Facilities Inspection (**34-81**)
    - iii. Federal Drug Administration (FDA) Animal Feed Directive (**82-284**)
    - iv. Prescription Drug Monitoring Programs (**285-310**)
    - v. Other
- H. Open Meetings Law and Public Records Law Presentation**

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**I. Administrative Procedures Presentation**

**J. Administrative Items Related to the Veterinary Examining Board (VEB) Transfer**

- 1) Boardvantage Demonstration (11:00 A.M.)
- 2) Travel, Per Diem Procedures

**K. Future Meeting Dates and Times for 2016**

- 1) Screening Committee November 16, December 18
- 2) Board Meeting Dates

**L. Future Agenda Items**

**M. Public Comments**

**N. Recess: Break for Lunch, Reconvene at 12:55 P.M.**

**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.).**

**O. Open Cases**

**P. Monitoring Matters**

- 1) Benjamin Blandin, D.V.M. – Requesting full licensure (311-322)

**Q. Administrative Warnings**

- 1) 14 VET 006 – T.D., D.V.M. (323-324)
- 2) 14 VET 019 - R.M.R., D.V.M. (325-326)

**R. Deliberation on Proposed Stipulations, Final Decisions and Orders**

- 1) Jagmohan Singh, D.V.M., 13 VET 028 (327-332)
- 2) Laurie D. McCabe, D.V.M., 13 VET 045 (333-339)
- 3) Elizabeth A. Nasal, D.V.M., 14 VET 006 (340-346)
- 4) Craig Schley, D.V.M., 14 VET 016 (347-352)
- 5) Jeffrey S. Schuette, D.V.M., 15 VET 020 (353-358)
- 6) Marla K. Lichtenberger, D.V.M., 13 VET 037; 13 VET 040; 14 VET 001; 14 VET 003 (359-367)

**S. Case Closing(s)**

- 1) 13 VET 044 – S.M., D.V.M. (368-369)
- 2) 13 VET 037 – C.M.J., D.V.M. (370-374)
- 3) 14 VET 008 - D.R.T., D.V.M. (375-378)
- 4) 15 VET 023 - T.J., D.V.M. (379-381)

**T. Consulting with Legal Counsel**

**U. Review of Veterinary Examining Board Pending Cases Status Report as of October 22,**

**RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION**

- V. Open Session Items Noticed Above not Completed in the Initial Open Session**
- W. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate**
- X. Ratification of Licenses and Certificates**

**ADJOURNMENT**

**VETERINARY EXAMINING BOARD  
MEETING MINUTES  
July 29, 2015**

**PRESENT:** Bruce Berth; Diane Dommer Martin, D.V.M.; Robert Forbes, D.V.M.; Philip Johnson, D.V.M.; Brenda Nemec, C.V.T.; Sheldon Schall; Neil Wiseley, D.V.M, Lisa Weisensel Nesson, D.V.M.

**STAFF:** Tom Ryan, Executive Director; Amber Cardenas, Legal Counsel; Nilajah Madison-Head, Bureau Assistant; Katie Vieira, Administrative Rules Coordinator and other Department staff

**CALL TO ORDER**

Philip Johnson, Chair, called the meeting to order at 9:32 A.M. A quorum of eight (8) members was confirmed.

**ADOPTION OF AGENDA**

**Amendments to the Agenda**

- *Under Item L, Add Proposed Stipulation, Final Decision and Order 14 VET 010 – Roger H. Newman, D.V.M.*

**MOTION:** Sheldon Schall moved, seconded by Brenda Nemec, to adopt the agenda as amended. Motion carried unanimously.

**APPROVAL OF MINUTES**

**MOTION:** Neil Wiseley moved, seconded by Lisa Weisensel Nesson, to approve the minutes of April 29, 2015 as published. Motion carried unanimously.

**LEGISLATIVE/ADMINISTRATIVE RULE MATTERS**

**Preliminary Rule Draft of VE 10 Relating to Continuing Education**

**MOTION:** Diane Dommer Martin moved, seconded by Sheldon Schall, to authorize The Chair or other member of the Board to approve the preliminary rule draft of VE 10 relating to Continuing Education for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

**Adoption Order for CR14-064, VE 2, 3, 8, Relating to Entrance to Examinations**

**MOTION:** Robert Forbes moved, seconded by Neil Wiseley, to approve the Adoption Order for Clearinghouse Rule CR 14-064, relating to Entrance to Examinations. Motion carried unanimously.

**Review of Model Practice Acts and Veterinary Examining Board Rules**

**MOTION:** Bruce Berth, seconded by Lisa Weisensel Nesson, to defer the discussion of revisions to a future meeting. Motion carried unanimously.

## CLOSED SESSION

**MOTION:** Sheldon Schall moved, seconded by Brenda Nemec, 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. and § 440.205, Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.). The Chair read the language of the motion aloud for the record. The vote of each member was ascertained by voice vote. Roll Call Vote: Bruce Berth – yes; Diane Dommer Martin – yes; Robert Forbes – yes; Philip Johnson – yes; Brenda Nemec – yes; Sheldon Schall – yes; Lisa Weisensel Nesson – yes; Neil Wiseley – yes. Motion carried unanimously.

The Board convened into Closed Session at 10:26 A.M.

## RECONVENE TO OPEN SESSION

**MOTION:** Robert Forbes moved, seconded by Brenda Nemec, to reconvene in Open Session at 11:47 A.M. Motion carried unanimously.

## VOTE ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION, IF VOTING IS APPROPRIATE

**MOTION:** Sheldon Schall moved, seconded by Brenda Nemec, to affirm all Motions made and Votes taken in Closed Session. Motion carried unanimously.

## ADMINISTRATIVE WARNINGS

### 13 VET 039 (T.C.D., D.V.M.)

**MOTION:** Robert Forbes moved, seconded by Diane Dommer Martin, to issue an Administrative Warning in the matter of DLSC case number 13 VET 039 (T.C.D., D.V.M.). Motion carried unanimously.

## PROPOSED STIPULATIONS, FINAL DECISIONS AND ORDERS BY THE DIVISION OF LEGAL SERVICES AND COMPLIANCE

### 12 VET 031 - Kurt Zaeske, D.V.M.

**MOTION:** Sheldon Schall moved, seconded by Lisa Weisensel Nesson, to adopt the Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter of Kurt Zaeske, D.V.M., DLSC case number 12 VET 031. Motion carried unanimously.

### 15 VET 006 - Scott McDonald, D.V.M.

**MOTION:** Neil Wiseley moved, seconded by Robert Forbes, to adopt the Findings of Fact, Conclusions of Law, Stipulations and Orders, in the matter of Scott McDonald D.V.M., DLSC case number 15 VET 006. Motion carried unanimously.

**14 VET 036 - David Williams, D.V.M.**

**MOTION:** Robert Forbes moved, seconded by Sheldon Schall, to adopt the Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter of David Williams, D.V.M., DLSC case number 14 VET 036. Motion carried unanimously.

**14 VET 010 - Roger H. Newman, D.V.M.**

**MOTION:** Lisa Weisensel Nesson moved, seconded by Sheldon Schall, to adopt the Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter of Roger H. Newman, D.V.M., DLSC case number 14 VET 010. Motion carried unanimously.

**CASE CLOSINGS**

**MOTION:** Diane Dommer Martin moved, seconded by Neil Wiseley, to close the following cases according to the recommendations by the Division of Legal Services and Compliance:

- 1) 15 VET 004 (R.S.) for Insufficient Evidence (IE).
- 2) 15 VET 015 (W.C.) for Prosecutorial Discretion (P6).
- 3) 15 VET 007 (J.D.F.) for No Violation (NV).
- 4) 14 VET 030 (V.A.L.) for Insufficient Evidence (IE).
- 5) 14 VET 037 (C.D.G.) for Prosecutorial Discretion (P3).
- 6) 15 VET 010 (T.E.) for No Violation (NV).

Motion carried unanimously.

**DELEGATION OF RATIFICATION OF EXAMINATION RESULTS  
AND RATIFICATION OF LICENSES AND CERTIFICATES**

**MOTION:** Robert Forbes moved, seconded by Sheldon Schall, to delegate ratification of examination results to DSPS staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

**ADJOURNMENT**

**MOTION:** Lisa Weisensel Nesson moved, seconded by Brenda Nemec, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:53 A.M.

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:		2) Date When Request Submitted:	
		Items will be considered late if submitted after 12:00 p.m. less than 8 business days.	
3) Name of Board, Committee, Council, Sections:  <b>Veterinary Examining Board</b>			
4) Meeting Date:  11/4/2015	5) Attachments: x Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page?  <b>9:30 A.M. PUBLIC HEARING – Chapter VE 10, Continuing Veterinary Education for Veterinarians and Veterinary Technicians</b> <ul style="list-style-type: none"> <li><input type="radio"/> Summary of the Proposed Change to Chapter VE 10</li> <li><input type="radio"/> Review and Respond to Clearinghouse Report</li> <li><input type="radio"/> Public Comments</li> </ul>	
7) Place Item in: x Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing?  No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:  Conduct a Public Hearing for Chapter VE 10, Continuing Veterinary Education for Veterinarians and Veterinary Technicians. Hear Public Hearing comments on the rule draft and then review and respond to Public Hearing Comments as well as the Clearinghouse Report.			
11) Authorization			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Bureau Director signature (indicates approval to add post agenda deadline item to agenda)		Date	

STATE OF WISCONSIN  
VETERINARY EXAMINING BOARD

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IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	VETERINARY EXAMINING
VETERINARY EXAMINING BOARD	:	BOARD
	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE )

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PROPOSED ORDER

An order of the Veterinary Examining Board to repeal VE 10.03 (3) (b) and (i) relating to continuing education.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:**

Section 453.062 (2) (a) and (b), Stats.

**Statutory authority:**

Sections 15.08 (5) (b), 227.11 (2) (a), and 453.03 (2), Stats.

**Explanation of agency authority:**

Section 15.08 (5) (b), Stats., provides examining boards, “shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains. . .” The proposed rule seeks to provide guidance to licensed veterinarians and licensed veterinary technicians on compliance with continuing education requirements.

Section 227.11 (2) (a), Stats., sets forth the parameters of an agency’s rule-making authority, stating an agency, “may promulgate rules interpreting provisions of any statute enforced or administered by the agency. . .but a rule is not valid if the rule exceeds the bounds of correct interpretation.”

Section 453.03 (2), Stats., provides that the, “examining board shall promulgate rules requiring training and continuing education sufficient to assure competency of veterinarians and veterinary technicians in the practice of veterinary medicine, . . .”

**Related statute or rule:**

None

**Plain language analysis:**

In accordance with s. 453.062 (2) (a) and (b), Stats., licensed veterinarians are required to complete 30 hours of continuing education and licensed veterinary technicians are required to complete 15 hours of continuing education. Continuing education requirements for both veterinarians and veterinary technicians are found in Chapter VE 10. Recently, the Veterinary Examining Board identified several provisions within ch. VE 10 that required revising, specifically s. VE 10.03 (3) (b). The Board determined that this provision allowing self-study of veterinary medical or scientific journals was obsolete due to the abundance of continuing education offered via the internet. The Board also identified s. VE 10.03 (3) (i), regarding certification to use, handle, distribute and dispose of pesticides as outdated due to recent legislation, 2009 Wisconsin Act 139. Act 139 specified that the Board may not require training or continuing education concerning the use, handling, distribution, and disposal of pesticides, other than for disciplinary purposes.

**Summary of, and comparison with, existing or proposed federal regulation:**

None.

**Comparison with rules in adjacent states:****Illinois:**

Illinois Administrative Code allows renewal applicants to use self-study courses offered by an approved provider (Ill. Admin. Code tit. 68, pt.1500.25 and Ill. Admin. Code tit. 68, pt. 1505.55).

**Iowa:**

Iowa Administrative Code allows the completion of distance education courses but does not explicitly allow for the completion of self-study courses to fulfill continuing education requirements (Iowa Admin. Code r. 811-11.1).

**Michigan:**

Continuing education is not required to renew a license as a veterinarian or a veterinary technician in the state of Michigan.

**Minnesota:**

Minnesota Administrative Code specifies that not more than ten hours of continuing education credit from noninteractive (self-study) sources may be accepted toward the 40-hour continuing education credit requirement for license renewal (Minn. R. 9100.100 subp. 5.)

**Summary of factual data and analytical methodologies:**

The Board reviewed the continuing education rules for consistency with the Wisconsin Statutes and contemporary practices. Adjacent states' requirements were also reviewed.

**Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:**

The rule was posted for public comment on the economic impact of the proposed rule, including how this proposed rule may affect businesses, local government units, and individuals for a period of 14 days. No comments were received.

**Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis document is attached.

**Effect on small business:**

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

**Agency contact person:**

Katie Vieira (Paff), Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-261-4472; email at Kathleen.Vieira@wisconsin.gov.

**Place where comments are to be submitted and deadline for submission:**

Comments may be submitted to Katie Vieira (Paff), Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8935, or by email to Kathleen.Vieira@wisconsin.gov. Comments must be received on or before the public hearing to be held on November 4, 2015 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. VE 10.03 (3) (b) and (i) are repealed.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

-----  
(END OF TEXT OF RULE)  
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Dated \_\_\_\_\_

Agency \_\_\_\_\_

Chairperson  
Veterinary Examining Board

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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1. Type of Estimate and Analysis

Original    Updated    Corrected

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2. Administrative Rule Chapter, Title and Number

VE 10

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3. Subject

Continuing education

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4. Fund Sources Affected

GPR    FED    PRO    PRS    SEG    SEG-S

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5. Chapter 20, Stats. Appropriations Affected

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6. Fiscal Effect of Implementing the Rule

No Fiscal Effect    Increase Existing Revenues    Increase Costs  
 Indeterminate    Decrease Existing Revenues    Could Absorb Within Agency's Budget  
 Decrease Cost

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7. The Rule Will Impact the Following (Check All That Apply)

State's Economy    Specific Businesses/Sectors  
 Local Government Units    Public Utility Rate Payers  
 Small Businesses (if checked, complete Attachment A)

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8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes    No

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9. Policy Problem Addressed by the Rule

In accordance with s. 453.062 (2) (a) and (b), Stats., licensed veterinarians are required to complete 30 hours of continuing education and licensed veterinary technicians are required to complete 15 hours of continuing education. Continuing education requirements for both veterinarians and veterinary technicians are found in Chapter VE 10. Recently, the Veterinary Examining Board identified several provisions within ch. VE 10 that required revising, specifically s. VE 10.03 (3) (b). The Board determined that this provision allowing self-study of veterinary medical or scientific journals was obsolete due to the abundance of continuing education offered via the internet. The Board also identified s. VE 10.03 (3) (i), regarding certification to use, handle, distribute and dispose of pesticides as outdated due to recent legislation, 2009 Wisconsin Act 139. Act 139 specified that the Board may not require training or continuing education concerning the use, handling, distribution, and disposal of pesticides, other than for disciplinary purposes.

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10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

This proposed rule was posted on the Department of Safety and Professional Services website and on the Wisconsin government website for 14 business days to solicit comments from the public. No businesses, business sectors, associations representing business, local governmental units, or individuals contacted the department about the proposed rule during that time period

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11. Identify the local governmental units that participated in the development of this EIA.

None. This rule does not affect local government units.

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12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local government units, or the state's economy as a whole.

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefits of implementing the proposed rule include bringing the administrative code in line with current technology, current practice within the profession, and the Wisconsin Statutes.

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14. Long Range Implications of Implementing the Rule

The long range implications of implementing the proposed rule include bringing the administrative code in line with current technology, current practice within the profession, and the Wisconsin Statutes.

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15. Compare With Approaches Being Used by Federal Government

None.

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16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois Administrative Code allows renewal applicants to use self-study courses offered by an approved provider (Ill. Admin. Code tit. 68, pt.1500.25 and Ill. Admin. Code tit. 68, pt. 1505.55).

Iowa Administrative Code allows the completion of distance education courses but does not explicitly allow for the completion of self-study courses to fulfill continuing education requirements (Iowa Admin. Code r. 811-11.1).

Continuing education is not required to renew a license as a veterinarian or a veterinary technician in the state of Michigan.

Minnesota Administrative Code specifies that not more than ten hours of continuing education credit from noninteractive (self-study) sources may be accepted toward the 40-hour continuing education credit requirement for license renewal (Minn. R. 9100.100 subp. 5.)

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17. Contact Name Katie Vieira (Paff)	18. Contact Phone Number (608) 261-4472
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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Scott Grosz**  
*Clearinghouse Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Margit S. Kelley**  
*Clearinghouse Assistant Director*

**Jessica Karls-Ruplinger**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE **15-062**

AN ORDER to repeal VE 10.03 (3) (b) and (i), relating to continuing education.

Submitted by **VETERINARY EXAMINING BOARD**

08-21-2015 RECEIVED BY LEGISLATIVE COUNCIL.

09-21-2015 REPORT SENT TO AGENCY.

MSK:MM

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES  NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES  NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES  NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS  
[s. 227.15 (2) (e)]

Comment Attached YES  NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES  NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL  
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES  NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES  NO



## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

**Scott Grosz**  
*Clearinghouse Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Margit Kelley**  
*Clearinghouse Assistant Director*

**Jessica Karls-Ruplinger**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE RULE 15-062

#### Comments

**[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]**

#### **4. Adequacy of References to Related Statutes, Rules and Forms**

In the rule summary, the references to ss. 453.03 and 453.062, Stats., should be corrected to ss. 89.03 and 89.062, Stats., respectively, to reflect the renumbering of those sections in 2015 Wisconsin Act 55.

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

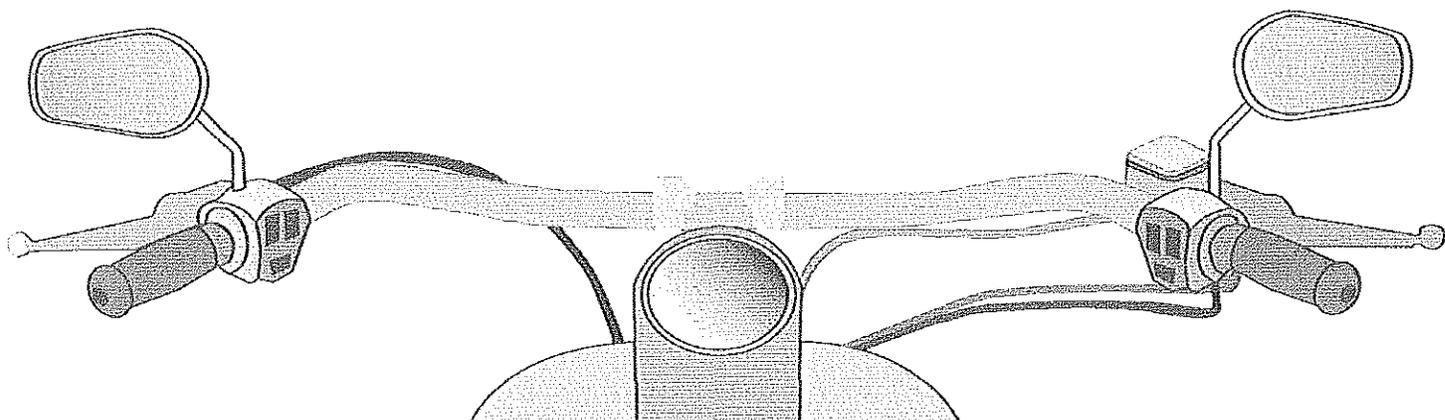
1) Name and Title of Person Submitting the Request:		2) Date When Request Submitted:	
		Items will be considered late if submitted after 12:00 p.m. less than 8 business days.	
3) Name of Board, Committee, Council, Sections:  <b>Veterinary Examining Board</b>			
4) Meeting Date:  11/4/2015	5) Attachments: x Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page?  <b>American Association of Veterinary State Boards (AAVSB) Matters</b> 1) Annual Meeting of the AAVSB Report – September 22-24, 2015 – Milwaukee, WI i. North Carolina Dental Board Case ii. Facilities Inspection iii. Federal Drug Administration (FDA) Animal Feed Directive iv. Prescription Drug Monitoring Programs v. Other	
7) Place Item in: x Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing?  No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:  Receive a report about the AAVSB Annual Meeting – September 22-24, 2015 – Milwaukee, WI and review several topics addressed by the AAVSB.			
11) <b>Authorization</b>			
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



2015 AAVSB Annual Meeting & Conference  
Milwaukee, Wisconsin

# BACKGROUND OF THE SUPREME COURT DECISION ON THE NC DENTAL BOARD CASE

Jack Nichols, JD





**N.C. Dental Board v. FTC**

Jack Nichols  
 Allen, Pinnix & Nichols, P.A.  
 Raleigh, NC  
 (919) 755-0505  
 mjn@allen-pinnix.com

**You Think You Want Whiter Teeth?**

- Your Dentist?
- Spa or Mall?

AAVSB

**How Are My Teeth Whitened?**

- Both use trays, but:
- Dentists use hydrogen peroxide at 25-40 percent.
- Others use hydrogen peroxide at 6-15 percent, or hydrogen carbamide (which breaks down to 3% hydrogen peroxide)

AAVSB

**What Does the Expert Say?**

*"My conclusions are that bleaching has some risk to the public safety and needs a proper dental exam prior to initiation due to the unknowns of what bleaching does in terms of masking pathology, also that there are concerns about the quality of products and pH issues and acid levels, and there's concern about what things like dental lights do in terms of bleaching."* (Emphasis added)

Dr. Van Haywood, DDS

AAVSB

**What does the statute Say?**

In 1879, the N.C. General Assembly stated: *"The practice of dentistry in the State of North Carolina is hereby declared to affect the public health, safety and welfare and to be subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the dental profession merit and receive the confidence of the public and that only qualified persons be permitted to practice dentistry in the State of North Carolina. This Article shall be liberally construed to carry out these objects and purposes."* (Emphasis added)

AAVSB

**What does the statute Say?**

(a) No person shall engage in the practice of dentistry in this State, or offer or attempt to do so, unless such person is the holder of a valid license or certificate of renewal of license duly issued by the North Carolina State Board of Dental Examiners.

AAVSB

### What does the statute Say?

(b) A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:

(2) Removes stains, accretions or deposits from the human teeth;

(Emphasis added).



2013 July, Public Law 84, NC 2013

### Factual History

- In 2003, Board received complaints about non-dentist providers of teeth whitening services.
- From 2005 - 2009, the Board sent 47 Cease & Desist letters to unlicensed persons or businesses.
- From 2003-2009, the Board conducted investigations of spas and kiosks in malls.



2013 July, Public Law 84, NC 2013

### Factual History

- Sometime in 2008, the FTC initiated an investigation of the State Board.
- From 2008 - 2010, the FTC interviewed 17 Board members & staff members (some twice) and requested thousands of pages.
- On June 17, 2010, the Commission filed an Administrative Complaint alleging that State Board had conspired to restrain trade by enforcing a state statute, N.C. Gen. Stat. § 90-29(b)(2).



2013 July, Public Law 84, NC 2013

### Factual History

- In addition, the administrative Complaint alleged that:
- The Board had engaged in conduct that would have the effect of restraining competition by preventing and deterring non-dentists from providing teeth whitening services in North Carolina.
  - That issuance of the C & D letters was without authority.



2013 July, Public Law 84, NC 2013

### Factual History

- The FTC ALJ conducted a 5 week trial and issued a 130 page Initial Decision on July 14, 2011.
- He ordered the Board to Cease and Desist from issuing Cease & Desist letters, but allowed the Board to file court actions against a non-dentist provider for alleged violation of the Dental Practice Act.



2013 July, Public Law 84, NC 2013

### Factual History - 4th Circuit

The Board appealed to the Fourth Circuit which affirmed the FTC in a 3-0 decision, with a concurring opinion. The Court held that:

- The Board was a private actor and not a state agency.
- The State did not "actively supervise" the Board.



2013 July, Public Law 84, NC 2013

PRESENTATIONS

### Factual History – 4<sup>th</sup> Circuit

- The Board, because it was made up of licensees, had the capacity to conspire.
- The FTC's findings of anti-competitive behavior were supported by substantial evidence.
- The pattern of sending C & D letters was concerted action.

HE 1301, PAPER E-MAIL, FA, 2014



### Factual History – SCOTUS

On Oct. 14, 2014, SCOTUS heard oral arguments and considered 17 amicus briefs.

The questions at the oral argument indicated that the Court is likely to establish a new test.

HE 1301, PAPER E-MAIL, FA, 2014



### Factual History – SCOTUS

During the oral argument, Justice Breyer asked the salient question, "...what the State says is: We would like this group of brain surgeons to decide who can practice brain surgery in this State. I don't want a group of bureaucrats deciding that. I would like brain surgeons to decide that."

HE 1301, PAPER E-MAIL, FA, 2014



### Factual History – SCOTUS

When the Deputy Solicitor General described the role of the Rules Review Commission as an independent "body of disinterested State actors who could pass on the validity of rules," Justice Scalia responded, "Really, really? ...I don't want that. I want a neurologist to decide that."

HE 1301, PAPER E-MAIL, FA, 2014



### Factual History – SCOTUS

*BUT*, other Court members expressed support for the FTC position. Justice Ginsburg asked, "Why should there be an antitrust exemption for conduct that is not authorized by state law? The objection here was that this board was issuing a whole bunch of cease and desist orders. They had no authority to do that. No authority at all."

HE 1301, PAPER E-MAIL, FA, 2014



### Factual History – SCOTUS

Justice Kagan said that the question is: "Is this party, this board of all dentists, is there a danger that it's acting to further its own interests rather than the governmental interests of the State? And that seem almost self-evidently to be true."

HE 1301, PAPER E-MAIL, FA, 2014



### Factual History – SCOTUS

Counsel for the Dental Board and Justice Kagan had a long colloquy about state supervision. Counsel noted that: *“There is a grave risk that if you require too much supervision as a condition of anti-trust [sic] immunity, no one will serve on these boards.”*



82 15th, P.O. Box 6, Norfolk, VA, 23510

### Factual History – SCOTUS

This concern was articulated by several of the amicus briefs. The N.C. State Bar, in its amicus brief, said: *“Lawyers will be reluctant to serve as bar councilors for fear of being sued – and of being held individually liable – in treble damage antitrust actions.”*



82 15th, P.O. Box 6, Norfolk, VA, 23510

### Factual History – AAVSB Brief to SCOTUS

The AAVSB & 18 other associations filed an amicus brief. The Brief argued that:

- The Dental Board was a duly constituted state agency that acted on behalf of the State.
- Congress never intended to subject OLB to FTC oversight.



82 15th, P.O. Box 6, Norfolk, VA, 23510

### Factual History – AAVSB Brief to SCOTUS

- Subjecting OLB to FTC Oversight would undermine the ability of States to regulate health provisions.
- Risk of antitrust oversight will discourage qualified professionals from serving on OLB.
- AMA argued that allowing FTC oversight would disrupt a 150 year tradition of State regulation.



82 15th, P.O. Box 6, Norfolk, VA, 23510

### What Happened To Separation Of Powers?

- EXECUTIVE,
- LEGISLATIVE, and
- JUDICIAL



82 15th, P.O. Box 6, Norfolk, VA, 23510

### Blind Men Examine an Elephant



82 15th, P.O. Box 6, Norfolk, VA, 23510

PRESENTATIONS

### Formulating the Question Formulates the Answer

- Agency Lawyers say:
- Antitrust Lawyers say:
- Free Enterprise types say:
- Constitutional Lawyers ...

HEALTH CARE & NETWORK, P.A. 2015



### Possible Outcomes

HEALTH CARE & NETWORK, P.A. 2015



### Possible Outcomes

1. Affirm the 1948 decision of *Parker v. Brown*, where the Court first articulated the policy of state agency exemption from antitrust laws.
2. Create a new test for State agencies.
3. Accept FTC's suggestion of a "hybrid board of self-interest market participants" with appropriate supervision of "disinterested state official to ensure no anticompetitive behavior."
4. Increase in State Supervision

HEALTH CARE & NETWORK, P.A. 2015



### Possible Outcomes

4. Increase in State Supervision by:
  - The PED proposed OLC;
  - New legislative oversight committee; or
  - Increased oversight by APO.

HEALTH CARE & NETWORK, P.A. 2015



### SCOTUS ISSUES DECISION

- On February 25, 2015, the Supreme Court issued its decision.
- By a vote of 6-3, the Court affirmed the Fourth Circuit and the FTC.
- The closing sentence of the opinion neatly summarizes the Court's Decision.
- "If a State wants to rely on active market participants as regulators, it must provide active supervision if state-action immunity under *Parker* is to be invoked."

HEALTH CARE & NETWORK, P.A. 2015



### SCOTUS ISSUES DECISION

Justice Kennedy, speaking for the majority, said: "A non-sovereign actor controlled by active market participants – such as the Board – enjoys *Parker* immunity only if it satisfies two requirements:

- 'the challenged restraint . . . [is] clearly articulated and affirmatively expressed as state policy,'
- and . . . 'the policy . . . [is] actively supervised by the State.'

HEALTH CARE & NETWORK, P.A. 2015



### What is State Supervision?

- Of course, the question becomes, what is "active supervision?"
- Justice Kennedy left that matter open.
- He stated, "Active supervision need not entail day-to-day involvement in an agency's operations or micromanagement of its every decision. Rather the question is whether the State's review mechanisms provide 'realistic assurance' that the nonsovereign's actor's anticompetitive conduct 'promotes state policy, rather than merely the party's individual interests.'"



### Dissenting Opinion

- In his dissent, Justice Alito, joined by Justices Scalia and Thomas, indicated he would have upheld Parker.
- "Today, however, the Court takes the unprecedented step of holding that Parker does not apply to the North Carolina Board because the Board is not structured in a way that merits a good-government seal of approval; that is, it is made up of practicing dentists who have a financial incentive to use the licensing laws to further the financial interest of the State's dentists. There is nothing new about the structure of the North Carolina Board."



### Dissenting Opinion

The dissent also criticized the new test under *Midcal* and the fact that municipalities

"benefit from a more lenient standard for state-action immunity than private entities. Yet, under the Court's approach, the North Carolina Board of Dental Examiners, a full-fledged state agency, is treated like a private actor and must demonstrate that the State actively supervise its actions."

Dissent, 135 S. Ct. at \_\_\_, 191 L. Ed. 2d at 61.



### Dissenting Opinion

In the final part of the dissent, Justice Alito, by asking questions, forecast the uncertainty of the future application of the Decision.

- "What is a 'controlling number'?"
- Is it a majority? And if so, why does the Court eschew that term?"
- Who is an 'active market participant'?"
- What is the scope of the market in which a member may not participate while serving on the board?"
- Must the market be relevant to the particular regulation being challenged or merely to the jurisdiction of the entire agency?"



### What is State Supervision?

My view of State Supervision is to consider all 3 branches of government.

- Judicial Branch
- Executive Branch
- Legislative Branch



### Going Forward, How Will Occupational Licensing Board Members Be Selected?

- The Fourth Circuit's concurring judge based her opinion on the subject of immunity on the fact that the N.C. Board members were elected by the state's dentists, rather than selected by the Executive Branch.
- But, the oral argument before the Supreme Court seemed to minimize that issue.



PRESENTATIONS

### Going Forward, How Will Occupational Licensing Board Members Be Selected?

- The Supreme Court's majority opinion avoided discussion of board selection or composition.
- But the dissent forecast the likelihood that some prospective board members would no longer be willing to serve.

2015 WL 42676, \*14 (N.C., 8/11/15)



### Going Forward, Will Occupational Licensing Board Members Be Liable?

- As noted previously, many of the amicus briefs before the Supreme Court raised the specter of occupational licensing board appointees declining to serve because of their concern about their personal liability.

2015 WL 42676, \*14 (N.C., 8/11/15)



### Going Forward, Will Occupational Licensing Board Members Be Liable?

- Justice Kennedy, speaking for the majority, said: "But this case, which does not present a claim for money damages, does not offer occasion to address the question whether agency officials, including board members, may, under some circumstances, enjoy immunity from damages liability. . . . And, of course, the States may provide for the defense and indemnification of agency members in the event of litigation." (Emphases added)

2015 WL 42676, \*14 (N.C., 8/11/15)



### Going Forward, Will Occupational Licensing Board Members Be Liable?

This is no longer an academic discussion.

- On April 24, 2015, a medical clinic, a doctor and the clinic owner sued the MS. Board of Medical Licensure because it forced him to see the clinic since he was not a physician.
- The complaint uses/follows the FTC's administrative complaint issued against the NC Dental Board. In fact, the plaintiffs' complaint accidentally includes this heading: **ANTICOMPETITIVE EFFECTS OF THE DENTAL BOARD'S ACTIONS**

2015 WL 42676, \*14 (N.C., 8/11/15)



### Going Forward, Will Occupational Licensing Board Members Be Liable?

Regarding active state supervision, the complaint alleges:

*"The Board is made up of nine (9) physicians, who participate in the provision of healthcare services in Mississippi. Even though the Board is made up of market participants it receives no supervision from a politically accountable state supervisor with veto power who is not a market participant."*

2015 WL 42676, \*14 (N.C., 8/11/15)



### Going Forward, Will Occupational Licensing Board Members Be Liable?

Plaintiffs seek:

- injunctive relief,
- declaratory relief,
- treble damages, and
- Attorney fees & costs.

2015 WL 42676, \*14 (N.C., 8/11/15)



### Going Forward, Will Occupational Licensing Board Members Be Liable?

- Does your Board have public liability insurance that will pay the cost of defense?
- Will it also pay damages?
- Probably, any coverage will exclude treble damages.

2014 May, Peter S. Neufeld, PA, 2014



### Going Forward, the FTC's Position

- In a March 31, 2015, speech to The Heritage Foundation, Maureen K. Ohlhausen, a member of the FTC, commented on the N.C. Dental Board Decision but noted that the comments were her own "and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner."

2014 May, Peter S. Neufeld, PA, 2014



### Going Forward, the FTC's Position

- Significantly, she noted "that decision represents the culmination of the Commission's efforts in the state action area."
- She also noted that the FTC's work on the subject began with the State Action Task Force, which formulated the goals of "reigning in antitrust exemptions and immunities."

2014 May, Peter S. Neufeld, PA, 2014



### Going Forward, the FTC's Position

Commissioner Ohlhausen observed that state boards:

- Should be "more cognizant of, and hopefully minimizing, the competitive effects of a board's regulatory decision...";
- "[N]eed not be controlled by active market participants";

2014 May, Peter S. Neufeld, PA, 2014



### Going Forward, the FTC's Position

- Could be actively supervised by the following methods: legislative committees, umbrella state agencies, rules review commissions, or other disinterested state officials in the event that the State prefers that a board is "controlled by market participants";
- Could be indemnified in the event that antitrust damages are imposed on individual board members;

2014 May, Peter S. Neufeld, PA, 2014



### Going Forward, the FTC's Position

- Should use the injunctive procedures in court and rely on the *Noerr-Pennington* doctrine.
- She later discussed the need for States to "take a step back to reconsider the composition and oversight of their regulatory boards ... to see if they are on balance helping or harming consumers."

2014 May, Peter S. Neufeld, PA, 2014



PRESENTATIONS

### What Will the FTC Do Now?

- Continue to work to weaken State Immunity
- Litigate Active Supervision
- Be more proactive in state OLB activity.

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### The Last Word....

However your Board operated before 2015, it will HAVE to operate differently from NOW ON!

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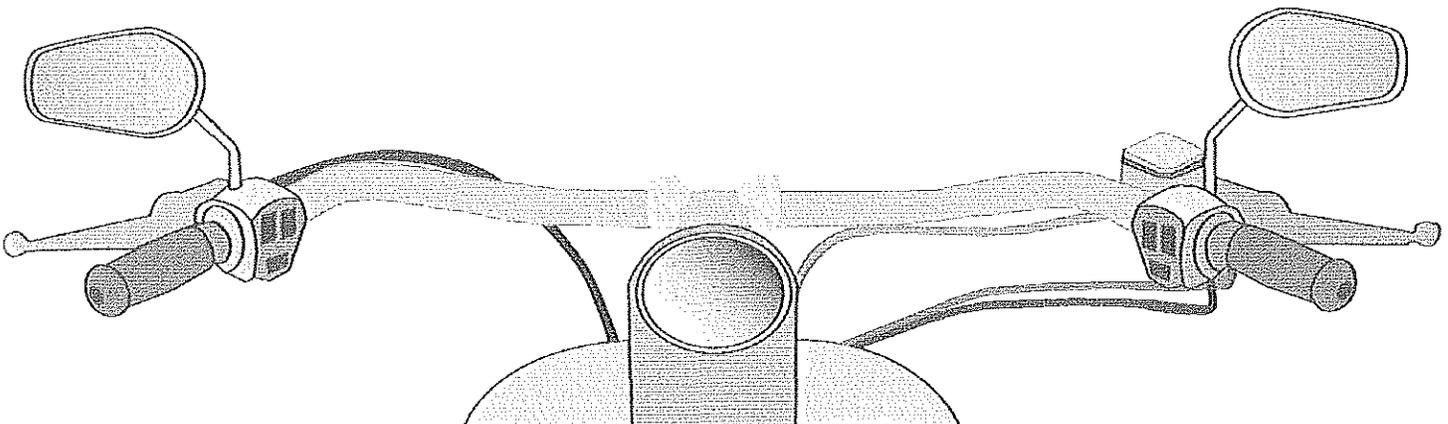




2015 AAVSB Annual Meeting & Conference  
Milwaukee, Wisconsin

# UPDATE ON EFFECTS OF SUPREME COURT DECISION ON THE NC DENTAL BOARD

Jennifer Semko, JD





**2015 AAVSB Annual Meeting & Conference  
September 17-19, 2015  
Milwaukee, Wisconsin**

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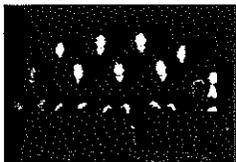
**EVOLUTION OF STATE ACTION IMMUNITY: WHAT NOW?**  
JENNIFER ANCONA SEMKO, ESQ.  
BAKER & MCKENZIE, LLP, WASHINGTON, D.C.

**Objectives**

- Recap of the U.S. Supreme Court *NC State Board* decision
- Potential implications for regulatory boards
- Recent developments
  - Litigation
  - State responses
- Food for thought

**Supreme Court's February 25 Ruling**

"If a State wants to rely on active market participants as regulators, it must provide active supervision if state-action immunity . . . is to be invoked."



**Overview of the Decision**

**(Brief) Overview of Ruling**

- 6 to 3 decision (Alito, Scalia and Thomas dissenting)
- **Majority's Conclusion:** Because a "controlling number" of the Board's decision makers are "active market participants in the occupation the Board regulates," the Board is treated as a private actor and must show active supervision by the State
  - The "active supervision" requirement was not met here
- **Dissent:** The majority seriously misunderstands the doctrine of state-action immunity. Board is a state entity. Period.

**Majority's Analysis**

- There are limits on immunity
- State agencies are not sovereign simply because of their governmental character
- Active state supervision is required and must be meaningful
- Compared Board to a trade association

### Majority's Analysis (cont'd)

#### Citizens need not be discouraged from serving

- Long tradition of professional self-regulation in US
- States may see benefits to staffing agencies with experts
- No claim for money damages here, so need not address whether board members may be immune from money damages in some circumstances
- State can provide for defense and indemnification
- State can ensure immunity by adopting clear policy to displace competition and (if agency controlled by active market participants) providing active supervision

2015 FARM 1015

FARM

### Majority's Analysis (cont'd)

#### How much state supervision is required?

- Test is "flexible and context-dependent"
- Don't need day-to-day involvement in operations or micromanagement of every decision
- Review mechanism must provide "realistic assurance" that conduct "promotes state policy, rather than merely the party's individual interests"
- Four requirements: (1) supervisor must review substance, not merely procedures; (2) must have power to veto/modify; (3) mere potential for supervision not enough; and (4) supervisor can't be active market participant

2015 FARM 1015

FARM

### Dissent's Viewpoint

- The NC Board is a state agency "and that is the end of the matter"
- "... until today... immunity was never conditioned on the proper use of state regulatory authority."
- Majority decision "will spawn confusion" and be difficult to apply
- States may now have to change composition of boards, "but it is not clear what sort of changes are needed to satisfy the test that the Court now adopts."

2015 FARM 1015

FARM

### Dissent: Unanswered Questions

- What is a "controlling number"? Majority? Voting bloc? Obstructionist minority? Powerful agency chair?
- Who is an "active market participant"?
- What is the scope of the market? Must market be relevant to the particular challenged conduct? Would result be different if Board members did not provide teeth whitening?
- How much participation makes person "active" in the market?
- Why stop at structure of the board when evaluating "board capture"?

2015 FARM 1015

FARM

### Potential Implications

### Why does this matter to you?

- Broader issue of "state action" is relevant to all regulatory boards
- Many boards include practitioner members
- Amount of interface with the state may vary
- Second recent Supreme Court ruling narrowing state-action defense; FTC strongly disfavors state action defense and seeks a high bar for "active supervision"



2015 FARM 1015

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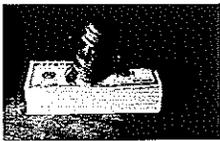
### So now what?

- FTC Commissioner Brill announced in June that FTC would issue guidance
- Talk to AG about your board/state
- Don't forget first prong: clearly articulated state policy to displace competition
- How clear is your enabling statute?
- Remember four requirements for active supervision: (1) supervisor must review substance, not merely procedures; (2) must have power to veto/modify; (3) mere potential for supervision not enough; and (4) supervisor can't be active market participant

### Recent Developments

### Litigation Consequences

- Likely to embolden private litigants to assert antitrust claims, even when merits not strong
- Does not mean boards will lose ... But have potentially lost straightforward grounds for early dismissal
- Suits are already being filed ...



### Access Medical Clinic

- Suit filed against Mississippi State Board of Medical Licensure in April 2015
- Challenges new rules imposed on pain management clinics




### Access Medical Clinic

- Clinic opened 2010
- In 2011, Board adopts rule requiring clinics to be owned by a hospital or licensed physician
- Plaintiff gives his majority interest to a physician without compensation
- Clinic later forced to close when Board imposes new rules requiring education/certification for physician owners

### Access Medical Clinic

- Antitrust Claims:
  - Excluding non-physicians from ownership of pain clinics and requiring approval from board before operating
  - Imposing special education/certification requirements for clinic owners not required of other physicians
- Seeking \$700,000 in damages, treble damages and attorney's fees

### Access Medical Clinic

- Board composition: 9 physicians (MDs and DOs)
- Plaintiff alleges board members are "market participants" and acted without a state supervisor with veto authority
  - Must the board members participate in pain management practice to be "market participants"?
- Note: Board oversees MDs, osteopaths, podiatrists, PAs, radiologist assistants and acupuncturists
  - Might state action immunity apply to decisions unrelated to practice of medicine?

8/11/2015

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### Teladoc, Inc. v. Texas Medical Board

- National telemedicine provider sues Texas Board in April 2015
- Seeking to stop rule requiring doctors to meet in person with new patients before writing prescriptions
- Alleges Board adopted rule only when Teladoc began to be a competitive threat to traditional practices



8/11/2015

FARR

### Teladoc, Inc. v. Texas Medical Board

- Board includes 12 practicing physicians (voted 13/1 for new rule)
- 203 of 206 public comments opposed the new rule
  - Two favoring statements came from the Texas Medical Association
- Board argues new rule clarifies and expands opportunities for telemedicine . . . Only scenario prohibited is treating unknown patient without objective diagnostic data or ability to follow up with patient

8/11/2015

FARR

### Robb v. CT Board of Veterinary Medicine

- Complaint filed in June 2015 against CT Board and its members
- DVM (and owner of Banfield Hospital franchise) seeking to block disciplinary action against him, arguing violation of antitrust laws
- Disciplinary action stems from plaintiff's decision to implement his own vaccination protocols



8/11/2015

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### Robb v. CT Board of Veterinary Medicine

- Characterizes licensing board as "competitors" seeking to prevent a threat to significant aspect of vet practices
- Application for TRO denied
- Also seeking compensatory and treble damages



8/11/2015

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### Oklahoma Response

- Governor issues executive order in late July
- State boards made up of majority of industry participants must submit all non-rulemaking actions (like licensure) to AG for review
- Must defer to AG on any modifications



8/11/2015

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PRESENTATIONS

Food for Thought



Potential Strategies in Response to Ruling

- Develop greater state supervision over existing board (e.g., "State Supervision Czar," legislative committee, state court)
  - Oklahoma approach: AG office
- Change board membership so not controlled by active market participants; argue for state entity status (e.g., more public members; remove practitioner majority)
- Combine boards to dilute market participants (e.g., umbrella boards)
- Seek state endorsement of decisions with significant effects on competition
- Abandon boards for certain professions
- Make no charges



Other Considerations

- Evaluate (establish?) state program for defense and indemnification of board members
- Some activities may be more likely to draw scrutiny than others (e.g., individual disciplinary action vs. broader scope-of-practice question)
- Prepare for potential increase in private antitrust claims in response to board actions
- FTC may be encouraged; complaints brought to FTC's attention may get receptive audience
- Method of board member selection not an express factor in Court's decision



Questions?

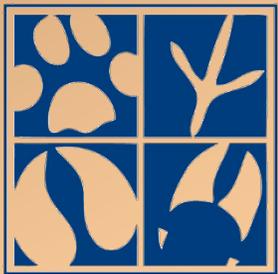
Jennifer Ancona Semko  
 Baker & McKenzie LLP  
 Washington, DC  
 (202) 835-4250  
[jennifer.semko@bakermckenzie.com](mailto:jennifer.semko@bakermckenzie.com)





# Facility Inspection System

**Virginia Board of Veterinary Medicine  
2015**



**AAVSB**  
AMERICAN ASSOCIATION OF  
VETERINARY STATE BOARDS

# Objectives

- The following information will be shared about the process used to
  - Develop a new inspection form
  - Develop a transparent disciplinary process for inspection violations
  - Implement an electronic inspection program
  - Update regulations related to inspections

# Board Structure

The authority for the establishment of the Board of Veterinary Medicine's (Board) and its duties and responsibilities are found in the Code of Virginia (Code).

- The Board is part of the Executive Branch of government.
- The Governor appoints the seven member board composed of
  - 5 licensed veterinarians
  - 1 licensed veterinary technician
  - 1 citizen member
- The Code designates that the Board be under the Health and Human Resources (HHR) Secretariat and that the Department of Health Professions (DHP) oversees its operation.
- DHP assigns appropriate staff to handle the day-to-day functions.

# Board Functions

As a member board under DHP, the Board adheres to the mission statement of the agency:

*Our mission is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.*

# Board Functions (continued)

- The Board regulates the practice of veterinary medicine, veterinary technology and equine dental technology by promulgating rules governing practice; licensing veterinarians and veterinary technicians and registering equine dental technicians and veterinary establishments; and disciplining licensees for misconduct that is a violation of statutes or regulations.
- The Board's specific authority to regulate the inspection process is found in § 54.1-3804(3) of the Code of Virginia which states:

*In addition to the powers granted in § 54.1-2400, the Board shall have the following specific powers and duties:*

*3. To regulate, inspect and register all establishments and premises where veterinary medicine is practiced.*



## Virginia Board of Veterinary Medicine



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### [Announcements](#)

#### Flurbiprofen-Containing Topical Pain Medications: FDA Alert - Illnesses and Deaths in Pets Exposed to Prescription Topical Pain Medication

**AUDIENCE:** Health Professional, Pharmacy, Consumer, Veterinary

**ISSUE:** FDA is alerting pet owners, veterinarians, health care providers and pharmacists that pets are at risk of illness and death when exposed to topical pain medications containing the nonsteroidal anti-inflammatory drug (NSAID) flurbiprofen. People using these medications should use care when applying them in a household with pets, as even very small amounts could be dangerous to these animals.

The FDA received reports of cats in two households that became ill or died after their owners used topical medications containing flurbiprofen on themselves to treat muscle, joint, or other pain. The pet owners had applied the cream or lotion to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication. The products contained the NSAID flurbiprofen and the muscle relaxer cyclobenzaprine, as well as other varying active ingredients, including baclofen, gabapentin, lidocaine, or prilocaine.

**BACKGROUND:** Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed signs that included reluctance to eat, lethargy, vomiting, melena (black, tarry, bloody stools), anemia, and dilute urine. These two cats died despite veterinary care. A third cat in the second household also died after the owner had stopped using the medication. Veterinarians performed necropsies on the three cats that died and found evidence in the kidneys and intestines that were consistent with NSAID toxicity.

**RECOMMENDATION:** FDA recommends that people who use topical medications containing flurbiprofen take care to prevent their pets from being exposed to them, even in ways that may seem unlikely to cause problems. Health care providers who prescribe topical pain medications containing flurbiprofen, and pharmacists who fill these prescriptions, should advise patients with pets to take care to prevent exposure of the pet to the medication.

[Read the MedWatch safety alert, including a link to the FDA CVM Alert.](#)

#### FDA News Release

April 2, 2015 - FDA alerts health care professionals and patients not to use products from the Prescription Center pharmacy in Fayetteville, N.C. - [Read the full news release.](#)

DEA Rescheduling Hydrocodone Combination Products From Schedule III to Schedule II

#### Board of Veterinary Medicine

Perimeter Center  
9960 Mayland Drive, Suite  
300  
Henrico, Virginia 23233-1463  
[Directions](#)

For Licensing: (804) 367-4497

All other questions: (804) 367-4468

Fax: (804) 527-4471

Complaints: (800) 533-1560  
Automated License

Verification: (804) 270-6836

Email:

[vetbd@dhp.virginia.gov](mailto:vetbd@dhp.virginia.gov)

Hours: Mon-Fri 8:15 to 5:00  
except [Holidays](#)

#### Other Citizen Services

VIRGINIA COORDINATED  
RESPONSE AGAINST  
**HUMAN  
TRAFFICKING**  
Get information about human  
trafficking, resources for  
victims, and reporting of a  
suspicion of trafficking.



# Starting Point

- No major updates to the inspection process in more than 10 years
- Board appointed an ad hoc Inspection Committee to review the inspection process and make recommendations to the full board
- Inspection Committee included
  - 2 Board Members
  - 2 Board Staff Members (executive director and operations manager)
  - 1 Veterinary Establishment Inspector
- Public business meetings held

# Prior Inspection Process

- Facility types
  - Full Service
  - Restricted (ambulatory, large and small animal practices)
- Routine inspections every three years
- Unannounced inspections completed to determine compliance with applicable laws and regulations
- Inspection summary completed
  - Copy left with veterinary establishment
  - Copy sent to the board office
- Response sent to the board office
- Action taken by Board if warranted

# Paper Inspection Form

The image shows a handwritten paper inspection form. The form is divided into several sections, each with a list of items to be inspected. The items are marked with checkboxes, and some have handwritten notes or initials next to them. The form is filled out with handwritten text, including names like 'ANTICH' and 'HOUSE FOR EMERGENCY', and various notes and initials.

Section	Item	Checked	Notes
GENERAL INFORMATION	1. Name of the facility	<input checked="" type="checkbox"/>	
	2. Address	<input checked="" type="checkbox"/>	
	3. Telephone	<input checked="" type="checkbox"/>	
	4. Fax	<input checked="" type="checkbox"/>	
FACILITY INFORMATION	5. Type of facility	<input checked="" type="checkbox"/>	
	6. Size of facility	<input checked="" type="checkbox"/>	
	7. Number of animals	<input checked="" type="checkbox"/>	
	8. Other information	<input checked="" type="checkbox"/>	
FACILITY OPERATIONS	9. Hours of operation	<input checked="" type="checkbox"/>	
	10. Location of facility	<input checked="" type="checkbox"/>	
	11. Access to facility	<input checked="" type="checkbox"/>	
	12. Security of facility	<input checked="" type="checkbox"/>	
FACILITY DESIGN	13. Design of facility	<input checked="" type="checkbox"/>	
	14. Construction of facility	<input checked="" type="checkbox"/>	
	15. Materials of facility	<input checked="" type="checkbox"/>	
	16. Other information	<input checked="" type="checkbox"/>	
FACILITY EQUIPMENT	17. Equipment of facility	<input checked="" type="checkbox"/>	
	18. Maintenance of equipment	<input checked="" type="checkbox"/>	
	19. Safety of equipment	<input checked="" type="checkbox"/>	
	20. Other information	<input checked="" type="checkbox"/>	
FACILITY PERSONNEL	21. Personnel of facility	<input checked="" type="checkbox"/>	
	22. Training of personnel	<input checked="" type="checkbox"/>	
	23. Qualifications of personnel	<input checked="" type="checkbox"/>	
	24. Other information	<input checked="" type="checkbox"/>	
FACILITY RECORDS	25. Records of facility	<input checked="" type="checkbox"/>	
	26. Maintenance of records	<input checked="" type="checkbox"/>	
	27. Accuracy of records	<input checked="" type="checkbox"/>	
	28. Other information	<input checked="" type="checkbox"/>	
FACILITY COMPLIANCE	29. Compliance with laws	<input checked="" type="checkbox"/>	
	30. Compliance with regulations	<input checked="" type="checkbox"/>	
	31. Compliance with guidance	<input checked="" type="checkbox"/>	
	32. Other information	<input checked="" type="checkbox"/>	

The previous form lacked specificity with regards to the laws, regulations and guidance information on inspection items.

# Overview: Inspection Review Process

- Committee tasked with reviewing the forms and the inspection process.
- **Step process**
  - Identify laws and regulations to include in an inspection
  - Format paper copy
  - Designate regulations as major or minor violations
  - Develop point system for use in board actions
  - Format electronic copy
  - Launch pilot program
  - Implement final program details
  - Update regulations

# Review Step 1

## Identified laws and regulations to include in an inspection

- Performed a comprehensive review of the current laws and regulations
- Determined which laws or regulations needed to be on the form
- Categorized the inspection items
  - Licenses and Permits
  - Veterinarian-in-Charge (VIC)
  - Requirements for drug storage, dispensing, destruction, and records for all establishments, full service and restricted.
  - Bulk Reconstitution of Injectable, Bulk Compounding or Prepackaging
  - Patient/Medical Recordkeeping
  - Standards for Veterinary Establishments (building, lab, surgery, radiology)

# Review Step 2

## Formatted paper copy

- Started with formatting a hard copy
- Cited statutory or regulatory language
- Included the beginnings of guidance information

# Review Step 3

## Designated regulations as major or minor violations

- Patterned after Board of Pharmacy
- Evaluated each regulation
- Assigned “major” designation if violation likely to cause harm
- Assigned “minor” designation if violation not likely to cause harm
- Started using new form in December of 2011

# Review Step 4

## Developed the point system for use in board actions

- Utilized Sanctioning Reference Points concept
- Assigned 2 to 5 points for “major” designations
- Assigned 1 point for “minor” designations
- Assigned double points for repeat violations
- Applied points to sampling of inspections

# Review Step 5

## Formatted electronic copy

- Added point system information
- Added guidance information
- Finalized the details of the E-Mobile inspection summary

# New Form

Guidance document: 76-21.2:1

Commonwealth of Virginia - Department of Health Professions  
 Veterinary Medicine Establishment Inspection Report  
[www.dhp.virginia.gov](http://www.dhp.virginia.gov)

Revised: October 28, 2013

## VETERINARY ESTABLISHMENT INSPECTION REPORT

	Date	Time	Inspection Hours
Name of Facility	Permit No <input type="checkbox"/> PENDING	Expiration Date	
Street Address	City	State VIRGINIA	ZIP
Hours of Operation	Phone No	Fax No	
Veterinarian-in-Charge	License No	Expiration Date	
Other Staff			
Type of Practice	Type of Inspection <input type="checkbox"/> New <input type="checkbox"/> Routine <input type="checkbox"/> Reinspection <input type="checkbox"/> Other (Describe)		

C = Compliant  
 NC = Not Compliant  
 NA = Not Applicable or Not reviewed

C/ NC/ NA	#	Major/ Minor/ Points	Law/Regulation	Description
<b>Licenses and Permits</b>				
	1	Minor 1 point	18VAC150-20-30(A)	All licenses and permits issued by the board shall be posted in a place conspicuous to the public or available at the establishment where veterinary services are being provided. Licensees who do relief work in an establishment shall carry a license with them or post at the establishment. Ambulatory veterinary practices or equine dental technicians that do not have an office accessible to the public shall carry their licenses and permits in their vehicles.  <u>Guidance</u> A license or permit is considered to be in a "place conspicuous to the public" when it is hung in an area that is easily accessed and read by the public. The original license or permit (not a photocopy) should be posted or available for inspection. Duplicate copies of a license can be obtained through the Board of Veterinary Medicine's office for a small fee. Any license or permit that is expired will be reported and documentation of practicing without a valid license or permit will be obtained.
	2	Major 5 points	§ 54.1-3805	No person shall practice veterinary medicine or as a veterinary technician in this Commonwealth unless such person has been licensed by the Board.
	3	Major	18VAC150-20-70(A)	All individual licenses are current. Failure to renew an individual license shall cause the license to lapse and become invalid.

Commonwealth of Virginia - Department of Health Professions  
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	12	Major 2 points	18VAC150-20-190(E)	Schedule II, III, IV and V are destroyed properly.  <u>Guidance</u> Inspectors will verify that Schedule II, III, IV and V drugs are properly destroyed in accordance with DEA requirements available at <a href="http://www.deadiversion.usdoj.gov/drug_disposal/index.html">http://www.deadiversion.usdoj.gov/drug_disposal/index.html</a>  <b>Disposal of Controlled Substances</b> A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III-V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years. It is recommended that Schedule VI drugs be destroyed in the same manner as Schedule III-V drugs. Expired drugs may be considered adulterated drugs, may not be transferred or donated and must be destroyed as required by federal and state laws and regulations.
	13	Major 5 points 4 points 3 points 2 points See guidance	18VAC150-20-190(F)	Drug storage area has appropriate refrigeration with interior thermometer maintained between 36°F and 46°F. Drugs stored at room temperature are maintained between 59°F and 86°F. Drugs are removed from working stock upon expiration.  <u>Guidance</u> The expiration date on all drugs, including prepackaged stock, should be regularly checked and drugs that are expired must be separated from working stock. A drug expires on the month, day and year listed on the container. If only a month and year are provided, drug expires on the last day of the month listed on container.  Points assigned: 5 points for more than 5 expired drugs; or 4 points for 1-5 drugs expired 60 days or more; or 3 points for 1-5 drugs expired less than 60 days; and 2 additional points for out-of-range temperatures.
	14	Major 5 points 3 points See guidance	§ 54.1-3404 18VAC150-20-190(G)	A distribution record shall be maintained in addition to the patient's record, in chronological order, for the administering and dispensing of Schedule II, III, IV and V drugs. Distribution records are to be maintained for a period of two years from the date of transaction. The distribution record shall include the following: <ol style="list-style-type: none"> <li>Date of transaction.</li> <li>Drug name, strength, and the amount dispensed, administered and wasted.</li> <li>Client and animal identification; and</li> <li>Identification of the veterinarian authorizing the administration or dispensing of the drug.</li> </ol> <u>Guidance</u> The veterinarian's initials are acceptable to meet the requirement of "identification of the veterinarian." The Board recommends that a veterinary establishment maintain a signature list of all employees in the veterinary establishment. The list should contain the individual's printed name, signature and initials.  When a veterinarian with a mobile or house call practice occasionally uses the surgery facilities of a full service veterinary hospital, the drug distribution log(s) must clearly reveal whose controlled substances were used for what purpose. If the facility's stock is used, the hospital log must show that the surgery was performed by a visiting veterinarian who has the patient record and a record of administration shall be maintained at the facility. If the visiting veterinarian uses his own stock of drugs, he must make entries in his own log and patient records and shall leave a copy of the record at the full-service facility.  Points assigned: 5 points for no record; or 3 points for incomplete record or records not maintained in chronological order.

# Review Step 6

## Launched pilot program

- Developed guidance document
- Presented at the 2013 Virginia Veterinary Medical Association's annual meeting
- Evaluated data to validate the point ranges

# Letter of Support from VVMA

## VIRGINIA VETERINARY MEDICAL ASSOCIATION

3801 Westerre Parkway, Suite D • Henrico, Virginia 23233  
(804) 346-2611 • (800)YES-VVMA • Fax: (804) 346-2655  
e-mail: vavvma@aol.com • www.vvma.org

### OFFICERS

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Mark Finkler, DVM  
*President-Elect*  
Jeffery Newman, DVM  
*Vice President*  
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*State Veterinarian*

### EXECUTIVE DIRECTOR

Robin R. Schmitz



October 16, 2012

Ms. Leslie L. Knachel, Director  
Virginia Board of Veterinary Medicine  
Virginia Department of Health Professions  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Henrico, Virginia 23233-1463

RE: Inspection Scoring System

Dear Ms. Knachel,

The Virginia Veterinary Medical Association (VVMA) offers the following comments to the Board of Veterinary Medicine on the above-referenced revision to facility inspections.

The VVMA shared information with our members on this issue, and we received no negative comments on the proposed scoring system for facility inspections. We appreciate the hard work and many hours you and the Inspection Committee have dedicated to improving the inspection process. We anticipate that the new scoring system will bring clarity and consistency to facility inspections, and we look forward to working with you and the Board as implementation begins. While we may have additional, more specific comments at a later date post implementation, we support the scoring system as developed by the Inspection Committee going forward at this time.

Thank you for this opportunity to comment.

Sincerely,

Donald G. Henry, DVM  
President, Virginia Veterinary Medical Association



# Guidance Document

Guidance document: 150-15

Adopted: October 17, 2012

## VIRGINIA BOARD OF VETERINARY MEDICINE

### Disposition of Routine Inspection Violations During Pilot Program

The Board of Veterinary Medicine (Board) is conducting a pilot program from January 1, 2013 to December 31, 2013, relating to the disposition of violation(s) found during a routine inspection. The guidance document, [76-21.2-1 Veterinary Establishment Inspection Report](#) provides the laws and regulations to which veterinary establishments must comply. The purpose of the pilot program is to provide a year-long time period for the licensees of the Board to become familiar with the changes to the routine inspection process and to collect data to evaluate the point ranges and the corresponding possible action.

The following information applies to routine inspections conducted between January 1, 2013 and December 31, 2013:

- The possible actions listed below will not be implemented until January 1, 2014.
  - All routine inspections conducted during the pilot program may be subject to disciplinary action to be determined by the current disciplinary process as described on the website at [http://www.dhp.virginia.gov/Enforcement/enf\\_DisciplineProcess.htm](http://www.dhp.virginia.gov/Enforcement/enf_DisciplineProcess.htm).
  - All veterinarians-in-charge may be subject to disciplinary action to be determined by the current disciplinary process as described on the website at [http://www.dhp.virginia.gov/Enforcement/enf\\_DisciplineProcess.htm](http://www.dhp.virginia.gov/Enforcement/enf_DisciplineProcess.htm).
  - Each veterinary establishment that undergoes an inspection will be provided with a point total for reference purposes.
- Feedback on the pilot program may be sent to the Board at [vetbd@dhp.virginia.gov](mailto:vetbd@dhp.virginia.gov).

#### Veterinary Establishment Proposed Effective Date of January 14, 2014

Total Points*	Possible Action
0 – 10 points	Routine inspection in five years
11 – 15 points	Confidential Consent Order; routine inspection in five years
16 – 20 points	Pre-hearing consent order issued by inspector; monetary penalty of \$250; unannounced inspection in two years
21 or more points	Pre-hearing consent order issued by inspector; monetary penalty of \$500; unannounced inspection in one year

#### Veterinarian-In-Charge Proposed Effective Date of January 14, 2014

Inspection Points	Possible Action
11 – 15 points	Confidential Consent Agreement
16 points or more	Pre-hearing consent order; monetary penalty of \$250

\* Point values are available on the guidance document, [76-21.2-1 Veterinary Establishment Inspection Report](#). Please note that violations cited during last and current inspections are repeat violations and receive double the assigned point value.

The pilot program was introduced to the veterinary community through a guidance document adopted by the Board. The guidance document included information on the inspection program as well as board actions for non-compliance.

# Review Step 7

## Implemented final program details

- Revised guidance document
- Trained inspectors on quantifying/qualifying violations
- Developed evidence collection process
- Identified process for amending inspection report
- Determined process for identifying repeat violations
- Developed follow-up evaluation process

# Review Step 8

## Updated regulations

- Identified current veterinary facility business models
- Identified regulations that needed to be updated

# Current Inspection Program

- Three year inspection cycle
- Four inspectors
  - 1090 facilities
  - Approximated 7 to 8 inspections/inspector/month
  - Average of 4.2 hours to conduct an inspection
- New form well received
- E-Mobile working well
- Board action based on point system
- Regulatory update ongoing

# Summary

- Steady and slow got the job done
- Objective method for determining board actions protects the Board, veterinary community and the public
- Follow-up evaluation process is key to ensuring program integrity

# Questions and Answers



# Facility Inspection System

**Virginia Board of Veterinary Medicine  
2015**



**AAVSB**  
AMERICAN ASSOCIATION OF  
VETERINARY STATE BOARDS

# Objectives

- The following information will be shared about the process used to
  - Develop a new inspection form
  - Develop a transparent disciplinary process for inspection violations
  - Implement an electronic inspection program
  - Update regulations related to inspections

# Board Structure

The authority for the establishment of the Board of Veterinary Medicine's (Board) and its duties and responsibilities are found in the Code of Virginia (Code).

- The Board is part of the Executive Branch of government.
- The Governor appoints the seven member board composed of
  - 5 licensed veterinarians
  - 1 licensed veterinary technician
  - 1 citizen member
- The Code designates that the Board be under the Health and Human Resources (HHR) Secretariat and that the Department of Health Professions (DHP) oversees its operation.
- DHP assigns appropriate staff to handle the day-to-day functions.

# Board Functions

As a member board under DHP, the Board adheres to the mission statement of the agency:

*Our mission is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.*

# Board Functions (continued)

- The Board regulates the practice of veterinary medicine, veterinary technology and equine dental technology by promulgating rules governing practice; licensing veterinarians and veterinary technicians and registering equine dental technicians and veterinary establishments; and disciplining licensees for misconduct that is a violation of statutes or regulations.
- The Board's specific authority to regulate the inspection process is found in § 54.1-3804(3) of the Code of Virginia which states:

*In addition to the powers granted in § 54.1-2400, the Board shall have the following specific powers and duties:*

*3. To regulate, inspect and register all establishments and premises where veterinary medicine is practiced.*



## Virginia Board of Veterinary Medicine



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### Announcements

#### Flurbiprofen-Containing Topical Pain Medications: FDA Alert - Illnesses and Deaths in Pets Exposed to Prescription Topical Pain Medication

**AUDIENCE:** Health Professional, Pharmacy, Consumer, Veterinary

**ISSUE:** FDA is alerting pet owners, veterinarians, health care providers and pharmacists that pets are at risk of illness and death when exposed to topical pain medications containing the nonsteroidal anti-inflammatory drug (NSAID) flurbiprofen. People using these medications should use care when applying them in a household with pets, as even very small amounts could be dangerous to these animals.

The FDA received reports of cats in two households that became ill or died after their owners used topical medications containing flurbiprofen on themselves to treat muscle, joint, or other pain. The pet owners had applied the cream or lotion to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication. The products contained the NSAID flurbiprofen and the muscle relaxer cyclobenzaprine, as well as other varying active ingredients, including baclofen, gabapentin, lidocaine, or prilocaine.

**BACKGROUND:** Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed signs that included reluctance to eat, lethargy, vomiting, melena (black, tarry, bloody stools), anemia, and dilute urine. These two cats died despite veterinary care. A third cat in the second household also died after the owner had stopped using the medication. Veterinarians performed necropsies on the three cats that died and found evidence in the kidneys and intestines that were consistent with NSAID toxicity.

**RECOMMENDATION:** FDA recommends that people who use topical medications containing flurbiprofen take care to prevent their pets from being exposed to them, even in ways that may seem unlikely to cause problems. Health care providers who prescribe topical pain medications containing flurbiprofen, and pharmacists who fill these prescriptions, should advise patients with pets to take care to prevent exposure of the pet to the medication.

[Read the MedWatch safety alert, including a link to the FDA CVM Alert.](#)

#### FDA News Release

April 2, 2015 - FDA alerts health care professionals and patients not to use products from the Prescription Center pharmacy in Fayetteville, N.C. - [Read the full news release.](#)

DEA Rescheduling Hydrocodone Combination Products From Schedule III to Schedule II

#### Board of Veterinary Medicine

Perimeter Center  
9960 Mayland Drive, Suite  
300  
Henrico, Virginia 23233-1463  
[Directions](#)

For Licensing: (804) 367-4497

All other questions: (804) 367-4468

Fax: (804) 527-4471

Complaints: (800) 533-1560  
Automated License

Verification: (804) 270-6836

Email:

[vetbd@dhp.virginia.gov](mailto:vetbd@dhp.virginia.gov)

Hours: Mon-Fri 8:15 to 5:00  
except [Holidays](#)

#### Other Citizen Services

VIRGINIA COORDINATED  
RESPONSE AGAINST  
**HUMAN  
TRAFFICKING**  
Get information about human  
trafficking, resources for  
victims, and reporting of a  
suspicion of trafficking.



# Starting Point

- No major updates to the inspection process in more than 10 years
- Board appointed an ad hoc Inspection Committee to review the inspection process and make recommendations to the full board
- Inspection Committee included
  - 2 Board Members
  - 2 Board Staff Members (executive director and operations manager)
  - 1 Veterinary Establishment Inspector
- Public business meetings held

# Prior Inspection Process

- Facility types
  - Full Service
  - Restricted (ambulatory, large and small animal practices)
- Routine inspections every three years
- Unannounced inspections completed to determine compliance with applicable laws and regulations
- Inspection summary completed
  - Copy left with veterinary establishment
  - Copy sent to the board office
- Response sent to the board office
- Action taken by Board if warranted

# Paper Inspection Form

The image shows a handwritten paper inspection form. The form is divided into several sections, each with a list of items to be inspected. The items are marked with checkboxes, and some have handwritten notes or initials next to them. The form is filled out with handwritten text, including names like 'ANTICH' and 'HOUSE FOR EMERGENCY', and various notes and initials.

Section	Item	Checked	Notes
GENERAL INFORMATION	1. Name of the facility	<input checked="" type="checkbox"/>	
	2. Address	<input checked="" type="checkbox"/>	
	3. Telephone	<input checked="" type="checkbox"/>	
	4. Fax	<input checked="" type="checkbox"/>	
FACILITY INFORMATION	5. Type of facility	<input checked="" type="checkbox"/>	
	6. Size of facility	<input checked="" type="checkbox"/>	
	7. Number of animals	<input checked="" type="checkbox"/>	
	8. Other information	<input checked="" type="checkbox"/>	
FACILITY DESIGN AND CONSTRUCTION	9. Construction	<input checked="" type="checkbox"/>	
	10. Ventilation	<input checked="" type="checkbox"/>	
	11. Lighting	<input checked="" type="checkbox"/>	
	12. Heating	<input checked="" type="checkbox"/>	
FACILITY EQUIPMENT	13. Water	<input checked="" type="checkbox"/>	
	14. Food	<input checked="" type="checkbox"/>	
	15. Bedding	<input checked="" type="checkbox"/>	
	16. Other	<input checked="" type="checkbox"/>	
FACILITY MANAGEMENT	17. Personnel	<input checked="" type="checkbox"/>	
	18. Records	<input checked="" type="checkbox"/>	
	19. Procedures	<input checked="" type="checkbox"/>	
	20. Other	<input checked="" type="checkbox"/>	
FACILITY SAFETY	21. Fire	<input checked="" type="checkbox"/>	
	22. Security	<input checked="" type="checkbox"/>	
	23. Hazardous materials	<input checked="" type="checkbox"/>	
	24. Other	<input checked="" type="checkbox"/>	
FACILITY COMPLIANCE	25. State	<input checked="" type="checkbox"/>	
	26. Federal	<input checked="" type="checkbox"/>	
	27. International	<input checked="" type="checkbox"/>	
	28. Other	<input checked="" type="checkbox"/>	

The previous form lacked specificity with regards to the laws, regulations and guidance information on inspection items.

# Overview: Inspection Review Process

- Committee tasked with reviewing the forms and the inspection process.
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  - Format paper copy
  - Designate regulations as major or minor violations
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  - Format electronic copy
  - Launch pilot program
  - Implement final program details
  - Update regulations

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## Identified laws and regulations to include in an inspection

- Performed a comprehensive review of the current laws and regulations
- Determined which laws or regulations needed to be on the form
- Categorized the inspection items
  - Licenses and Permits
  - Veterinarian-in-Charge (VIC)
  - Requirements for drug storage, dispensing, destruction, and records for all establishments, full service and restricted.
  - Bulk Reconstitution of Injectable, Bulk Compounding or Prepackaging
  - Patient/Medical Recordkeeping
  - Standards for Veterinary Establishments (building, lab, surgery, radiology)

# Review Step 2

## Formatted paper copy

- Started with formatting a hard copy
- Cited statutory or regulatory language
- Included the beginnings of guidance information

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## Designated regulations as major or minor violations

- Patterned after Board of Pharmacy
- Evaluated each regulation
- Assigned “major” designation if violation likely to cause harm
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- Started using new form in December of 2011

# Review Step 4

## **Developed the point system for use in board actions**

- Utilized Sanctioning Reference Points concept
- Assigned 2 to 5 points for “major” designations
- Assigned 1 point for “minor” designations
- Assigned double points for repeat violations
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# Review Step 5

## Formatted electronic copy

- Added point system information
- Added guidance information
- Finalized the details of the E-Mobile inspection summary

# New Form

Guidance document: 76-21.2:1

Commonwealth of Virginia - Department of Health Professions  
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Revised: October 28, 2013

## VETERINARY ESTABLISHMENT INSPECTION REPORT

		Date	Time	Inspection Hours
Name of Facility		Permit No <input type="checkbox"/> PENDING	Expiration Date	
Street Address		City	State VIRGINIA	ZIP
Hours of Operation		Phone No	Fax No	
Veterinarian-in-Charge		License No	Expiration Date	
Other Staff				
Type of Practice	Type of Inspection <input type="checkbox"/> New <input type="checkbox"/> Routine <input type="checkbox"/> Reinspection <input type="checkbox"/> Other (Describe)			

C = Compliant  
 NC = Not Compliant  
 NA = Not Applicable or Not reviewed

C/ NC/ NA	#	Major/ Minor/ Points	Law/Regulation	Description
<b>Licenses and Permits</b>				
	1	Minor 1 point	18VAC150-20-30(A)	All licenses and permits issued by the board shall be posted in a place conspicuous to the public or available at the establishment where veterinary services are being provided. Licensees who do relief work in an establishment shall carry a license with them or post at the establishment. Ambulatory veterinary practices or equine dental technicians that do not have an office accessible to the public shall carry their licenses and permits in their vehicles.  <u>Guidance</u> A license or permit is considered to be in a "place conspicuous to the public" when it is hung in an area that is easily accessed and read by the public. The original license or permit (not a photocopy) should be posted or available for inspection. Duplicate copies of a license can be obtained through the Board of Veterinary Medicine's office for a small fee. Any license or permit that is expired will be reported and documentation of practicing without a valid license or permit will be obtained.
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[www.dhp.virginia.gov](http://www.dhp.virginia.gov)

	12	Major 2 points	18VAC150-20-190(E)	Schedule II, III, IV and V are destroyed properly.  <u>Guidance</u> Inspectors will verify that Schedule II, III, IV and V drugs are properly destroyed in accordance with DEA requirements available at <a href="http://www.deadiversion.usdoj.gov/drug_disposal/index.html">http://www.deadiversion.usdoj.gov/drug_disposal/index.html</a>  <b>Disposal of Controlled Substances</b> A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III-V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years. It is recommended that Schedule VI drugs be destroyed in the same manner as Schedule III-V drugs. Expired drugs may be considered adulterated drugs, may not be transferred or donated and must be destroyed as required by federal and state laws and regulations.
	13	Major 5 points 4 points 3 points 2 points See guidance	18VAC150-20-190(F)	Drug storage area has appropriate refrigeration with interior thermometer maintained between 36°F and 46°F. Drugs stored at room temperature are maintained between 59°F and 86°F. Drugs are removed from working stock upon expiration.  <u>Guidance</u> The expiration date on all drugs, including prepackaged stock, should be regularly checked and drugs that are expired must be separated from working stock. A drug expires on the month, day and year listed on the container. If only a month and year are provided, drug expires on the last day of the month listed on container.  Points assigned: 5 points for more than 5 expired drugs; or 4 points for 1-5 drugs expired 60 days or more; or 3 points for 1-5 drugs expired less than 60 days; and 2 additional points for out-of-range temperatures.
	14	Major 5 points 3 points See guidance	§ 54.1-3404 18VAC150-20-190(G)	A distribution record shall be maintained in addition to the patient's record, in chronological order, for the administering and dispensing of Schedule II, III, IV and V drugs. Distribution records are to be maintained for a period of two years from the date of transaction. The distribution record shall include the following: <ol style="list-style-type: none"> <li>Date of transaction.</li> <li>Drug name, strength, and the amount dispensed, administered and wasted.</li> <li>Client and animal identification; and</li> <li>Identification of the veterinarian authorizing the administration or dispensing of the drug.</li> </ol> <u>Guidance</u> The veterinarian's initials are acceptable to meet the requirement of "identification of the veterinarian." The Board recommends that a veterinary establishment maintain a signature list of all employees in the veterinary establishment. The list should contain the individual's printed name, signature and initials.  When a veterinarian with a mobile or house call practice occasionally uses the surgery facilities of a full service veterinary hospital, the drug distribution log(s) must clearly reveal whose controlled substances were used for what purpose. If the facility's stock is used, the hospital log must show that the surgery was performed by a visiting veterinarian who has the patient record and a record of administration shall be maintained at the facility. If the visiting veterinarian uses his own stock of drugs, he must make entries in his own log and patient records and shall leave a copy of the record at the full-service facility.  Points assigned: 5 points for no record; or 3 points for incomplete record or records not maintained in chronological order.

# Review Step 6

## Launched pilot program

- Developed guidance document
- Presented at the 2013 Virginia Veterinary Medical Association's annual meeting
- Evaluated data to validate the point ranges

# Letter of Support from VVMA

## VIRGINIA VETERINARY MEDICAL ASSOCIATION

3801 Westerre Parkway, Suite D • Henrico, Virginia 23233  
(804) 346-2611 • (800)YES-VVMA • Fax: (804) 346-2655  
e-mail: vavvma@aol.com • www.vvma.org

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*President*  
Mark Finkler, DVM  
*President-Elect*  
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*State Veterinarian*

### EXECUTIVE DIRECTOR

Robin R. Schmitz



October 16, 2012

Ms. Leslie L. Knachel, Director  
Virginia Board of Veterinary Medicine  
Virginia Department of Health Professions  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Henrico, Virginia 23233-1463

RE: Inspection Scoring System

Dear Ms. Knachel,

The Virginia Veterinary Medical Association (VVMA) offers the following comments to the Board of Veterinary Medicine on the above-referenced revision to facility inspections.

The VVMA shared information with our members on this issue, and we received no negative comments on the proposed scoring system for facility inspections. We appreciate the hard work and many hours you and the Inspection Committee have dedicated to improving the inspection process. We anticipate that the new scoring system will bring clarity and consistency to facility inspections, and we look forward to working with you and the Board as implementation begins. While we may have additional, more specific comments at a later date post implementation, we support the scoring system as developed by the Inspection Committee going forward at this time.

Thank you for this opportunity to comment.

Sincerely,

Donald G. Henry, DVM  
President, Virginia Veterinary Medical Association



# Guidance Document

Guidance document: 150-15

Adopted: October 17, 2012

## VIRGINIA BOARD OF VETERINARY MEDICINE

### Disposition of Routine Inspection Violations During Pilot Program

The Board of Veterinary Medicine (Board) is conducting a pilot program from January 1, 2013 to December 31, 2013, relating to the disposition of violation(s) found during a routine inspection. The guidance document, [76-21.2-1 Veterinary Establishment Inspection Report](#) provides the laws and regulations to which veterinary establishments must comply. The purpose of the pilot program is to provide a year-long time period for the licensees of the Board to become familiar with the changes to the routine inspection process and to collect data to evaluate the point ranges and the corresponding possible action.

The following information applies to routine inspections conducted between January 1, 2013 and December 31, 2013:

- The possible actions listed below will not be implemented until January 1, 2014.
  - All routine inspections conducted during the pilot program may be subject to disciplinary action to be determined by the current disciplinary process as described on the website at [http://www.dhp.virginia.gov/Enforcement/enf\\_DisciplineProcess.htm](http://www.dhp.virginia.gov/Enforcement/enf_DisciplineProcess.htm).
  - All veterinarians-in-charge may be subject to disciplinary action to be determined by the current disciplinary process as described on the website at [http://www.dhp.virginia.gov/Enforcement/enf\\_DisciplineProcess.htm](http://www.dhp.virginia.gov/Enforcement/enf_DisciplineProcess.htm).
  - Each veterinary establishment that undergoes an inspection will be provided with a point total for reference purposes.
- Feedback on the pilot program may be sent to the Board at [vetbd@dhp.virginia.gov](mailto:vetbd@dhp.virginia.gov).

#### Veterinary Establishment Proposed Effective Date of January 14, 2014

Total Points*	Possible Action
0 – 10 points	Routine inspection in five years
11 – 15 points	Confidential Consent Order; routine inspection in five years
16 – 20 points	Pre-hearing consent order issued by inspector; monetary penalty of \$250; unannounced inspection in two years
21 or more points	Pre-hearing consent order issued by inspector; monetary penalty of \$500; unannounced inspection in one year

#### Veterinarian-In-Charge Proposed Effective Date of January 14, 2014

Inspection Points	Possible Action
11 – 15 points	Confidential Consent Agreement
16 points or more	Pre-hearing consent order; monetary penalty of \$250

\* Point values are available on the guidance document, [76-21.2-1 Veterinary Establishment Inspection Report](#). Please note that violations cited during last and current inspections are repeat violations and receive double the assigned point value.

The pilot program was introduced to the veterinary community through a guidance document adopted by the Board. The guidance document included information on the inspection program as well as board actions for non-compliance.

# Review Step 7

## Implemented final program details

- Revised guidance document
- Trained inspectors on quantifying/qualifying violations
- Developed evidence collection process
- Identified process for amending inspection report
- Determined process for identifying repeat violations
- Developed follow-up evaluation process

# Review Step 8

## Updated regulations

- Identified current veterinary facility business models
- Identified regulations that needed to be updated

# Current Inspection Program

- Three year inspection cycle
- Four inspectors
  - 1090 facilities
  - Approximated 7 to 8 inspections/inspector/month
  - Average of 4.2 hours to conduct an inspection
- New form well received
- E-Mobile working well
- Board action based on point system
- Regulatory update ongoing

# Summary

- Steady and slow got the job done
- Objective method for determining board actions protects the Board, veterinary community and the public
- Follow-up evaluation process is key to ensuring program integrity

# Questions and Answers



# CVM/FDA Activities regarding use of medically important antibiotics in food-animals.

Mike Murphy DVM, JD, PhD  
Veterinary Medical Officer  
Office of the Director  
Center for Veterinary Medicine



## Overview

Status of Regulatory & Policy Progress

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## Overview

# Status of Regulatory & Policy Progress

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CVM: Antibiotic Use in Food Animals.



# Status of Regulatory & Policy Progress

## Guidance Rule



## Policy Aspects of VFDs **Guidance**

(See Reference slides for full title and url links to GFI full text.)

### Guidance for Industry (GFI) #

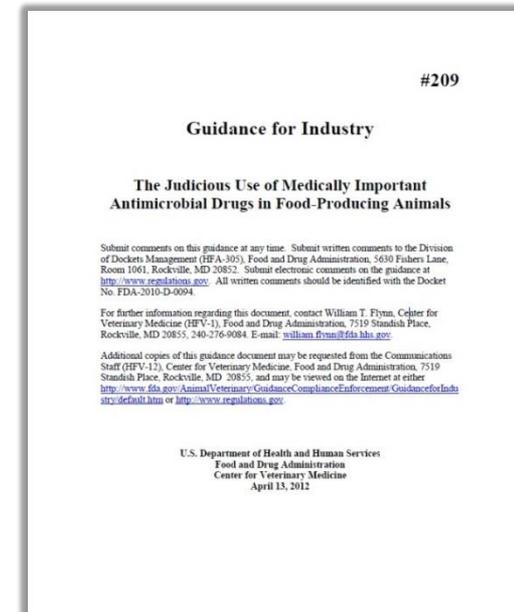
209

213

152

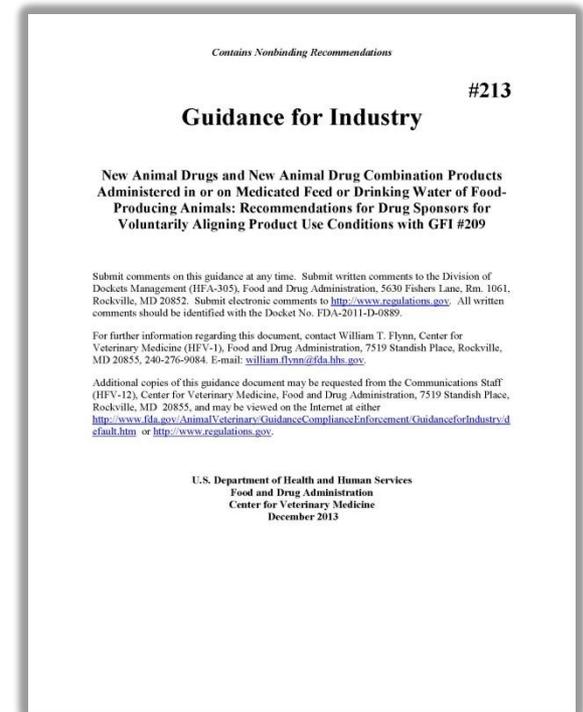
# Judicious Use of Antimicrobials

- Guidance #209 – “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”
  - Published as draft in June 2010
  - Finalized April 2012
  - Describes overall policy direction
- Two key principles outlined in Guidance #209:
  1. Limit use of medically important antimicrobial drugs to those uses considered necessary for ensuring animal health (i.e., therapeutic purposes)
  2. Limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation.



# Guidance #213: Overview

- Finalized December 2013
- Provides more detailed guidance on implementation of key principles in Guidance #209
  - Definition of medically important
  - Process for updating product labels
  - Data required to obtain approval of any new (therapeutic) uses
- December 2016 - Target for drug sponsors to implement changes to use conditions of affected products to:
  - Withdraw approved production uses
  - Require veterinary oversight



# Guidance #213: Affected Drugs

- Medically important antimicrobials
  - All antimicrobial drugs and their associated classes that are listed in Appendix A of GFI #152
  - Drugs not currently classified as medically important according to Appendix A of GFI #152 are not affected
    - Examples: bacitracin, ionophores
- Administered in feed or water
- Available over-the-counter (OTC)



CVM: Antibiotic Use in Food Animals.



## Policy

### Guidance for Industry # 213

#### Implementation timeline

3 months after finalization of Guidance 213

March 2014 - Hear from drug sponsors as to their intentions



## Policy - Guidance for Industry # 213

### Implementation timeline

3 months after finalization of Guidance 213

### Status:

Commitment from all sponsors.

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm378331.htm>



CVM: Antibiotic Use in Food Animals.



## Policy

### Guidance for Industry # 213

#### Implementation timeline

3 years after finalization of Guidance 213

**December 2016** - Target for implementing changes to use conditions of affected products



## Policy - Guidance for Industry # 213

### Implementation timeline

3 years after finalization of Guidance 213

December 2016 - Target for implementing changes to use conditions of affected products

### Status:

**The timetable in Guidance for Industry # 213 expects that production indications will be withdrawn by December of 2016.**



## Overview

Status of Regulatory & Policy Progress

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## Regulatory Rule

### Veterinary Feed Directive (VFD) Rule

(See Reference slides for urls to full text of statute and rule.)

#### Statute:

1996: Animal Drug Availability Act passed by Congress stating that medicated feeds which require veterinary supervision are designated VFDs.

#### Rule:

2001: FDA finalized regulations for distribution and use of VFDs.

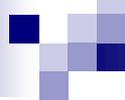
2013: December – Advanced Notice of Proposed Rulemaking proposing changes to VFD Rule.

2015: 3 June 2015 - FDA Finalized VFD Rule  
**1 October 2015 – Effective date of VFD final rule.**

# Updating VFD Process

- Changes intended to make process more efficient
- VFD Final Rule
  - June 2015 – FDA finalized the VFD Rule
  - October 1, 2015 – VFD Final Rule goes into effect
- Draft Guidance #120 – Veterinary Feed Directive Regulation Questions and Answers
  - June 3, 2015 – Draft Guidance Published
  - August 3, 2015 – Comment Period Closes





# VFD Final Rule: Major Provisions

- Revised definitions
- Information required on VFD
- Expiration Dates and Refills
- Transmitting VFD and Recordkeeping
- Veterinary Client Patient Relationship (VCPR)



CVM: Antibiotic Use in Food Animals.



## **Rule & Policy**

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

(See Reference slides for url links to the documents.)

## **Information required on VFD form**

Transmitting VFD

Recordkeeping requirements

VCPR – Veterinary Client Patient Relationship



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

### Information required on VFD form

#### **21 CFR Sec. 558.6(b)**

- (3) The veterinarian must assure that the following information is fully and accurately included on the VFD:**
- (i) The veterinarian's name, address, and telephone number;**
  - (ii) The client's name, business or home address, and telephone number;**



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

### Information required on VFD form

- (3) The veterinarian must assure that the following information is fully and accurately included on the VFD:**
- (iii) The premises at which the animals specified in the VFD are located;
  - (iv) The date of VFD issuance;



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

(3) The veterinarian must assure that the following information is fully and accurately included on the VFD:

(v) The expiration date of the VFD.

This date must not extend beyond the expiration date specified in the approval, ... if such date is specified.

In cases where the expiration date is not specified in the approval, ... the expiration date of the VFD must not exceed 6 months after the date of issuance;



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

- (3) The veterinarian must assure that the following information is fully and accurately included on the VFD:
- (vi) The name of the VFD drug(s);
  - (vii) The species and production class of animals to be fed the VFD feed;



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

- (3) The veterinarian must assure that the following information is fully and accurately included on the VFD:
- (ix) The indication for which the VFD is issued;
  - (x) The level of VFD drug in the VFD feed and duration of use;



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

- (3) The veterinarian must assure that the following information is fully and accurately included on the VFD:
- (xi) The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

- (3) The veterinarian must assure that the following information is fully and accurately included on the VFD:
- (xii) The number of reorders (refills) authorized, if permitted by the drug approval, ... .

In cases where reorders (refills) are not specified on the labeling for an approved, ... VFD drug, reorders (refills) are not permitted.



## CVM: Antibiotic Use in Food Animals.



### Rule

#### Veterinary Feed Directive (VFD) Rule

#### DRAFT Guidance for Industry # 120

#### Information required on VFD form

(3) The veterinarian must assure that the following information is fully and accurately included on the VFD:

(xiii) The statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra-label use) is not permitted.";



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

- (3) The veterinarian must assure that the following information is fully and accurately included on the VFD:
- (xiv) An affirmation of intent for combination VFD drugs as described in paragraph (6) of this section; and
  - (xv) The veterinarian's electronic or written signature.



## CVM: Antibiotic Use in Food Animals.



### Rule

#### Veterinary Feed Directive (VFD) Rule

#### DRAFT Guidance for Industry # 120

#### Information required on VFD form

- (4) The veterinarian may, at his or her discretion, enter the following information on the VFD to more specifically identify the animals authorized to be treated/fed the VFD feed:

location

age

weight range

other ID information



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

(6) The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or may expand such authorization to allow the use of the cited VFD drug(s) along with one or more over-the-counter (OTC) animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

Information required on VFD form

(6)

- (i) "This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs."



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

(6)

- (ii) "This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination medicated feeds that contain the VFD drug(s) as a component." [List specific approved combination medicated feeds following this statement.]



## Rule

### Veterinary Feed Directive (VFD) Rule

### DRAFT Guidance for Industry # 120

### Information required on VFD form

(6)

- (iii) "This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination medicated feed that contain the VFD drug(s) as a component."



CVM: Antibiotic Use in Food Animals.



## **Rule**

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

Information required on VFD form

## **Transmitting VFD**

Recordkeeping requirements

Specificity of order

VCPR – Veterinary Client Patient Relationship



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

# Transmitting VFD

21 CFR 558.3 (b)(7)

A "veterinary feed directive" is a written (nonverbal) statement issued by a licensed veterinarian that orders the use of a VFD drug or combination VFD drug in or on an animal feed. ...



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

# Transmitting VFD

21 CFR 558.3 (b)(7)

...

This statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug or combination VFD drug in or on an animal feed to treat the client's animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the Food and Drug Administration (FDA).



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

# Transmitting VFD

21 CFR 558.3 (b)(7) Comments

Fax: Section 558.6(b) provides more clarity by specifying that a facsimile (fax) also can be used.

Electronic: If the VFD is transmitted electronically, the veterinarian would no longer be required to send the original in hardcopy to the distributor. See 558.6(a)(4).



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

# Transmitting VFD

21 CFR 558.3 (b)(7) Comments

Part 11 does not apply to paper records that are, or have been, transmitted by electronic means (such as facsimile, e-mail attachments, etc.).



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

# Transmitting VFD

21 CFR 558.3 (b)(7) Comments

Written transmittal by phone:

One comment requested that FDA modify the requirement that a veterinarian may not transmit a VFD by phone to state that the veterinarian must not verbally transmit a VFD because technology may allow for a written VFD to be transmitted by a phone.

**FDA finalizes this change in the regulatory text.**



CVM: Antibiotic Use in Food Animals.



## **Rule**

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

Information required on VFD form

Transmitting VFD

# **Recordkeeping requirements**

VCPR – Veterinary Client Patient Relationship



Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

# Recordkeeping requirements

## 21 CFR 558.6

(a) General requirements related to veterinary feed directive (VFD) drugs:

...

(4) All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The copy may be kept as an electronic copy or hardcopy.



CVM: Antibiotic Use in Food Animals.



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

# Recordkeeping requirements

## 21 CFR 558.6

(a) General requirements related to veterinary feed directive (VFD) drugs:

...

(5) All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA.



CVM: Antibiotic Use in Food Animals.



## **Rule**

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

Information required on VFD form

Transmitting VFD

Recordkeeping requirements

**VCPR – Veterinary Client Patient  
Relationship**



## Rule

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

## VCPR – Veterinary Client Patient Relationship

(b) Responsibilities of the veterinarian issuing the VFD:

(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

**(i) be licensed to practice veterinary medicine; and**



## VCPR – Veterinary Client Patient Relationship

### (b) Responsibilities of the veterinarian issuing the VFD:

(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must: ...

**(ii) be operating in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a valid veterinarian-client-patient relationship (VCPR) as defined by the state. ...**



## VCPR – Veterinary Client Patient Relationship

### (b) Responsibilities of the veterinarian issuing the VFD:

(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

**(ii) ... If applicable VCPR requirements are not defined by such state, the veterinarian must issue the VFD in the context of a VCPR as defined in 530.3(i) of this chapter.**



## VCPR – Veterinary Client Patient Relationship

Three key elements:

- (1) Engage with the client to assume responsibility for making clinical judgments about patient health,**
- (2) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and**
- (3) provide for any necessary follow-up evaluation or care.**



CVM: Antibiotic Use in Food Animals.



VCPR – Veterinary Client Patient Relationship

Policy - DRAFT Guidance for Industry # 120

State/Federal VCPR List

**FDA will ask State regulatory  
authorities ... and ... compile a list**



## VFDs: What You Need to Know.



VCPR – Veterinary Client Patient Relationship

Policy - DRAFT Guidance For Industry # 120

**VFD Rule effective 1 October 2015**

State/Federal VCPR List

**This list will be provided online at**

**<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>**

**prior to 1 October 2015.**



CVM: Antibiotic Use in Food Animals.



VCPR – Veterinary Client Patient Relationship

Policy - DRAFT Guidance For Industry # 120

Extra-Label Use

**Can I write a VFD for OTC Drug ?**

No. A practicing veterinarian may not write a VFD order for an OTC drug.

GFI # 120. ...



## Overview

Status of Regulatory & Policy Progress

VFD Rule

**Data Collection**

References

Comments/Questions



## Data Collection

### **Proposed Rule:**

Published: 20 May 2015

Comment period closes: 18 August 2015

<http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm446803.htm>

<http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm446803.htm>



## Data Collection

### **Proposed Rule:**

### **Goal:**

to obtain estimates of sales by major food-producing species (cattle, swine, chickens, and turkeys)



VFDs: What You Need to Know.



## Additional Changes

Distributors

Category II Drugs



## Overview

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**References**

Comments/Questions



VFDs: What You Need to Know.



## Brochures

**Please pick up  
Brochures at CVM's  
Booth # 231**



VFDs: What You Need to Know.



**Please check CVM's  
Veterinary Feed Directive  
Website at**

**<http://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm>**



VFDs: What You Need to Know.



Veterinary Responsibilities  
Veterinary Feed Directive Rule

**Please also check the presentation**

***Regulatory Aspects of Veterinary Feed  
Directives (567)***

In the Public and Corporate Practice: Preventative Medicine  
Monday 13 July 2015 4:00-4:50 pm in Room 205A

**for additional information regarding  
the VFD rule.**



## References

### Regulation:

#### Statute:

Animal Drug Availability Act of 1996 - PL 104-250 (Oct. 9, 1996)

<http://www.gpo.gov/fdsys/pkg/PLAW-104publ250/html/PLAW-104publ250.htm>

#### Regulation:

#### VFD:

2001: Animal Drug Availability Act; Veterinary Feed Directive, Final Rule 65 FR 76924, 8 December 2000

2013: Advanced Notice of proposed rulemaking.

<https://www.federalregister.gov/articles/2013/12/12/2013-29696/veterinary-feed-directive>

<http://www.regulations.gov/#!docketBrowser:rpp=25;po=0;D=FDA-2010-N-0155>

<http://www.fda.gov/aboutfda/reportsmanualsforms/reports/economicanalyses/ucm378113.htm>

2015: Final VFD Rule [80 FR 31708]

<http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf>



## References

Regulation:

Guidance:

- # 120: DRAFT: Veterinary Feed Directive Regulation Questions and Answers  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>
- # 152: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>
- # 209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>
- # 213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>



VFDs: What you need to know.



## References

Use:

Blue Bird Labels:

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm>

[www.fda.gov](http://www.fda.gov)

Lower left, under regulatory information, click Code of Federal regulations. In the Search Database window enter the active ingredient.

Animal Drugs at FDA:

Another way to search: [www.fda.gov](http://www.fda.gov), click, animal & veterinary, upper right “animal drugs” upper right, “Animal Drugs@FDA” enter ingredient, species of interest, etc.



CVM: Antibiotic Use in Food Animals.



## Overview

Status of Regulatory Progress

VFD Rule

Data Collection

References

**Comments/Questions**



# VFDs: What you need to know

Mike Murphy DVM, JD, PhD  
Veterinary Medical Officer  
Office of the Director  
Center for Veterinary Medicine



VFDs What You Need to Know.



## Overview

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Client Education

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Comments/Questions



VFDs: What You Need to Know.



## Overview

# Regulatory Aspects

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VFDs: What You Need to Know.



## Regulatory Aspects of VFDs

# Veterinary Feed Directive Rule

(See Reference slides for a url link to the rule).

Effective date

1 October 2015



## VFDs: What You Need to Know.



### **Rule**

#### Veterinary Feed Directive (VFD) Rule

(See Reference slides for url link.)

#### Statute:

1996: Animal Drug Availability Act passed by Congress stating that medicated feeds which require veterinary supervision are designated VFDs.

#### Rule:

2001: FDA finalized regulations for distribution and use of VFDs.

2013: December – Advanced Notice of Proposed Rulemaking proposing changes to VFD Rule.

2015: 3 June 2015 - Final VFD Rule

**1 October 2015 – Date final rule goes into effect.**

# Updating VFD Process

- Changes intended to make process more efficient
- VFD Final Rule
  - June 2015 – FDA finalized the VFD Rule
  - October 1, 2015 – VFD Final Rule goes into effect
- Draft Guidance #120 – Veterinary Feed Directive Regulation Questions and Answers
  - June 3, 2015 – Draft Guidance Published
  - August 3, 2015 – Comment Period Closes





VFDs: What You Need to Know.



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Regulatory & Policy Aspects  
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References  
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VFDs: What You Need to Know.



## **Veterinary Responsibilities**

Some sources of information

Current VFD approved applications

DVM Responsibilities



VFDs: What You Need to Know.



## **Veterinary Responsibilities**

### Some sources of information

Current VFD approved applications

DVM Responsibilities



VFDs: What You Need to Know.



Veterinary Responsibilities  
Veterinary Feed Directive Rule  
Some sources of information

**Please pick up  
Brochures at CVM's  
Booth # 231**



VFDs: What You Need to Know.



Veterinary Responsibilities  
Veterinary Feed Directive Rule  
Some sources of information

Please check CVM's  
**Veterinary Feed Directive Website**  
at

**<http://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm>**



VFDs: What You Need to Know.



# Veterinary Responsibilities

Some sources of information

**Current VFD approved applications**

DVM Responsibilities



VFDs: What You Need to Know.



# VFD Approved Applications

Example

## Tilmicosin



VFDs: What You Need to Know.

VFD Approved Applications

## Tilmicosin

### Swine:

**For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida***

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm081802.htm>



VFDs: What You Need to Know.

VFD Approved Applications

## Tilmicosin

### Cattle:

**Beef and nonlactating dairy cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in groups of beef and nonlactating dairy cattle, where active BRD has been diagnosed in at least 10 percent of the animals in the group.**

**<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm072534.htm>**



VFDs: What You Need to Know.



# VFD Approved Applications

Example

## Florfenicol



VFDs: What You Need to Know.



VFD Approved Applications - example

## Florfenicol

### Swine:

**For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Streptococcus suis*, and *Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD.**

**See 21 CFR Sec. 558.261 (e )(1).**



VFDs: What You Need to Know.



VFD Approved Applications - example

## Florfenicol

### Catfish:

**For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri***

**<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm072521.htm>**



VFDs: What You Need to Know.



VFD Approved Applications - example

## Florfenicol

Freshwater-reared salmonids:

**For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida*.**

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm072521.htm>



VFDs: What You Need to Know.



VFD Approved Applications - example

## Florfenicol

Freshwater-reared finfish:

**For the control of mortality due to columnaris disease associated with *Flavobacterium columnare*.**

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm072521.htm>



VFDs: What You Need to Know.



Overview

VFD Approved Application - example

## Florfenicol

Freshwater-reared warm water finfish:

**For the control of mortality due to streptococcal septicemia associated with *Streptococcus iniae*.**

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm072521.htm>



VFDs: What You Need to Know.

VFD Approved Application - example

## Avilamycin

### Swine:

**For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.**

**<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm081802.htm>**



VFDs: What You Need to Know.



## **Veterinary Responsibilities**

Some sources of information

Current VFD approved applications

**DVM Responsibilities**



VFDs: What You Need to Know.



Veterinary Responsibilities  
Veterinary Feed Directive Rule

**Please also check the presentation**

***FDA CVM: Activities Regarding Antimicrobial  
Resistance and Food-Producing Animals (1171)***

In the Food Safety Symposium

Public and Corporate Practice: Food Safety

Sunday 12 July 2015 4:00-4:50 pm in Room 204A

**for detailed DVM requirements  
under the VFD rule.**



VFDs: What You Need to Know.



Veterinary Responsibilities  
Veterinary Feed Directive Rule

**Changes between  
the currently effective rule  
and the rule effective  
1 October 2015**



VFDs: What You Need to Know.



## Rule

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

Applications:

Definitions:

Veterinary Responsibilities:

VCPR

Distributor Responsibilities:



VFDs: What You Need to Know.



## **Rule**

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

**Applications:**

**Definitions:**

**Veterinary Responsibilities:**

**VCPR**

**Distributor Responsibilities:**



## VFDs: What You Need to Know.



### Rule

Veterinary Feed Directive (VFD) Rule

### Applications: **VDF Format**

21 CFR Sec. 514.1 (b) (9):

**Veterinary feed directive. Three copies of a veterinary feed directive (VFD) must be submitted in a form that accounts for the information described under §§ 558.6(b)(3) and 558.6(b)(4) of this chapter.**



VFDs: What You Need to Know.



## **Rule**

Veterinary Feed Directive (VFD) Rule

**Applications: VDF Format**

**Sec. 558.6(b)(3) – required information.**

**Sec. 558.6(b)(4) – discretionary information.**



VFDs: What You Need to Know.



## **Rule**

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

Applications:

**Definitions:**

Veterinary Responsibilities:

VCPR

Distributor Responsibilities:



## VFDs: What You Need to Know.



### **Rule**

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

### **Definitions:**

#### 21 CFR Sec. 558.3 (b)

(1)(ii) Category II

(6) “veterinary feed directive (VFD) drug”

(7) “veterinary feed directive”

(9) “distributor”

(11) “acknowledgment letter”

(12) “combination veterinary feed directive (VFD) drug”



VFDs: What You Need to Know.



## **Rule**

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

Applications:

Definitions:

**Veterinary Responsibilities:**

**VCPR:**

Distributor Responsibilities:



VFDs: What You Need to Know.



## **Rule**

Veterinary Feed Directive (VFD) Rule

DRAFT Guidance for Industry # 120

**Veterinary Responsibilities:**

VCPR—Veterinary Client Patient Relationship:

**Rule effective now**

**Vs**

**Rule effective 1 October 2015**



## VFDs: What You Need to Know.



### **Rule**

Veterinary Feed Directive (VFD) Rule

**VFD Rule effective now.**

VCPR – Veterinary Client Patient Relationship

21 CFR Sec 558.6

(a) What conditions must I meet if I am a veterinarian issuing a veterinary feed directive (VFD)?

(1) You must be appropriately licensed.



## VFDs: What You Need to Know.



### Rule

Veterinary Feed Directive (VFD) Rule

VFD Rule Effective now.

VCPR – Veterinary Client Patient Relationship

21 CFR Sec 558.6

(a) What conditions must I meet if I am a veterinarian issuing a veterinary feed directive (VFD)? ...

**(2) You must issue a VFD only within the confines of a valid veterinarian-client-patient relationship (see definition at 530.3(i) of this chapter).**



## VFDs: What You Need to Know.



Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

### **VFD Rule effective 1 October 2015.**

VCPR – Veterinary Client Patient Relationship

(b) Responsibilities of the veterinarian issuing the VFD:

**(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:**

**(i) be licensed to practice veterinary medicine; and**



## VFDs: What You Need to Know.



VCPR – Veterinary Client Patient Relationship

### VFD Rule effective 1 October 2015

(b) Responsibilities of the veterinarian issuing the VFD:

(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must: ...

**(ii) be operating in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a valid veterinarian-client-patient relationship (VCPR) as defined by the state. ...**



## VFDs: What You Need to Know.



VCPR – Veterinary Client Patient Relationship

### VFD Rule effective 1 October 2015

(b) Responsibilities of the veterinarian issuing the VFD:

(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

**(ii) ... If applicable VCPR requirements are not defined by such state, the veterinarian must issue the VFD in the context of a VCPR as defined in 530.3(i) of this chapter.**



## VCPR – Veterinary Client Patient Relationship

Three key elements:

- (1) Engage with the client to assume responsibility for making clinical judgments about patient health,**
- (2) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and**
- (3) provide for any necessary follow-up evaluation or care.**



VFDs: What You Need to Know.



VCPR – Veterinary Client Patient Relationship

DRAFT Guidance for Industry # 120

**VFD Rule effective 1 October 2015**

State/Federal VCPR List

**FDA will ask State regulatory  
authorities ... and ... compile a list ...**



VFDs: What You Need to Know.



VCPR – Veterinary Client Patient Relationship

DRAFT Guidance For Industry # 120

## **VFD Rule effective 1 October 2015**

State/Federal VCPR List

This list will be provided online at

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>

prior to 1 October 2015.



VFDs: What You Need to Know.



## Rule

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

## Veterinary Responsibilities:

21 CFR Sec. 558.6 (b):

*Responsibilities of the veterinarian issuing the VFD:*

**Please see AVMA Booth # 231 for  
brochures of veterinary responsibilities.**



## VFDs: What You Need to Know.



### VCPR – Veterinary Client Patient Relationship

Policy - DRAFT Guidance For Industry # 120

Extra-Label Use

## **Can I write a VFD for OTC Drug ?**

No. A practicing veterinarian may not write a VFD order for an OTC drug.

GFI # 120. ...



VFDs: What You Need to Know.



## **Rule**

Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

Applications:

Definitions:

Veterinary Responsibilities:

VCPR:

**Distributor Responsibilities:**



VFDs: What You Need to Know.



Veterinary Feed Directive (VFD) Rule  
DRAFT Guidance for Industry # 120

## **Distributor Responsibilities:**

21 CFR Sec. 558.6 (c ):

*Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug:*

**Please see AVMA Booth # 231 for brochures of distributor responsibilities.**



VFDs What You Need to Know.



## Overview

Regulatory Aspects

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VFD: What you need to know.



## Client Education

# **VFD Rule Statements OTC to VFD changes**



VFD: What you need to know.



## Client Education

# VFD Rule Statements

OTC to VFD changes



VFD: What you need to know.



## Client Education

### VFD Rule Statements

21 CFR Sec. 558.6 (a) (6):

**... "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."**



VFD: What you need to know.



## Client Education VFD Rule Statements

### 21 CFR Sec. 558.6 (b)(3)(xiii):

**... “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.”**



VFD: What you need to know.



# Client Education

## Policy

Transition from

OTC to VFD or Rx

for

**Medically Important Antibiotics**

**intended for use in food animals**

**expected to be completed in**

**December of 2016**



VFD: What you need to know.



## Policy

**OTC to VFD or Rx**

## **Guidance Documents**

**(See reference slides for url links to documents.)**



VFDs: What You Need to Know.



# Regulatory Aspects of VFDs

## Policy

## Guidance

(See Reference slides for titles of guidance documents.)

### Guidance for Industry #

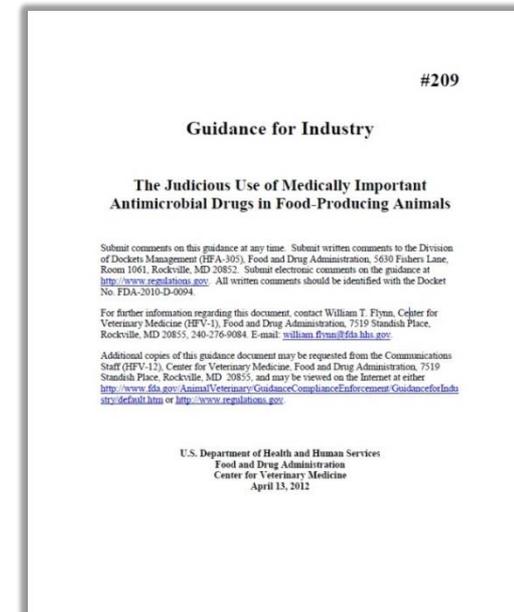
209

213

152

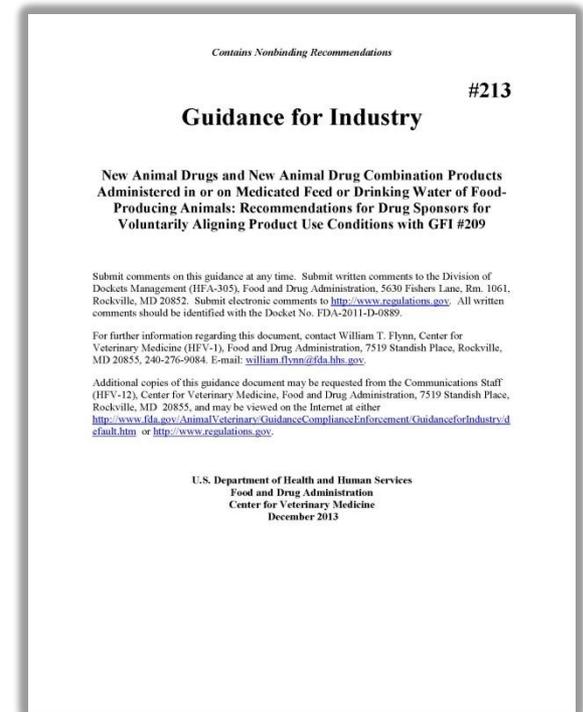
# Judicious Use of Antimicrobials

- Guidance #209 – “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”
  - Published as draft in June 2010
  - Finalized April 2012
  - Describes overall policy direction
- Two key principles outlined in Guidance #209:
  1. Limit use of medically important antimicrobial drugs to those uses considered necessary for ensuring animal health (i.e., therapeutic purposes)
  2. Limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation.



# Guidance #213: Overview

- Finalized December 2013
- Provides more detailed guidance on implementation of key principles in Guidance #209
  - Definition of medically important
  - Process for updating product labels
  - Data required to obtain approval of any new (therapeutic) uses
- December 2016 - Target for drug sponsors to implement changes to use conditions of affected products to:
  - Withdraw approved production uses
  - Require veterinary oversight



# Guidance #213: Affected Drugs

- Medically important antimicrobials
  - All antimicrobial drugs and their associated classes that are listed in Appendix A of GFI #152
  - Drugs not currently classified as medically important according to Appendix A of GFI #152 are not affected
    - Examples: bacitracin, ionophores
- Administered in feed or water
- Available over-the-counter (OTC)



## VFDs: What You Need to Know.



### Policy - Guidance for Industry # 213

#### Implementation timeline

3 months after finalization of Guidance 213

March 2014 - Hear from drug sponsors as to their intentions

**Note: All sponsors have voluntarily agreed.**

3 years after finalization of Guidance 213

**December 2016 - Target for implementing changes to use conditions of affected products**



VFDs: What you need to know.



Policy

Route

**Feed**

**OTC to VFD**

**Drinking or Medicated water**

**OTC to Rx**



VFDs: What you need to know.



# Client Education

**An example of Affected Applications**

**For production versus therapeutic uses**



VFDs: What you need to know.



Client Education  
**Affected applications**  
**Feed – some examples**

**Chlortetracycline**



## **Production use – An example**

**Chlortetracycline:**

**(i) 10 to 50 g/ton**

**Growing turkeys: For increased rate of weight gain and improved feed efficiency.**



## Therapeutic use – An example

Chlortetracycline:

(ii) 200 g/ton

**Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.**



VFDs: what you need to know.

Client Education

Feed – examples

Production and Therapeutic Uses

## Turkeys

### Disease

**Bluecomb:**

**Coccidiosis:**

**CRD:**

**Fowl cholera:**

**Hexamitiasis**

**Infectious synovitis**

**Paratyphoid:**

**See Blue Bird Labels**

**[http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/Medications/BlueBirdLabels/ucm081798.htm#Growing\\_Turkeys](http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/Medications/BlueBirdLabels/ucm081798.htm#Growing_Turkeys)**



VFDs: What you need to know.

Client Education –  
Feed – examples  
Production and Therapeutic Uses

## **Chickens**

### **Disease**

**Air sacculitis**

**Coccidiosis**

**CRD**

**E coli**

**Fowl cholera**

**Infectious coryza**

**Infectious synovitis**

**Necrotic enteritis**

**See**

**Blue Bird Labels**

**<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm081798.htm>**



VFDs: What you need to know.

Client Education –

Feed – examples

Production and Therapeutic Uses

## Swine

### Disease

**Bacterial enteritis**

**Bacterial pneumonia**

**Cervical lymphadenitis**

**Leptospirosis**

**Mycoplasma pneumonia**

**PPE**

**Swine dysentery**

**See:**

**Blue Bird Labels**

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/ucm081802.htm>



VFDs: What you need to know.

Client Education –

Feed – examples

Production and Therapeutic Uses

## Cattle

### Disease

**Anaplasmosis**

**Bacterial enteritis**

**Bacterial pneumonia**

**Liver abscess**

**Shipping fever**

**See Blue Bird labels:**

**<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/Medications/BlueBirdLabels/ucm072534.htm>**



VFDs What You Need to Know.



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## References

### Regulation:

#### Statute:

Animal Drug Availability Act of 1996 - PL 104-250 (Oct. 9, 1996)

<http://www.gpo.gov/fdsys/pkg/PLAW-104publ250/html/PLAW-104publ250.htm>

#### Regulation:

#### VFD:

2001: Animal Drug Availability Act; Veterinary Feed Directive, Final Rule 65 FR 76924, 8 December 2000

2013: Advanced Notice of proposed rulemaking.

<https://www.federalregister.gov/articles/2013/12/12/2013-29696/veterinary-feed-directive>

<http://www.regulations.gov/#!docketBrowser:rpp=25;po=0;D=FDA-2010-N-0155>

<http://www.fda.gov/aboutfda/reportsmanualsforms/reports/economicanalyses/ucm378113.htm>

2015: Final VFD Rule [80 FR 31708]

<http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf>



## References

Regulation:

Guidance:

# 120: DRAFT: Veterinary Feed Directive Regulation Questions and Answers  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>

# 152: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>

# 209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>

# 213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>



VFDs: What you need to know.



## References

Use:

Blue Bird Labels:

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm>

[www.fda.gov](http://www.fda.gov)

Lower left, under regulatory information, click Code of Federal regulations. In the Search Database window enter the active ingredient.

Animal Drugs at FDA:

Another way to search: [www.fda.gov](http://www.fda.gov), click, animal & veterinary, upper right “animal drugs” upper right, “Animal Drugs@FDA” enter ingredient, species of interest, etc.



VFDs What You Need to Know.



## Overview

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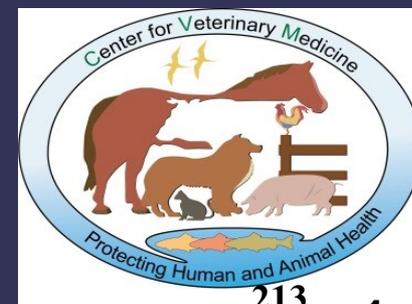
References

**Comments/Questions**

# Medically Important Antibiotics in Animal Agriculture

Mike Murphy DVM, JD, PhD  
Office of the Director  
Center for Veterinary Medicine

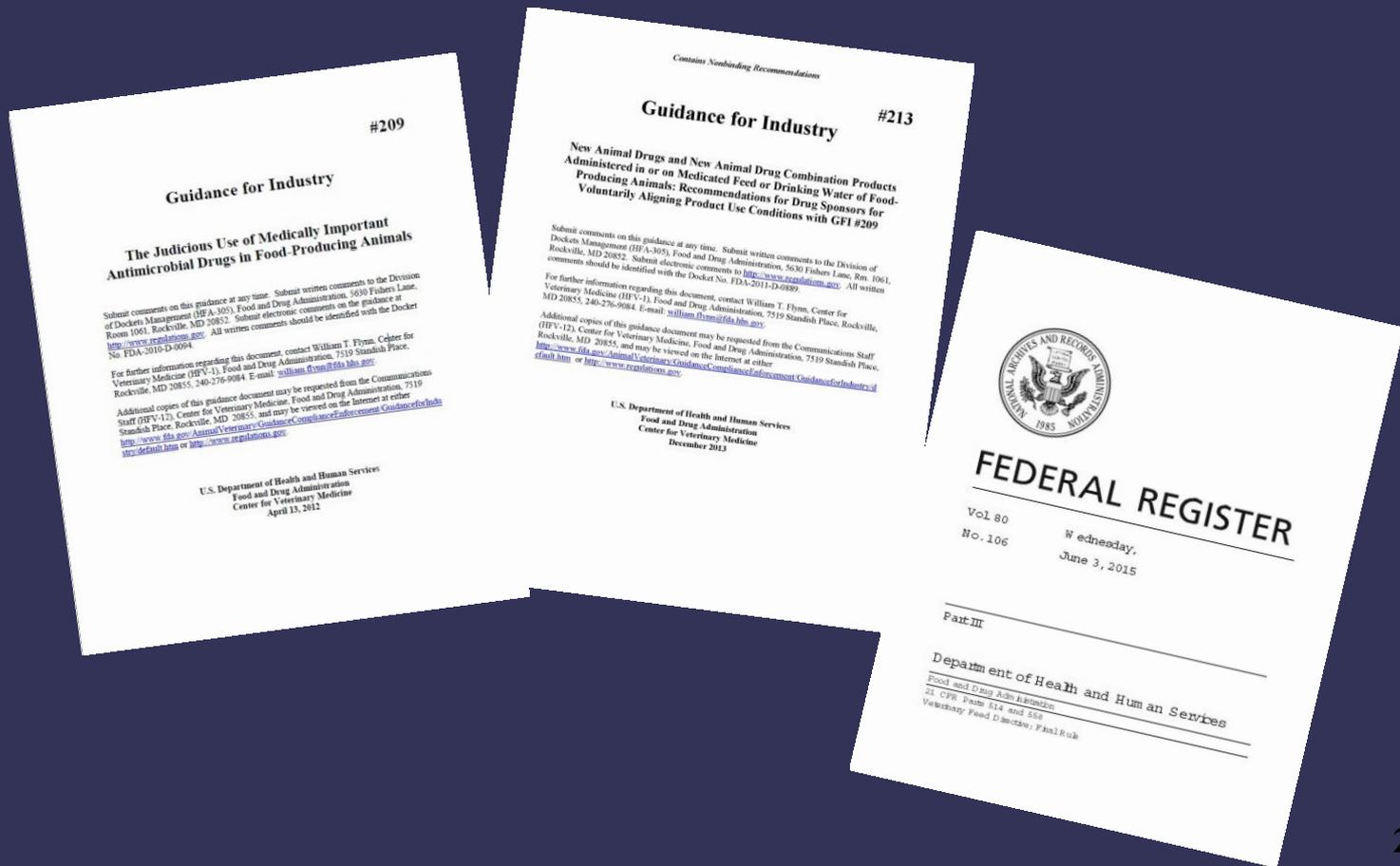
Farm Foundation  
Antimicrobial Stewardship Workshop  
Amarillo, TX  
September 11, 2015



# Outline – Questions to Be Addressed

- What changes are being made and why?
- What drugs are affected, which ones are not?
- What is a veterinary feed directive?
- What are key elements of VFD regulation?
- When will this go into effect?

# What changes are being made and why?



# Antimicrobial Resistance – In Perspective

- Complex, multi-factorial issue
  - Acquired vs. naturally occurring
- Use as a driver of resistance
  - All uses (human, animal, horticultural, other) are part of the picture

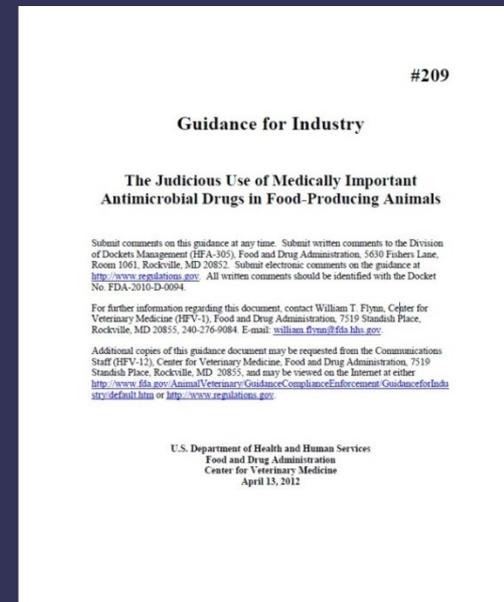


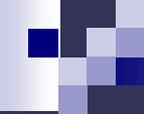
# Antibiotic Use in Animal Agriculture

- Subject of scientific and policy debate for decades
- The science continues to evolve
- Despite complexities and uncertainties steps can be identified to mitigate risk
- Intent is to implement measures that address public health concern while assuring animal health needs are met

# Guidance #209: Outlined AMR policy

- Describes overall policy direction





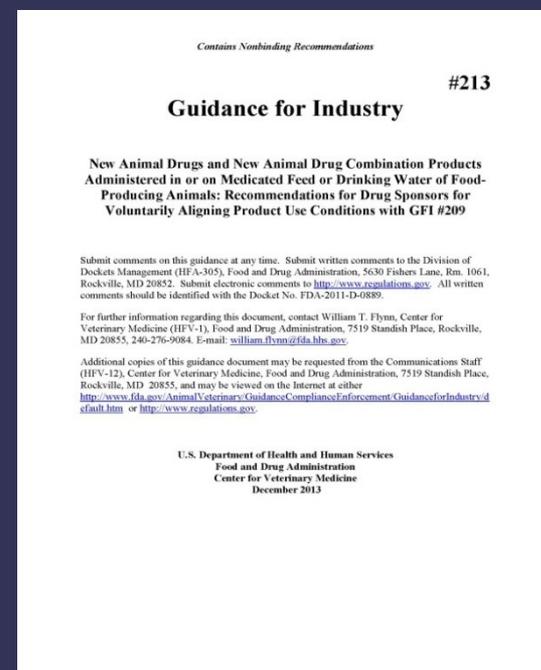
# FDA's Judicious Use Strategy

Two key principles outlined in Guidance #209:

1. Limit medically important antimicrobial drugs to therapeutic purposes (i.e., those uses considered necessary for ensuring animal health)
2. Require veterinary oversight or consultation for such therapeutic uses in food-producing animals

# Guidance #213: Implementation

- Finalized December 2013
- More detailed guidance on implementing key principles in Guidance #209
  - Timeline
  - Defines medically important



# Guidance #213: Overview

- December 2016 - Target for drug sponsors to implement changes to use conditions of medically important antibiotics in food and water to:
  - Withdraw approved production uses
    - such as “increased rate of weight gain” or “improved feed efficiency”
  - Such production uses will no longer be legal

# Guidance #213: Removing Production Uses

- However, therapeutic uses are to be retained
  - treatment, control, and prevention indications
- Require veterinary oversight

# Guidance #213: Veterinary Oversight

- Key principle is to include veterinarian in decision-making process
  - Does not require direct veterinarian involvement in drug administration
  - Does require use be authorized by licensed veterinarian
- This means changing marketing status from OTC to Rx or VFD
  - Water soluble products to Rx – “medicated water”
  - Products used in or on feed to VFD – “medicated feed”

# What drugs are affected, which ones are not?



## Guidance #213: Scope

- Only affects antibiotics that are:
  - “Medically important”
  - Administered in feed or drinking water
    - Other dosage forms (e.g., injectable, bolus) not affected

# “Medically Important” antibiotics

- Includes antimicrobial drugs that are considered important for therapeutic use in humans
- Guidance #213 defines “medically important” to include:
  - All antimicrobial drugs/drug classes that are listed in Appendix A of FDA’s Guidance #152

# Affected feed-use antibiotics

Antimicrobial Class	Specific drugs approved for use in feed
Aminoglycosides	Apramycin, Hygromycin B, Neomycin, Streptomycin
Diaminopyrimidines	Ormetoprim
Lincosamides	Lincomycin
Macrolides	Erythromycin, Oleandomycin, Tylosin
Penicillins	Penicillin
Streptogramins	Virginiamycin
Sulfas	Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline
Tetracycline	Chlortetracycline, Oxytetracycline

# Affected water-use antibiotics

Antimicrobial Class	Specific drugs approved for use in water
Aminoglycosides	Apramycin, Gentamicin, Neomycin, Spectinomycin, Streptomycin
Lincosamides	Lincomycin
Macrolides	Carbomycin, Erythromycin, <u>Tylosin</u>
Penicillins	Penicillin
Sulfas	Sulfachloropyrazine, Sulfachlorpyridazine, Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline
Tetracycline	Chlortetracycline, Oxytetracycline, Tetracycline

# Drugs not affected by Guidance #213

## ■ Antibiotics

- that are already VFD – avilamycin, florfenicol, tilmicosin; or Rx - Tylosin.
- that are not medically important for example:
  - Ionophores (monensin, lasalocid, etc. )
  - Bacitracin (BMD, bacitracin zinc)
  - Bambermycins

## ■ Other drugs (that are not antibiotics), including:

- Anthelmintics: Coumaphos, Fenbendazole, Ivermectin
- Beta agonists: Ractopamine, Zilpaterol
- Coccidiostats: Clopidol, Decoquinatate, Diclazuril

# What is a veterinary feed directive?



# VFD Definitions

- **VFD drug**
- **Veterinary Feed Directive (VFD) -**

# VFD Definitions

- **VFD drug** –
- (6) A “veterinary feed directive (VFD) drug” is a drug intended for use in or on animal feed which is limited by a [CVM] approved application ... to use under the professional supervision of a licensed veterinarian. ...

# VFD Definitions

- **VFD drug - ...**
- Use of animal feed bearing or containing a VFD drug must be authorized by a lawful veterinary feed directive.

# VFD Definitions

- **Veterinary Feed Directive (VFD) –**
- (7) A “veterinary feed directive” is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed. ...

# VFD Definitions

- **Veterinary Feed Directive (VFD) – ...**
- This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client's animals only in accordance with the conditions for use approved ... by the Food and Drug Administration.

# Veterinary Feed Directive

- Existing framework for veterinary oversight of feed use drugs is the *veterinary feed directive* (VFD)
- In 1996 Congress passed Federal Law stating that medicated feeds which require veterinary oversight are VFDs
- In 2000 FDA finalized regulations for authorization, distribution and use of VFDs
- Although a similar concept, (... *by or on the order of a licensed veterinarian*) VFDs are not Rx

# Updates to VFD regulation

- Changes intended to make process more efficient while continuing to provide public health protections
- VFD Final Rule
  - June 3, 2015 – VFD final rule published
  - October 1, 2015 – VFD final rule becomes effective

# Current VFD Drugs

Currently Approved VFD Drugs	Approved for Use in the Following Species
Avilamycin	Swine – reduction of diarrhea – E. coli.
Florfenicol	Fish – control of mortality (various diseases by fish type) Swine – control of SRD
Tilmicosin	Cattle – control of BRD Swine – control of SRD

**Note:** Only the drugs that are currently approved as VFD drugs (above) will be affected by the VFD final regulation when it goes into effect on October 1, 2015.

# Examples of medicated feed-use antibiotics that are expected to transition to VFD status

Antimicrobial Class	Specific drugs approved for use in feed
Aminoglycosides	Apramycin, <i>Neomycin</i> , Streptomycin
Diaminopyrimidines	Ormetoprim
Hygromycin B	Hygromycin B
Lincosamides	<i>Lincomycin</i>
Macrolides	Erythromycin, <u>Oleandomycin</u> , <i>Tylosin</i>
Penicillins	<u>Penicillin - Currently only production uses.</u>
Streptogramins	<i>Virginiamycin</i>
Sulfas	Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline
Tetracycline	<i>Chlortetracycline</i> , <i>Oxytetracycline</i>

# What are key elements of VFD regulation?



# Information Required on VFD Form

- Regulation lists all information that must be included on VFD in order for it to be lawful
- Veterinarian is responsible for making sure the form is complete and accurate
- See brochures for listing of required information

# VFD Final Rule: Distributors

- A “distributor” means any person who distributes a medicated feed containing a VFD drug to another person.
  - Such other person may be another distributor or the client-recipient of the VFD medicated feed.

There are two kinds of distributors:

1. Only distributes VFD feed
2. Manufactures and distributes VFD Feed

- Distributors must notify FDA:
  - Prior to the first time they distribute animal feed containing a VFD drug
  - Within 30 days of any change of ownership, business name, or business address

# VFD Final Rule: Drug Categories

- Feed-use drugs are assigned to one of two categories:
  - **Category I** - drugs having the lowest potential for residues
  - **Category II** - drugs having the highest potential for residues
- Category determines whether a facility needs to be licensed to handle the drug in the Type A form
- Definition of **Category II** has been revised to eliminate the automatic classification of VFD drugs into Category II
- This change applies to the existing approved VFD drug products, in addition to the products that will become VFD under GFI #213

# Expiration Date and Duration of Use

## ■ Expiration Date –

- Specifies the period of time for which the VFD authorization is valid
- A VFD feed should not be fed after the expiration date (i.e., after VFD authorization expires)
- May be specified on the product label; if not – it cannot exceed 6 months after the date of issuance.
- The veterinarian can use his or her medical judgment to determine whether a more limited period is warranted

# Expiration Date and Duration of Use

## ■ The Duration of Use –

- A separate concept from the expiration date
- The length of time that the animal feed containing the VFD drug is allowed to be fed to the animals
- Established as part of the approval, conditional approval, or index listing process
- If the VFD order will expire before completing the duration of use on the order, the client should contact his/her veterinarian to request a new VFD order

# Current VFD Drugs

Currently Approved VFD Drugs	Approved for Use in the Following Species	VFD Expiration Date	Duration of Use
Avilamycin	Swine – reduction of diarrhea – E. coli.	42 d	21 d
Florfenicol	Fish – control of mortality (various diseases by fish type)	15 d	10 d
	Swine – control of SRD	90 d	5 d
Tilmicosin	Swine – control of SRD	90 d	21 d
	Cattle – control of BRD	45 d	14 d

# Medically important antibiotics used in animal feed expected to transition from OTC to VFD marketing status.

- VFD Expiration Date: not to exceed 6 months
- Duration of Use: See CVM Blue Bird Label website
- <http://www.fda.gov/animalveterinary/products/animalfoodfeeds/medicatedfeed/bluebirdlabels/default.htm>

# Refills

- Refills (reorders) – Are only permitted to be issued by veterinarians if the drug approval, conditional approval, or index listing expressly allows a refill (or reorder)
  - If a label is silent on refills, a refill may not be authorized
  - Currently, there are no approved VFD drugs that allow refills or reorders as a condition of their approval, conditional approval, or index listing

# Approximate Number of Animals

- VFD must include an approximate number of animals:
  - The potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed manufactured according to the VFD at the specified premises by the expiration date of the VFD

# Approximate Number of Animals

- VFD will no longer be required to specify the amount of feed to be fed
  - Expectation is that feed mill will work with the client and veterinarian to determine an appropriate amount of feed to manufacture and distribute under the VFD
    - based on the approximate number of animals, duration of use, and expiration date

# Combination VFD drugs

- **“Combination VFD drug”** - (12) A “combination veterinary feed directive (VFD) drug” is a combination new animal drug ... intended for use in or on animal feed which is limited by a [CVM] approved application ... to use under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug.
  - The new VFD rule requires the issuing veterinarian to include one of three **“affirmation of intent”** statements to affirm his or her intent as to whether the VFD drug being authorized can or cannot be used in approved combinations
  - Expect that this will be addressed through inclusion of a check box on the VFD form

# Current VFD Drugs

Currently Approved VFD Drugs	Approved for Use in the Following Species	Combinations/ Affirmation
Avilamycin	Swine – reduction of diarrhea – E. coli.	None/ 1
Florfenicol	Fish – control of mortality (various diseases by fish type)	None/ 1
	Swine – control of SRD	None/ 1
Tilmicosin	Swine – control of SRD	None/ 1

# Current VFD Drugs

<b>Currently Approved VFD Drug</b>	<b>Currently Approved Combination</b>	<b>Approved for Use in the Following Species</b>	<b>Affirmation</b>
Tilmicosin	Tilmicosin only	Cattle – control of BRD	1
	+ Monensin	Cattle – control of BRD + Coccidiosis	2 or 3
	+ Monensin	Cattle – control of BRD + Feed efficiency	2 or 3

# Substitution of VFD drugs

Use of an approved generic VFD drug as a substitute for an approved pioneer VFD drug in cases where the pioneer VFD drug is identified on the VFD.

- If the veterinarian does not specify that a substitution is not allowed, the feed manufacturer may use either the approved pioneer or an approved generic VFD drug to manufacture the VFD feed.
- However, the feed manufacturer may not substitute a generic VFD drug for a pioneer VFD drug in a combination VFD feed if the generic VFD drug is not part of an approved combination VFD drug.

# Current VFD Drugs

Currently Approved VFD Drugs	Approved for Use in the Following Species	Pioneer	Generic
Avilamycin	Swine – reduction of diarrhea – E. coli.	Yes	NA
Florfenicol	Fish – control of mortality (various diseases by fish type)	Yes	NA
	Swine – control of SRD	Yes	NA
Tilmicosin	<b>Swine – control of SRD</b>	<b>Yes</b>	<b>Yes</b>
		Substitution Option	
	Cattle – control of BRD	Yes	NA

# Veterinary Client Patient Relationship (VCPR)

- Veterinarian issuing a VFD is required to be licensed to practice veterinary medicine and operate in compliance with either:
  - **State-defined VCPR** – if VCPR defined by such State includes the key elements of a valid VCPR defined in § 530.3(i); or
  - **Federally-defined VCPR** - where no applicable or appropriate State VCPR requirements exist

# Veterinary Client Patient Relationship (VCPR)

- The State-defined VCPR must at least address the concepts that the veterinarian:
  - 1) engage with the client to assume responsibility for making clinical judgments about patient health;
  - 2) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where patient is managed; and
  - 3) provide for any necessary follow-up evaluation or care

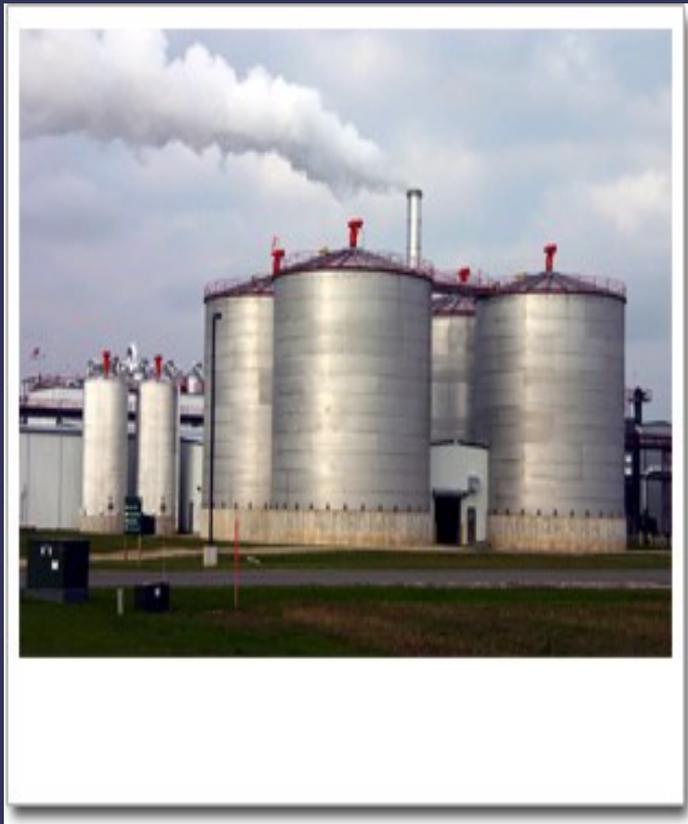
# Veterinary Client Patient Relationship (VCPR)

- FDA is working with State regulatory authorities to verify whether that state has VCPR requirements in place that:
  - apply to the issuance of a VFD, and
  - include the key elements of the federally-defined VCPR

# Veterinary Client Patient Relationship (VCPR)

- FDA will provide an online list of such states at the time the final GFI #120 publishes
  - CVM intends to publish this list on its VFD website by October 1, 2015
  - This list will be updated periodically as FDA receives and verifies information from states if they change their VCPR definition or its applicability

When will this go into effect?



# Implementation Timeline Summary

- **October 1, 2015** – VFD Final Rule goes into effect
  - Applies to current VFD drugs
- **January 1, 2017** – Target for all medically important antimicrobials for use in or on feed to require a VFD
  - December 2016 – Target for drug sponsors to implement changes to use conditions of products affected by GFI #213

# Ongoing activities/Next steps

- GFI # 120:

- Review comments received on GFI #120
- Publish final version of GFI #120

Publish VCPR list, by 1 October 2015

- Develop guidance on format of VFD form

# References and Resources

- **See Veterinary Feed Directive and Judicious Use CVM/FDA Sources of Information - In your packet.**

Thank You





Good day!

As you may know, the FDA is proposing "Guidance for Industry-Compounding Animal Drugs from Bulks Drug Substances." This guidance is remarkable in its restrictions and impact to the veterinary community such as:

- documenting clinical need on each prescription for compounded drugs
- no office stock of compounded medicinals, sterile or otherwise
- scripts to be pet-specific--no flocks, fish or groups of shelter animals
- no allowance for dispensing of acute amounts from office stock

Not only do we find these guidelines contrary to the practice of contemporary veterinary medicine, they are also detrimental to pharmacies, many of whom are no longer making sterile products.

Enclosed is the AVMA response to this proposal which addresses serious deficiencies, intensified record keeping and discusses the need and urgency for compounded sterile items for office use as well as the need to be able to dispense compounds for acute conditions. Additionally, I am enclosing a copy of a letter to the FDA from several congressmen who oppose the FDA's process. They feel the FDA has exceeded its authority and ask that the FDA proposal be withdrawn.

In spite of this recognized shortcomings, some state boards of pharmacy are already seriously considering this FDA proposal for incorporation into their own regulations through a Memorandum of Understanding. Most, if not all, states are reviewing compounding legislation, to include office use items and the compounding of sterile products. It has been our experience that most state boards have little experience with veterinary medicine and often fail to consider ramifications to animal health when they regulate the practice of pharmacy based on human medicine.

Roadrunner Pharmacy has been a partner in the veterinary community for more than 16 years; we know how important these issues are to you and your colleagues. While state VMAs are essential to this process, conveying the unique needs and practice formats to boards of pharmacy, as the state's expert on these matters, your opinion weighs heavily. In the presence of an 18 page letter from an organization that represents more than 85,000 veterinarians AND serious misgivings from members of Congress, I think there is more than enough input to consider a veterinary exclusion or, at the very least, less restrictions for animal products that are compounded.

ROBERT L. EATON, JR.  
President/CEO  
Roadrunner Pharmacy, Inc



August 14, 2015

Mr. Eric Nelson  
Center for Veterinary Medicine  
Division of Compliance  
FDA Center for Veterinary Medicine  
7519 Standish Pl  
Rockville, MD 20852

**RE: [Docket Nos. FDA-2015-D-1176 and FDA-2003-D-0202] Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Withdrawal of Compliance Policy Guide; Section 608.400 Compounding of Drugs for Use in Animals**

Dear Mr. Nelson:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical organization in the world with over 86,500 members. The AVMA's mission is to lead the profession by advocating for its members and advancing the science and practice of veterinary medicine to improve animal and human health.

The AVMA recognizes that the FDA Draft Guidance for Industry #230 sets forth the Food and Drug Administration's (FDA) policy regarding compounding animal drugs from bulk drug substances by state-licensed pharmacies, licensed veterinarians, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b). We understand this guidance describes the conditions under which FDA generally does not intend to take action for violations of the following sections of the FD&C Act: section 512 (21 U.S.C. 360b), section 501(a)(5) (21 U.S.C. 351(a)(5)), section 502(f)(1) (21 U.S.C. 352 (f)(1)), and, where specified, section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), when a state-licensed pharmacy, licensed veterinarian, or an outsourcing facility compounds animal drugs from bulk drug substances.

Additionally, we recognize that this draft guidance only addresses the compounding of animal drugs from bulk drug substances, and that it does not apply to the compounding of animal drugs from approved new animal or new human drugs. The AVMA was a leader in the development of, and advocacy for, the enactment of the Animal Medicinal Drug Use Clarification Act on behalf of our members and the patients they serve. Extralabel drug use, including the compounding of preparations from FDA-approved drugs, continues to provide access to critical medications and our members continue to rely on this FDA-regulated activity in the practice of veterinary medicine within the confines of the 21 CFR 530.

The AVMA appreciates the FDA's recognition that there is a need for preparations compounded from bulk drug substances. We also share the agency's concern about the use of these preparations when approved alternatives exist that can be used as labeled or in an extralabel manner consistent

with the requirements of FDA's extralabel provisions. The AVMA continues to believe that three circumstances exist wherein compounds prepared from bulk drug substances might be necessary:

- the approved product is not commercially available, or
- the needed compounded preparation cannot be made from the approved product, or
- there is no approved product from which to compound the needed preparation.

While we are formally submitting these comments today, we will continue to assess whether the draft guidance can realistically address the needs of veterinary patients and ask that the FDA continue its dialog with us.

### ***Overarching comments***

#### **Drug Availability**

Veterinary medicine is unique in that we treat a multitude of species with an even greater number of unique diseases and conditions. Approval of new animal drugs is critical to veterinary medicine and engaging with the Agency in facilitating that process remains a high priority for our Association. However, compounding from bulk drug substances is still a necessary practice for veterinarians because there are, and always will be, a limited number of FDA-approved drug products for the many species and conditions that we treat. Intermittent drug shortages and commercial unavailability of FDA-approved drug products drive the need for compounded preparations within veterinary practice. While FDA has not identified cost as appropriate reason for compounding from bulk drug substances, the AVMA acknowledges that cost can be a reason veterinarians utilize compounded preparations because that is the only way a client can afford to treat their pet.

Our members have clearly conveyed that they need access to safe and efficacious drug products that can be practicably used in their patients. While recognizing FDA's jurisdiction is limited to issues related to safety and efficacy, not cost or commercial availability of drug products, we underscore the increasingly critical need for effective pathways for drug products to achieve legal marketing status. A robust, competitive animal health industry can benefit animal patients by way of increased numbers of legally marketed products that can be prescribed, dispensed or used in the preparation of compounds.

#### **Existing pathways to legal marketing**

- We continue to support the concept of user fees, so long as those fees go toward expedited reviews. Increased numbers of both pioneer and nonproprietary approved drug products can help to minimize the impacts of drug shortages.
- FDA's indexing process can be a valuable way to increase the number of legally marketed drug products for use in minor species or in major species with rare conditions. We recognize that indexing provides a process to obtain legal marketing status for eligible products. The indexing process should be utilized to a fuller extent, or revised accordingly, so that well-vetted drugs that have undergone expert panel scrutiny can be used legally for wildlife, aquaria, zoo, aquacultural, and laboratory animal species, and for major species with rare conditions.

#### **Innovative pathways to legal marketing**

- In 2010, the FDA published a Federal Register notice FDA-2010-N-0528 seeking comments related to identification of emerging paths toward legal status of drugs that are medically necessary and manufactured using good manufacturing processes. At the time, FDA conveyed that it is open to using both the agency's existing authority and new approaches to

make more drugs legally available to veterinarians, producers, and pet owners. We commended the FDA on its pursuit at the time and urge the FDA to implement innovative strategies to legal marketing. The AVMA stands ready to discuss possible approaches further with FDA.

#### **Non-food minor species**

In species including but not limited to zoo animals, laboratory animals, exotic pets, wildlife, aquaria animals, and non-food aquacultural animals, the use of compounded preparations is unquestionably necessary. We urge FDA to carefully consider the critical need for access to compounded preparations within these species, as FDA further refines its guidance. There are few choices of FDA-approved or indexed products available for use in these species; therefore, availability of properly compounded preparations to be maintained for office use in appropriate strengths and formulations, and the ability to mix and dilute medications are necessary to provide adequate veterinary care. Several provisions within this draft guidance should not apply to non-food minor species in their respective environments, such as limiting preparations to be maintained in office for urgent or emergent needs, patient-specific prescriptions, and detailed labeling requirements for compounded preparations maintained for office use.

#### **Federal vs. State Jurisdiction**

The licensure of veterinarians is regulated by state governmental authorities. Given this is a federal guidance, not a regulation, coupled with the existence of a wide range of state compounding rules, we would appreciate clarification on how GFI #230 will be enforced by the FDA. State rules regulating compounding in veterinary practice vary greatly. Some even provide substantial permissiveness for veterinarians to obtain preparations compounded for office use, and administer and dispense from the compounded preparations maintained in their office.

- How will the FDA evaluate whether the compounding of animal drugs is done in accordance with the conditions outlined in the guidance?
- Will the FDA rely on state boards of pharmacy and boards of veterinary medicine to enforce provisions within GFI #230, and how will the FDA reconcile discrepancies between state rules and GFI #230?

#### **Enforcement**

For many years the AVMA has advocated for, and applauded, the FDA's enforcement of illegal manufacturing activities. The AVMA asserts that large-scale manufacturing of animal drugs under the guise of compounding does not serve to benefit animal health; rather, circumvention of the drug approval process yields substances with unknown safety, efficacy, and potency, potentially allowing disease to progress. Animal drug manufacturers also contend that these compounded preparations result in a supply/demand disincentive for new FDA-approved drug products.

- As FDA is concerned about the use of animal drugs compounded from bulk drug substances, especially when approved alternatives exist that can be used as labeled or in an extralabel manner consistent with the requirements of FDA's extralabel provisions, how does this guidance change the FDA's ability to take action to address these concerns?
- Does the FDA currently have the needed resources and enforcement capabilities to fully enforce all egregious compounding activities, or are new authorities and appropriations necessary for the agency?
- Will the FDA develop and provide a user's guide on implementing the GFI #230 for state boards of pharmacy, state boards of veterinary medicine, individual veterinarians, and pharmacists to follow? We anticipate that time for a transition to the new paradigm will be

needed across stakeholder groups, especially given the wide array of state rules that exist related to veterinary compounding. Some veterinary state boards might not be prepared to inspect veterinary facilities for compliance with standards delineated within GFI #230.

- How will FDA's enforcement of compounded preparations be reconciled with the Drug Enforcement Administration's expectations that preparations containing controlled substances must only be prepared pursuant to patient-specific prescriptions?
- We also encourage FDA to coordinate with all relevant governmental agencies related to use of bulk drug substances in depopulation efforts, which might be needed during large-scale national emergencies. The AVMA stands ready to serve as a resource to FDA related to this topic.

### **Adverse Event Reporting System**

The AVMA contends that there is a need for the continued development and strengthening of adverse event reporting systems for all adverse events, including lack of efficacy. We believe that there must be a strong, science-based, transparent and systematic surveillance system, especially considering the wide scope of species and disease conditions that veterinarians treat. The AVMA supports development of a user-friendly, easy to access form for all adverse events related to compounding. A user-friendly electronic system would be anticipated to promote both reporting by those compounding, and ease of review by FDA. For example, FDA could maintain a database of recently reported adverse events for veterinarians and pharmacists to use as a resource. Sufficient and meaningful data inputs, or adverse event reports, are imperative for a strong reporting system foundation.

- Does the FDA's current 1932a form, as a means of capturing adverse events, provide the robustness FDA needs to detect and act on trends? The AVMA contends that all adverse events associated with compound preparations should be reported, not just serious adverse events. Adverse events related to lack of efficacy should also be collected and analyzed.

### ***Comments on Specific Provisions within Draft GFI #230***

#### **Scope of AVMA Comments**

The AVMA has chosen to comment on the sections and questions that impact veterinary medicine. We will defer to the pharmacy community for feedback related to the practice of pharmacy and functioning of outsourcing facilities: pharmacist supervision (Section III.A.1. and Section III.C.2); compounding in advance of receipt of a prescription (Section III.A.2); determining and documenting that the compounded drug cannot be made from the FDA-approved drug(s) (Section III.A.5); current Good Manufacturing Practices (cGMP) (Section III.C.4); certain labeling requirements (Section III.C.10); and reporting requirements from 503B of the FD&C Act (Section III.C.8).

#### **Definitions**

We request the FDA provide clarification on the following terms:

- "Outsourcing facility"—Draft GFI #230 defines an "outsourcing facility" as a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. Section 503B(d)(4) defines an outsourcing facility as a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of that section of the law.

As the use of outsourcing facilities in veterinary medicine is an entirely new concept, we are still assessing how the requirements for registration as an outsourcing facility would impact

the ability to meet veterinary needs. We wish to underscore that there is a substantial need for both non-sterile and sterile compounded preparations to be maintained for office use in veterinary medicine. We appreciate that the use of outsourcing facilities in the preparation of office stock is intended to increase safety of compounded preparations, yet we caution that use of outsourcing facilities might have the unintended consequence that some preparations of critical importance to animal health may no longer be available due to economic or other business considerations.

We ask the FDA to clarify how it will reconcile the clear discrepancies between statutory language and provisions in various agency documents:

- Specifically, it is our understanding that outsourcing facilities in compliance with Section 503B are only exempt from the *human drug approval requirements* in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to be labeled with adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the track and trace requirements in section 582 of the FD&C Act (21 U.S.C. 360eee-1). How does this guidance impact the facility's exemption from animal drug approval requirements?
- Per the FDA's draft guidance for industry *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, referenced in draft GFI #230, outsourcing facilities are required to meet certain conditions to qualify. Of particular concern is the requirement that the outsourcing facilities must not compound drugs that appear on a list published by the FDA of drugs that have been withdrawn or removed from the market because the drugs or components of such drugs have been found to be unsafe or not effective *for humans*. We are aware of a number of such compounded preparations needed in veterinary medicine, including but not limited to cisapride, asparaginase, and chloramphenicol. In these cases, the FDA-approved product was withdrawn from the market due to human safety concerns, leaving us with no alternative to treat animal patients.
- An additional concern is that a facility, in order to meet the definition of an outsourcing facility, must be engaged in the compounding of sterile human drugs. The draft guidance clearly states that "you should not register a facility as an outsourcing facility if the only activities conducted at the facility are... animal drugs,...because none of the products produced at the facility would qualify for the exemptions provided in section 503B." A number of pharmacies currently exist that serve the needs of veterinarians and would need to register as an outsourcing facility per GFI #230, but they are explicitly prevented from registering per Section 503B because they do not meet certain requirements and were told not to register by the agency in another Guidance for Industry.
- "Compounding" as defined within 503A does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling. Defined within 503B, compounding is the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering a drug or bulk drug substance to create a drug. Is the administration of a bulk drug substance directly to an animal (for example, dissolution of metronidazole powder in aquaria for medical treatment of pet fish) considered compounding, or would administration be considered compounding only if the bulk drug

substance is mixed with another active or inactive ingredient? We ask the FDA to fully clarify its definition of animal drug compounding within this guidance.

- “Bulk drug substance” is defined within 21 CFR 207.3(a)(4) as “any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.” We understand that compressed gases, household items, herbals and homeopathics, and manufactured unapproved drugs such as glucosamine, would be outside the scope of this guidance. We ask the FDA to fully clarify what it considers a bulk drug substance for purposes of this guidance.
  - In its Table 1—Estimated Annual Recordkeeping Burden, please clarify details surrounding FDA’s estimate that 75,000 pharmacies will receive approximately 6,350,000 prescriptions for compounded animal drugs annually. From where were these numbers obtained, and are these numbers specific to preparations compounded from bulk drug substances or prescriptions for all compounded preparations?
- “Patient” is defined by the AVMA (<https://www.avma.org/KB/Policies/Pages/Model-Veterinary-Practice-Act.aspx>) as an animal or group of animals examined or treated by a veterinarian, which would include herds, flocks, groups of shelter animals, laboratory animal colonies or groups, and zoo animal and aquaria collections. We respectfully request the use of this definition for the term “patient.”
- “Non-ornamental fish” needs further clarification. Which definition is the FDA using for this term? The FDA-CVM’s Program Policy and Procedures Manual *Enforcement Priorities For Drug Use In Non-Food Fish* includes a definition of “ornamental fish.” For purposes of GFI #230, are all fish not included in that definition to be considered “non-ornamental fish” and therefore food-producing animals?
- “Clinical difference” is not expressly defined within Section 503B or in the draft GFI #230. How will “clinical difference” be evaluated by the FDA, or does the FDA intend to seek state enforcement of this component?
- The terms “sale” and “transferred” need to be more clearly defined. For example, does this include the sharing of a compounded preparation between one clinic and a co-owned satellite clinic, between multiple zoological institutions or government agencies, or from one university laboratory to another within the same university system?

### Section III.A.

(2) We have serious concerns with the verbiage “The drug is dispensed...for an individually identified animal patient...” AVMA fully supports the requirement that a veterinarian-client-patient relationship must exist for the use of a compounded preparation in an animal patient. However, the requirement that a patient must be ‘individually identified’ would eliminate the ability for veterinarians to obtain a preparation for a collection of animals, such as in a zoo, laboratory animal research facility or aquarium. In some of these situations, the patient cannot be individually identified or the entire group needs to be treated; it would not be feasible or reasonable to write an individual prescription for each animal.

- We request the FDA delete the words “individually identified” and use the AVMA’s definition of “patient”: <https://www.avma.org/KB/Policies/Pages/Model-Veterinary-Practice-Act.aspx>.

(3) “Food-producing animal” defined to include all cattle, swine, chickens, turkeys, sheep, and goats is consistent with our understanding and definition of a “food-producing animal.”

The AVMA contends that compounding from bulk drug substances in food-producing animals is medically necessary for certain poison antidotes, euthanasia, and depopulation medications. There must be some allowance for compounding from bulk ingredients for these explicit situations, when there is no FDA-approved product or the approved product cannot feasibly be used per label or in an extralabel fashion. Veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; for example, methylene blue is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians’ need to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA’s extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

We are not opposed to the requirement that the prescription or documentation accompanying the prescription for a non-food animal must contain the statement “This patient is not a food-producing animal.” The statement also helps to distinguish those patients that could be a food-producing animal in some situations, independent of species (e.g., rabbits, captive elk, captive deer).

We also would appreciate clarification on the wording in the latter half of this provision: “...any other animal designated on the prescription or in documentation accompanying the prescription by the veterinarian as a food-producing animal, regardless of species, is considered to be a food-producing animal.”

- Would this mean that a veterinarian would state “This patient is a food-producing animal” to identify for the pharmacist that a bulk drug substance is not to be used?

(4)(a) The AVMA disagrees with the requirement that a pharmacy may compound a preparation using a bulk drug substance that is a component of any marketed FDA-approved animal or human drug only if the change between the compounded drug and the FDA-approved drug would produce a clinical difference. We assert that compounding should be allowable if the approved product is not commercially available for other reasons (i.e., unavailable) and no therapeutic alternatives exist, or if the needed compounded preparation cannot be made from the approved product (such as preparation of metronidazole benzoate for use in a cat) as allowed per Section III.A.5. We ask the agency to amend the provision accordingly. Given the frequency of FDA-approved drug product shortages and backorders, including all marketed FDA-approved drugs is too restrictive for the needs of veterinary patients.

(4)(b) The AVMA has concerns with, and is opposed to, the requirement for a statement from the veterinarian that the compounded preparation “produces a clinical difference for the individually identified animal patient” with an explanation of that difference. We contend that a medical rationale is necessary for use of compounds, and is a more applicable term than “clinical difference.” However, we believe documentation of why the compounded preparation was chosen is more appropriate for the medical record.

- Should FDA still choose to require inclusion of a statement in documentation, will the statements be evaluated by the FDA, or does the FDA intend to seek state enforcement of this component?

Additionally, we believe that the term “clinical difference” does not capture other medical needs for compounded preparations, such as certain worker and client safety needs, client compliance, and animal stress situations (e.g., fractious cats). These safety/animal handling needs are not related to clinical differences but rather, the ability to adequately medicate patients.

(5) Related to pharmacists documenting that a compounded preparation cannot be made from an FDA-approved drug, what does the FDA consider to be “acceptable documentation,” and to whom will the documentation be provided?

(6)(b) In concept, the AVMA does not oppose the requirement that the statement “There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under section 512(a)(4) or (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed” be documented on the prescription or documentation accompanying the prescription, because we believe veterinarians need to carefully consider their therapeutic options. However, the statement could inadvertently discourage use of FDA-approved drugs in preparing compounded medications. For example, we understand that sometimes the best starting ingredient for a pharmacist’s preparation of a compounded medication is the FDA-approved drug. If the veterinarian includes the above statement, that essentially would direct the pharmacist to utilize a bulk drug substance. Moreover, the veterinarian writing the prescription would not necessarily know whether the FDA-approved drug or the bulk drug substance is best for the preparation. We wholeheartedly agree with the need for veterinarians to utilize FDA-approved products whenever feasible. We ask that FDA discuss this topic further with the AVMA.

(9) We would like clarification on the statement that “a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care.” It is our understanding that under the guidance, the compounded preparation may only be dispensed by the pharmacy to the patient’s owner or caretaker, a concept with which the AVMA disagrees. Does this provision in some way allow for the veterinarian to receive the compounded preparation from the pharmacy, and then administer and dispense the preparation to the patient’s owner or caretaker? The AVMA asserts that the prescribing veterinarian should be able to dispense these preparations to help ensure that the medications are being used and administered appropriately by the client. Such dispensing also keeps the prescribing veterinarian more closely attuned to the current status of the patient should client questions or concerns (such as adverse events) arise.

We request that the FDA amend the provision to allow dispensing: “...a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care, or the dispensing of a compounded drug by the veterinarian to the owner or caretaker of an animal under his or her care.”

### **Section III.B.**

(1) Again, the AVMA contends that compounding should be done within the confines of a veterinarian-client-patient relationship. However, veterinarians must be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations, including compounds prepared by veterinarians and pharmacies. In fact, the

maintenance of preparations for office use is lawful for veterinarians under some states' rules. We request that the FDA include an allowance for the preparation of compounds by veterinarians in advance of a specific patient's need.

(2) For food animals, the AVMA, again, asserts that a publically available list of bulk drug substances for veterinarians to prepare poison antidotes, euthanasia, and depopulation preparations should be made available.

As previously stated in Section III (A) 3, veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; for example, methylene blue is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians' need to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA's extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

(3) If the veterinarian is prescribing a medication to be compounded in lieu of an FDA-approved drug, then there is a clinical need that has already been determined by the prescribing veterinarian. Thus the AVMA agrees with the purpose of the provision. We do not support any additional reporting or recordkeeping requirements related to this provision.

We request that the FDA amend the provision to allow for compounding from bulk ingredients if the approved product is not commercially available (either due to a backorder, shortage, or no longer marketed) or if the needed compounded preparation cannot be made from the approved product. As stated with respect to Sec. III.A.4.a., the frequency of FDA-approved drug product shortages and backorders makes inclusion of all marketed FDA-approved drugs too restrictive for the needs of veterinary patients.

(4) The AVMA supports the intentions of this provision as the AVMA believes that an FDA-approved drug product should always be used first and foremost.

(5) The AVMA supports the requirement that veterinarians compounding from bulk drug substances do so in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

(6) The AVMA agrees with the requirements for use of bulk drug substances that are accompanied by a valid certificate of analysis and that come from FDA-registered manufacturers.

(7) The AVMA agrees with the provision's allowance for veterinarians to administer the preparation to the patient or dispense to the owner or caretaker. The AVMA also agrees that this should all be done within the confines of a veterinarian-client-patient relationship.

The AVMA contends that dispensing practices by veterinarians should be regulated by individual state boards of veterinary medicine. We would like the FDA to clarify what the agency would consider to be the "transfer" of compounded preparations to another veterinarian or a satellite facility.

### Section III.C.

(1) Please see our comments in the section below related to Appendix A. We have reservations about the outline drafted for the creation of such a list and whether patient needs can be met through the use of such a list.

(3) We do not oppose the requirement for a statement on the prescription or supporting documentation that “This drug will not be dispensed for or administered to food-producing animals.” Including such a statement is important to help minimize the risk of the medication being used in a food animal.

As stated previously, the AVMA contends that compounding from bulk drug substances in food-producing animals is medically necessary for certain poison antidotes, euthanasia, and depopulation medications. There must be some allowance for compounding from bulk ingredients for these explicit situations, when there is no FDA-approved product or the approved product cannot feasibly be used per label or in an extralabel fashion. Veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; one example also stated previously is methylene blue, which is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians’ needs to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA’s extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

(6) As the draft guidance is currently written, outsourcing facilities would be the only way by which a veterinarian could obtain office stock of certain compounded preparations. Many of these preparations are not only needed for immediate in-house administration by the veterinarian but also for dispensing to the patient’s owner or caretaker for treatment at home, up to a 14-day timeframe. This allows for dispensing for emerging needs, and to help ensure the drug is going to be effective in a particular patient. It would also help to avoid a client needing two prescriptions for one drug in a short timeframe (which could decrease compliance), and would allow time to detect any immediate adverse events (e.g., intolerance to the drug, such as seen when amlodipine results in inappetence in cats).

We request that the FDA amend the provision to allow dispensing: “...a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care, or the dispensing of a compounded drug by the veterinarian to the owner or caretaker of an animal under his or her care.” This would bring the provision in line with what is allowed for physicians under Sec. 503B of the FD&C Act.

(9) At this time, the AVMA has reservations related to the requirement that a veterinarian’s order state that the product will be used in a manner and in a species that complies with the list of permitted bulk ingredient uses under Appendix A. If any such list is created, it needs to be maintained properly and reflect veterinarians’ needs. These concerns will be further addressed in the feedback below on Appendix A.

(10) The AVMA contends that certain information should be incorporated into labels/packaging and generally agrees with inclusion of:

- a. Active ingredient(s)
- b. Dosage form, strength, and flavoring, if any
- c. Directions for use, as provided by the veterinarian prescribing or ordering the drug

- d. Quantity or volume, whichever is appropriate
- e. The statement "Not for resale."
- f. The statement "For use only in [fill in species and any associated condition or limitation listed in Appendix A]."
- g. The statement "Compounded by [name of outsourcing facility]."
- h. Lot or batch number of drug
- i. Special storage and handling instructions
- j. Date the drug was compounded, and date of dispensing, if dispensed
- k. Beyond use date (BUD) of the drug
- l. Name of veterinarian prescribing or ordering the drug
- m. The address and phone number of the outsourcing facility that compounded the drug
- n. Inactive ingredients
- o. The statement "Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a."
- p. If the drug is compounded pursuant to a patient specific prescription, the species of the animal patient, name of the animal patient, number of refills if applicable, and name of the owner or caretaker of the animal patient. We wish to underscore that "patient" can also mean a herd, collection or group of shelter animals. We assert that the AVMA's definition of "patient" should be used.

We also request that FDA require all compounded preparations be labeled that they are not FDA-approved products. We believe it is important for consumers to recognize that safety, efficacy, potency and sterility, where applicable, of compounded preparations have not been assessed or verified by the FDA.

Labeling requirements for preparations to be maintained for office use can be difficult for minor species, including but not limited to zoo, aquaria, laboratory-animal, and wildlife collections and/or facilities. For example, some compounds maintained for office use will be used to treat lameness in a number of species in a zoo collection. The labeling requirement as posed in (f) would be particularly difficult in these collections.

#### **Pertaining to Provisions Which Appear in Multiple Sections**

##### Related to Labeling by Pharmacies and Veterinarians (Section III.A.11 and Section III.B.9)

AVMA requests that the labeling requirements for pharmacists and veterinarians include name of client; veterinarian's name and address; identification of animal(s) treated, species and numbers of animals treated, when possible; date of dispensing; name, active ingredient, and quantity of the drug preparation to be dispensed; drug strength (if more than one strength available); dosage and duration; route of administration; number of refills; cautionary statements as needed; beyond use date; and the statement "Compounded by [name, address, and contact number of the pharmacy or veterinarian]."

We also assert that compounded preparations should be labeled that they have not been approved by FDA. Patient owners or caretakers should have information available to contact the compounding entity, be it a pharmacy, veterinarian or outsourcing facility.

The AVMA agrees with inclusion of the name of the owner or caretaker and species of animal. AVMA contends that a patient may be an animal or group of animals so the "name" of the animal patient should only be required for prescriptions where applicable and appropriate.

Related to Patient-Specific Prescriptions (Section III.A.2 and Section III.B.1)

Veterinarians must be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations. These cannot be obtained through patient-specific prescriptions. Examples are many, and include: methylene blue to treat nitrate toxicosis; apomorphine to induce emesis in dogs; antibiotics, such as metronidazole, formulated into an appropriate dose for small dogs and cats and a palatable flavor for non-human primates to treat acute diarrhea; and nonsteroidal anti-inflammatory drugs, such as meloxicam, for pain control in small mammals.

This guidance's allowance that preparations that appear in a list will only be available from an outsourcing facility will greatly restrict veterinarians' access to critical medications and hamstring their ability to provide appropriate care in a timely manner. We must ask the FDA to reconsider provisions related to preparations compounded for office use and engage in discussion with the AVMA and the veterinary profession to better ascertain how to best meet the needs of both the FDA and veterinary patients.

Related to Sourcing of, and Information on, Bulk Drug Substances (Section III.A.7, Section III.B.6, and Section III.C.5)

Section III.A.7 states that "Any bulk drug substance used to compound the drug is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 510) and is accompanied by a valid certificate of analysis." How does the intent related to this statement differ from the intents for Section III.B.6 and Section III.C.5, which both state "Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis"?

The AVMA agrees with the requirement that any bulk drug substance used by either a pharmacy, veterinarian, or outsourcing facility be manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.

Related to USP-Related Requirements (Section III.A.8 and Section III.B.5)

The AVMA asserts that compliance with USP guidelines continues to be an element that can be utilized when a veterinarian considers the quality of a compounding pharmacy's preparations. The AVMA supports the requirement that veterinarians, outsourcing facilities, and pharmacists compounding from bulk drug substances do so in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

Related to the Sale or Transfer of Compounded Preparations (Section III.A.9 and Section III.B.7)

The AVMA advocates that compounded preparations should not be wholesaled. However, we seek clarification from FDA related to the definition of "sale" and "transfer" as indicated previously in our comments.

Related to Adverse Event Reporting Requirements (Section III.A.10, Section III.B.8, and Section III.C.7)

The AVMA advocates for robust, strong adverse event reporting systems. However, we ask whether the FDA's current 1932a form, as a means of capturing adverse events, provides the robustness FDA

needs to detect and act on trends? The AVMA underscores that all adverse events associated with compounded preparations should be reported by those compounding the preparations, rather than just serious adverse events. Adverse events related to lack of efficacy should also be collected and analyzed.

The AVMA contends there is a need for the continued development and strengthening of adverse event reporting systems for all adverse events, including lack of efficacy. We believe there must be a strong, science-based, transparent and systematic surveillance system, especially considering the wide scope of species and disease conditions that veterinarians treat. The AVMA supports development of a user-friendly, easy to access form for all adverse events related to compounding. A user-friendly electronic system would be anticipated to promote both reporting by those compounding and ease of review by the FDA. For example, the FDA could maintain a database of recently reported adverse events for veterinarians and pharmacists to use as a resource. Sufficient and meaningful data inputs, or adverse event reports, are imperative for a strong reporting system.

Related to the proposed requirement for submission of all adverse events within 15 days, the AVMA asserts that this timeframe is acceptable for veterinarians. We hope that such a timeframe is amenable to pharmacies and outsourcing facilities.

#### **Appendix A, List of Bulk Drug Substances That May Be Used By An Outsourcing Facility to Compound Drugs for Use in Animals**

In GFI #230, the FDA conveys its general intent to enforce all adulteration and misbranding provisions of the FD&C Act against entities compounding animal drugs from bulk drug substances if they are not in accordance with provisions delineated within the guidance. The AVMA understands this to mean that while all compounding from bulk drug substances continues to be illegal, those activities not provided for within the confines of GFI #230 are subject to *greater* likelihood of enforcement.

Although we want compounded preparations that veterinarians maintain for office use to be safe, we have concerns that the explicit use of outsourcing facilities might have the unintended consequence of making some preparations unavailable.

The AVMA asserts that use of a compounded preparation should be limited to those individual patients for which no other method or route of drug delivery is practical; those drugs for which safety, efficacy, and stability have been demonstrated in the specific compounded form in the target species; or disease conditions for which a quantifiable response to therapy or drug concentration can be monitored. Needs vary greatly across species treated by veterinarians.

- Zoo animals, laboratory animals, wildlife, exotic pets, camelids, aquaria species, and non-food aquacultural species: These minor species have few FDA-approved animal or human drug products or indexed drugs that can be used as labeled or in an extralabel manner to treat conditions. For example, diminutive dosages and volumes are required for some exotic pets, so office use is critical. Zoo veterinarians have advised they need to have office stock to be able to readily treat lameness or other conditions that can arise at any time among the large collections of animals they treat. For that reason, the importance of having preparations compounded from bulk drug substances in anticipation of the patient's need and available in the hospital or clinic for administration, and dispensing when appropriate, is undeniable.
- Food-producing animals: The AVMA suggests that the FDA draft a separate guidance to address compounding from bulk drug substances for food producing animals. The draft GFI

#230 provides no allowance for the preparation of compounds from bulk drug substances for food-producing animals. The AVMA has advocated for a publically available, current list of bulk drug substances that can be legally compounded within a veterinarian-client-patient relationship specific and limited to euthanasia, depopulation, and poison antidote compounds for food-producing animals. There currently exist no FDA-approved animal or human drug products or indexed drugs that can be used for these specific needs. Therefore, it is imperative that veterinarians have these preparations available and in their clinic when the need arises. Not only is compounding from bulk drug substances necessary for food-producing animals, the FDA must allow for the preparations to be obtained in anticipation of a specific patient's need (i.e. via a nonpatient-specific prescription or prescription order) for treating certain toxicoses and for euthanasia or depopulation.

- Dogs, cats, and horses: While there are a number of FDA-approved drug products for dogs, cats and horses, there remain circumstances where there is no FDA-approved drug product available to treat a particular animal with a particular condition, because either no drug product is approved for a specific animal species or no approved drug product is available or feasible for use under the extralabel drug use provisions. For example, some shelters receive 20,000 to 30,000 animals per year and have immediate needs that require compounded preparations for adequate treatment. Another example is the need for compounded buprenorphine when an owner is unable to adequately medicate their painful cat with the injectable or oral treatment at home. In instances such as these, having access to these compounded preparations for administration and dispensing by the veterinarian is critical to preventing animal suffering and death.

The criteria that all substances must meet to be included on the list are challenging.

- As asked previously, will the identified "significant safety concern specific to the use of the bulk drug substance to compound animal drugs" be related to safety concerns for humans or for animal patients? For example, cisapride was removed from the market due to human safety concerns, but is critical in feline medicine. We contend that safety concerns related to the use of compounded medications in human medicine should have no bearing on their use in animal patients in most circumstances.
- Additionally, evidence clearly indicating the ineffectiveness of a substance to be used should be a criterion by which the substance is not included on the list.

We have concerns related to the feasibility of creating an all-encompassing list of bulk drug substances within the paradigm framed by FDA, with supporting documentation as outlined in the Docket No. FDA-2015-N-1196. In lieu of the list, we contend that compounding from bulk drug substances should be allowed in three general sets of circumstances: the approved product is not commercially available, the needed compounded preparation cannot be made from the approved product, or there is no approved product from which to compound the needed preparation.

AVMA will be providing a separate set of comments pursuant to the Federal Register notice titled, "List of Bulk Drug Substances That May be Used by an Outsourcing Facility to Compound Drugs for Use in Animals."

### ***Specific Topics for Comment***

*Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable (e.g., disruptions in the manufacture or supply chain; business*

*decisions to stop marketing the drug; drug is subject to Agency action based on safety, effectiveness, or manufacturing concerns)?*

The AVMA is committed to the continued availability of medicinal products that are pure, safe, potent and efficacious for animals. While we recognize that many factors can impact a manufacturer's decision or ability to produce and make FDA-approved drug products available, the short and long-term breaks in availability or complete withdrawal of a product from the market make access to compounded preparations even more important. Lack of information regarding why the products have been removed from the market and when they might return causes frustration and uncertainty for veterinarians and pet owners as they plan for treatment of patients.

Accordingly, the AVMA contends that the lack of commercially available FDA-approved drug products is a valid reason for veterinarians to prescribe compounds prepared from bulk drug substances for patients. For example, ticarcillin-clavulanic acid is critical for treatment of certain types of bacterial otitis externa in dogs and must be compounded when commercially unavailable. We ask that the final guidance address the issue of compounding preparations from bulk drug substances when the FDA-approved drug products are unavailable for any reason. As requested earlier in our comments, does the FDA have the needed resources to address and minimize impacts of drug unavailability on patient care? Additionally, what protocols and procedures will FDA follow to assure that timely notification is made regarding emerging drug shortages that impact veterinary medicine and notification when the drug is once again commercially available? And how does FDA know when a shortage of a human FDA-approved drug will impact veterinary medicine?

*How should these situations be addressed in the final guidance?*

The AVMA contends that a robust, nimble, current drug shortage list should be made publically available. While we do not yet have a recommendation on whether this action should be incorporated into the provisions delineated within GFI #230, implemented elsewhere for the agency to manage, or maintained by an external stakeholder(s), appropriate resources must be dedicated toward its continual upkeep. In the interim, any role that the FDA plays with regard to identification of drug shortages needs to be well-informed and more broadly encompassing than the current list housed at

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm267669.htm>.

*How should the final guidance define the terms "shortage" and "unavailable"?*

A "shortage" refers to insufficient quantities of a needed FDA-approved product. "Unavailable" means that the FDA-approved product is entirely inaccessible to practitioners. Shortages and unavailability of products may be due to a back order, temporary discontinuation, or other supply interruption, resulting in limited or no accessibility through regular distribution channels.

*What criteria should FDA use to determine if an approved animal or human drug is in shortage or otherwise unavailable?*

FDA should consider products that are backordered, temporarily discontinued, no longer marketed, or provided intermittently in limited quantities when determining whether a product is in shortage or unavailable.

*Do United States Pharmacopeia and National Formulary (USP-NF) [2] chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?*

The USP chapters 795 and 797 are suitable standards for compounding from bulk drug substances by veterinarians.

*Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a State-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?*

We seek FDA's clarification related to the definitions of "sell," "transfer," and "dispense" before we can provide feedback related to this concept. In general, we assert that the prescribing veterinarian should be able to dispense preparations compounded by pharmacies or outsourcing facilities to his or her clients.

*How should FDA apply the condition to identify an individual patient when it is not possible to identify an individual animal (e.g., koi in a koi pond)?*

The AVMA contends that a "patient" is an animal or group of animals examined or treated by a veterinarian and does not need to always be individually identified. So long as the licensed veterinarian is meeting the requirements of his/her state veterinary practice act with respect to prescribing, then being able to identify an individual patient when it is not possible is unnecessary.

*Should facilities registered as outsourcing facilities under section 503B of the FD&C Act be able to compound animal drugs from bulk drug substances that do not appear on Appendix A for an individually identified animal patient under conditions similar to those applicable to state-licensed pharmacies (i.e., the conditions contained in section III.A. of the draft guidance)?*

Yes, so long as the outsourcing facility is a state-licensed pharmacy.

*Is additional guidance needed to address the repackaging of drugs for animal use?*

- *How widespread is the practice of repackaging drugs for animal use?*
- *What types of drugs are repackaged for animal use, and why are they repackaged?*
- *Have problems been identified with repackaged drugs for animal use?*

We understand repackaging to mean "The act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients." If this is FDA's definition, the AVMA agrees and understands that veterinarians sometimes need to repackage drugs, including compounded preparations, into smaller aliquots for administration by the owner or agent, as long as the repackaging does not affect the stability, efficacy, purity, safety, and potency of the product (e.g., light-sensitive drugs).

*Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under section 512(a)(4) or (a)(5) of the FD&C Act and part 530?*

No. The AVMA was a key leader in the development and advocacy for the Animal Medicinal Drug Use Clarification Act on behalf of our members and the patients they serve. Extralabel drug use, including the preparation of compounds from FDA-approved drugs, continues to be a needed activity in veterinary medicine, and our members continue to utilize this FDA-regulated activity in the practice of veterinary medicine, within the confines of the 21 CFR 530.

*Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?*

Yes. The AVMA suggests that the FDA draft a separate guidance to address compounding from bulk drug substance for food producing animals.

The AVMA continues to recommend that there be a publically available, current list of bulk drug substances that can be legally compounded within a veterinarian-client-patient relationship specific and limited to euthanasia, depopulation, and poison antidote compounds for food animal species. If adequate scientific information is not available to determine a withdrawal time, the AVMA contends that the compounded preparation cannot be used in a food animal or the treated animal cannot enter the food supply.

*As one condition under which FDA does not generally intend to take action for certain violations of the FD&C Act if this and the other conditions are followed, FDA is proposing that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from bulk drug substances to FDA within 15 days of becoming aware of the product defect or serious adverse event. Outsourcing facilities are required to report adverse events associated with the drugs they compound. FDA believes it is important to receive this information from State-licensed pharmacies and veterinarians because there are no other State Departments of Health or Federal Agencies (e.g., the CDC) charged with identifying and tracing animal injuries or disease associated with an animal drug compounded by these entities. FDA has the following specific questions with respect to this proposed condition:*

- *How many State-licensed pharmacies and veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to FDA?*

We are unaware of any data that could assist in answering this question. Anecdotally, we understand that few veterinarians personally compound from bulk drug substances.

- *Are State-licensed pharmacies and veterinarians reporting the same or similar information to any State regulatory agency (e.g., State boards of pharmacy, State boards of veterinary medicine)? If so, how many reports on average does each State-licensed pharmacy and veterinarian submit to these State agencies each year?*

It is our understanding that adverse events are grossly underreported to FDA; however, members have conveyed that when they do report an adverse event, they generally report the adverse event to the respective compounding pharmacy. We do not know the actual number of these reports, nor are we aware of the number of events reported by veterinarians to their state boards.

- *For purposes of the guidance, how should FDA define the terms “product defect” and “serious adverse event”?*

AVMA contends that “serious adverse events” are ones that are fatal, life-threatening, require professional intervention, cause an abortion, stillbirth, infertility, congenital anomaly, prolonged or permanent disability, or disfigurement as referenced in 21 CFR 514.3.

A “product defect” would include any obvious physical abnormalities, such as consistency, color and precipitant materials or contents, or problems with the amount, type or effectiveness of an ingredient triggered by production errors, poor quality bulk drug substances, or problems with transportation and/or storage. Any obvious physical defects of the container, seal or stopper and of the label of the product container would also constitute a product defect.

AVMA believes lack of efficacy is an adverse event and should be included in any reporting system.

- *Can FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from a bulk drug substance through means other than product defect and serious adverse event reporting, and if so, what other means? For example, would reports of product defects alone achieve the same objective?*  
We are unable to provide a clear answer without additional definitions for the terms “product defect” and “serious adverse event,” which would help inform our understanding and opinion.

We appreciate the opportunity to comment on the draft Guidance for Industry and provide needed feedback on behalf of the AVMA’s membership. For questions or concerns regarding the AVMA’s comments, please contact Drs. Ashley Morgan ([amorgan@avma.org](mailto:amorgan@avma.org); 202-289-3210) and Lynne White-Shim ([lwhite@avma.org](mailto:lwhite@avma.org); (800) 248-2862 ext. 6784).

Sincerely,

W. Ron DeHaven, DVM, MBA  
CEO and Executive Vice President

October ##, 2015

Commissioner Stephen Ostroff, M.D.  
Food & Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Commissioner Ostroff:

We are writing to express our serious concern with FDA's proposed "Guidance for Industry - Compounding Animal Drugs from Bulk Drug Substances", which the agency issued on May 19, 2015. Through a draft guidance, FDA is proposing a new regulatory scheme for compounded animal drugs that prohibits veterinarians from properly treating their animal patients. These fundamental changes are proposed despite the fact that Congress has not passed any statute giving FDA the broad authority it would need to make such a substantial change in animal health.

Under the proposed guidance, veterinarians would be singled out as the only health care professionals required to document in writing a clinical need before they can prescribe a medication. The draft guidance mandates very specific language that veterinarians must include on each and every prescription for a compounded preparation. This represents an unprecedented and dangerous intrusion into the state-regulated practice of veterinary medicine

The draft guidance also eliminates the ability of veterinarians to maintain an office stock of medications from compounding pharmacies that are necessary for animal health. This access to important compounded medications, commonly referred to as "office use," is permitted under most state laws. Office use of compounded medications is critical in the practice of animal health because veterinary clinics often serve as emergency rooms and hospitals for animals, and certain compounded medications must be immediately available in order to insure proper patient outcomes.

Through the draft guidance, the agency establishes and authorizes §503B outsourcing facilities to compound and distribute medications for veterinary use. When Congress established that category of FDA-registered and regulated facilities within the Drug Quality and Security Act of 2013, it was specific to the provision of sterile drug products for human use. The agency has far exceeded its authority by presuming to extend these entities into veterinary medicine.

This proposed guidance takes portions of the statute related to compounding contained in the Drug Quality and Security Act and attempts, without authorization and through a guidance document, to apply these provisions to animal drug compounding despite the fact that the Act is expressly limited to human compounding. If FDA believes that fundamental changes are needed in the regulation of animal drug compounding, the agency should instead submit a specific legislative proposal for Congress to consider. As a result, we ask that you withdraw this proposed guidance.

Thank you for your attention in this matter. We look forward to the withdrawal of this proposed guidance and please do not hesitate to contact our offices if you require any further information.

Sincerely,  
Matt Salmon  
Member of Congress

Kurt Schrader  
Member of Congress

Contact Greg Soften ([greg.safsten@mail.house.gov](mailto:greg.safsten@mail.house.gov)) in Rep. Salmon's office, or Chris Huckleberry ([huck@mail.house.gov](mailto:huck@mail.house.gov)) in Rep. Schrader's with questions and to sign onto the letter.



# Prescription Drug Monitoring Programs (PDMP)

**Barbara A Carter, Manager  
MN Prescription Monitoring Program  
September 19, 2015**



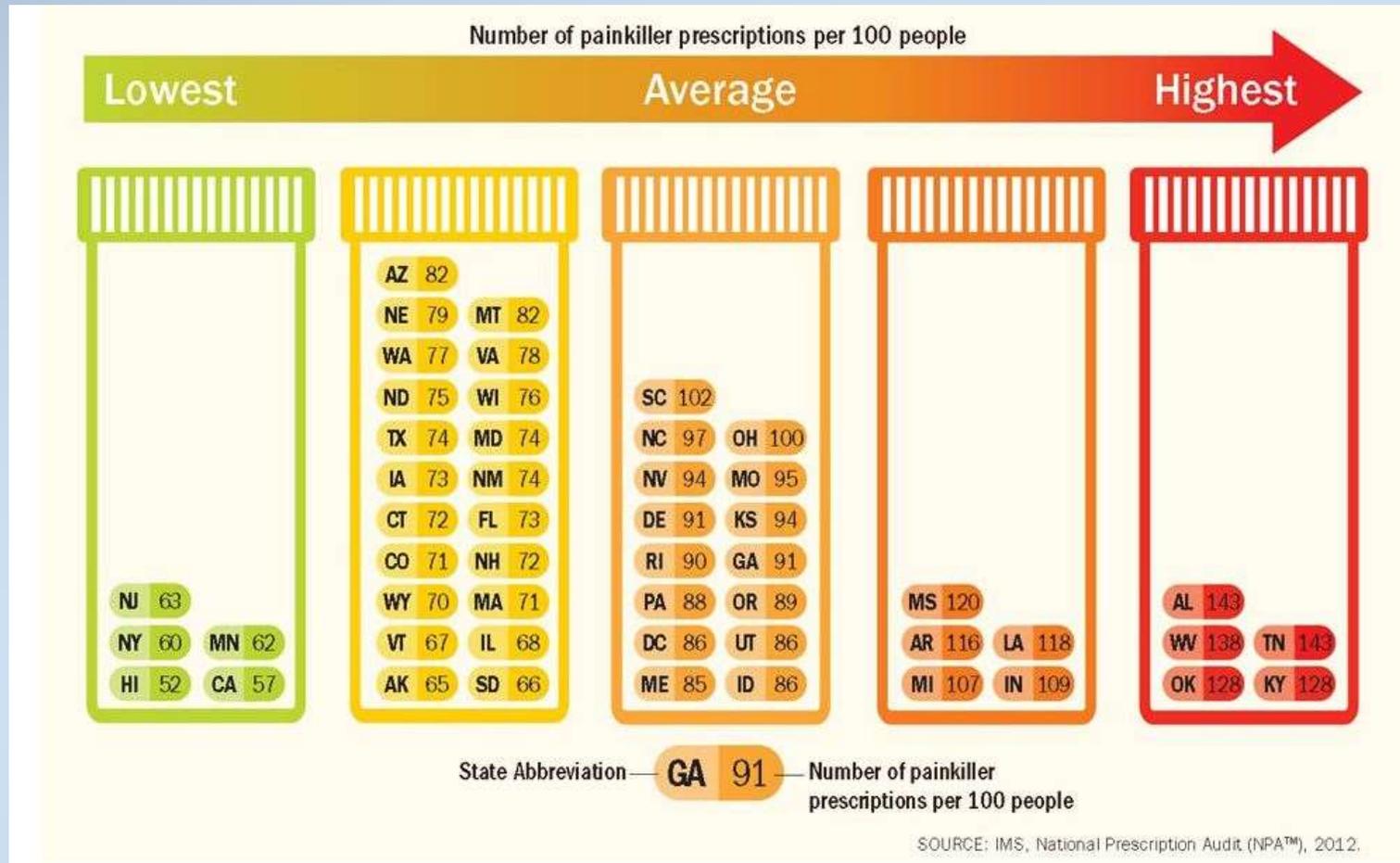
# Prescription Opioid Abuse A National Crisis

- 46 PEOPLE DIE EACH DAY FROM AN OVERDOSE OF PRESCRIPTION PAINKILLERS IN THE U.S. (1)
- 4 TIMES AS MANY DEATHS OCCURRED IN 2013 AS IN 1999 (2)
- FOR EVERY PRESCRIPTION OPIOID OVERDOSE DEATH IN 2011, THERE WERE:
  - ✓ 12 TREATMENT ADMISSIONS FOR OPIOIDS
  - ✓ 25 EMERGENCY DEPARTMENT VISITS FOR OPIOIDS
  - ✓ 105 PEOPLE WHO ABUSED OR WERE DEPENDENT ON OPIOIDS, AND
  - ✓ 659 NONMEDICAL OPIOID USERS (2)

(1) CDC, Opioid Pain Killer Prescribing: Where You Live Makes a Difference. (2014). *CDC Vital Signs*. Retrieved from [www.cdc.gov/vitalsigns/opioid-prescribing](http://www.cdc.gov/vitalsigns/opioid-prescribing)

(2) Dowell, D., Aleshire, N. A CDC Primer on the Prescription Opioid Overdose Epidemic. (2015, April 6). Presentation at 2015 National Rx Summit. Available from [www.nationalrxdrugabusesummit.org](http://www.nationalrxdrugabusesummit.org)

# 259M prescriptions for painkillers in 2012



SOURCE: IMS, National Prescription Audit (NPA™), 2012.

# Pets and Prescriptions



- Drug abusers turning to pet meds to feed habit
- Drug abusers may be injuring pets to get pain killers  
(*Dayton Daily News-12/11/13 & 12/12/13*)



# Scams to Obtain Prescriptions

The Racehorse Scam



The Guard Dog Scam

The Overweight House Pet Scam



# Our Journey

- Definition and purposes
- Brief history
- Overview of PDMP/PMPs

# Definition and Purpose

- **Statewide** electronic databases - collect specified data on prescription controlled substances from dispensers.
  - Sometimes drugs of concern – e.g. butalbital
  - Includes dispensing practitioners
  - Provide patient prescription data to prescribers, dispensers, regulatory officials, law enforcement/prosecutors, selected other

- 5 common purposes for a PDMP/PMP
  - Support access to controlled substances for legitimate medical use
  - Help identify and deter diversion-reducing overdose and overdose deaths
  - Help identify and intervene with persons abusing or addicted to prescription drugs
  - Inform public health initiatives through trends
  - Educate public about abuse, addiction and diversion

# Brief History

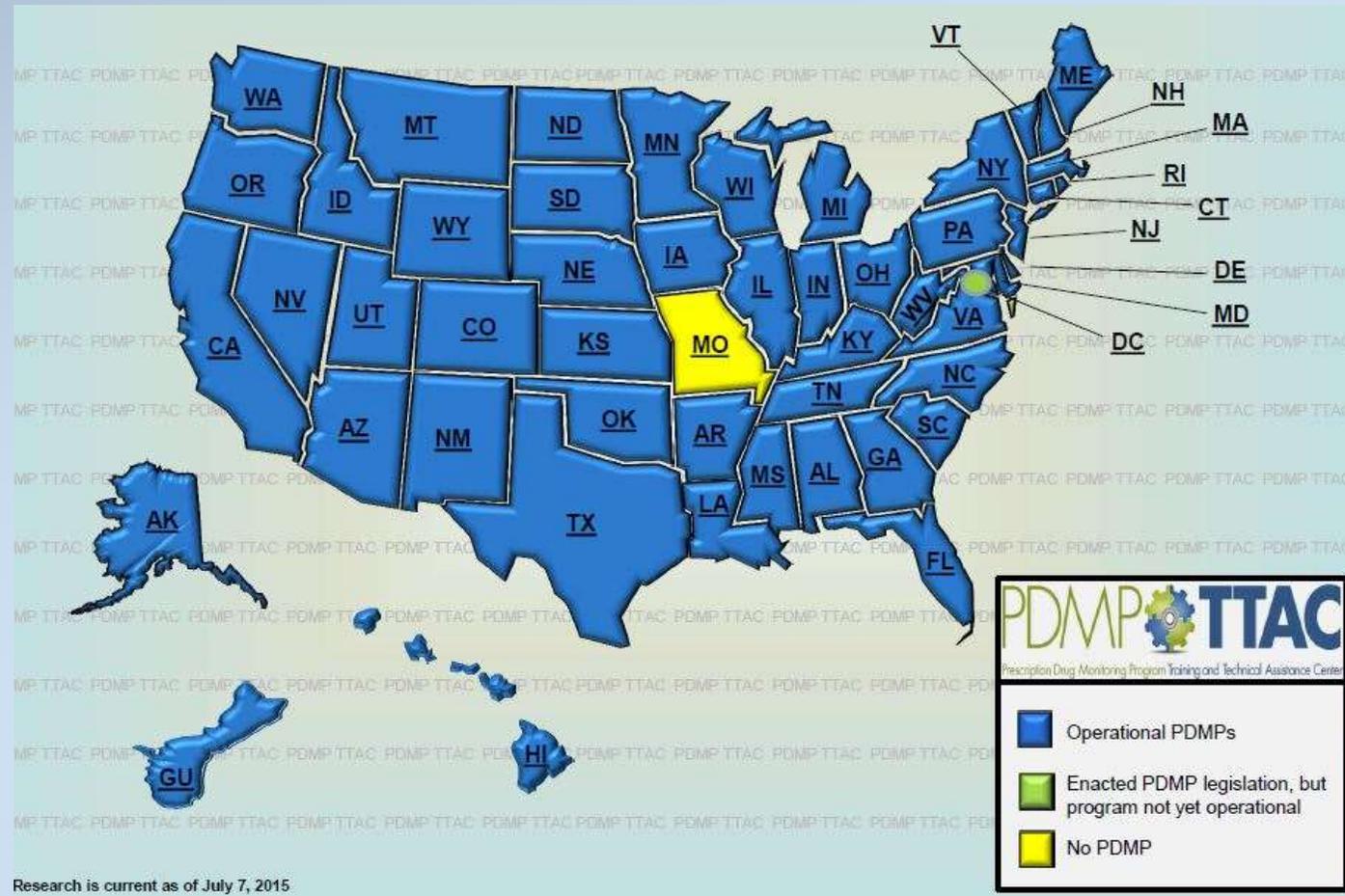
- In the beginning....
  - 1918 – New York State
  - 1939-43
    - California - 1939 (Oldest Continuous Program)
    - Hawaii – 1943
  - 1960-89
    - Illinois (1961)
    - Idaho (1967)
    - Pennsylvania (1972)
    - New York (1972)\*
    - Rhode Island (1978)
    - Texas (1981)
    - Michigan (1988)

# The electronic era.....

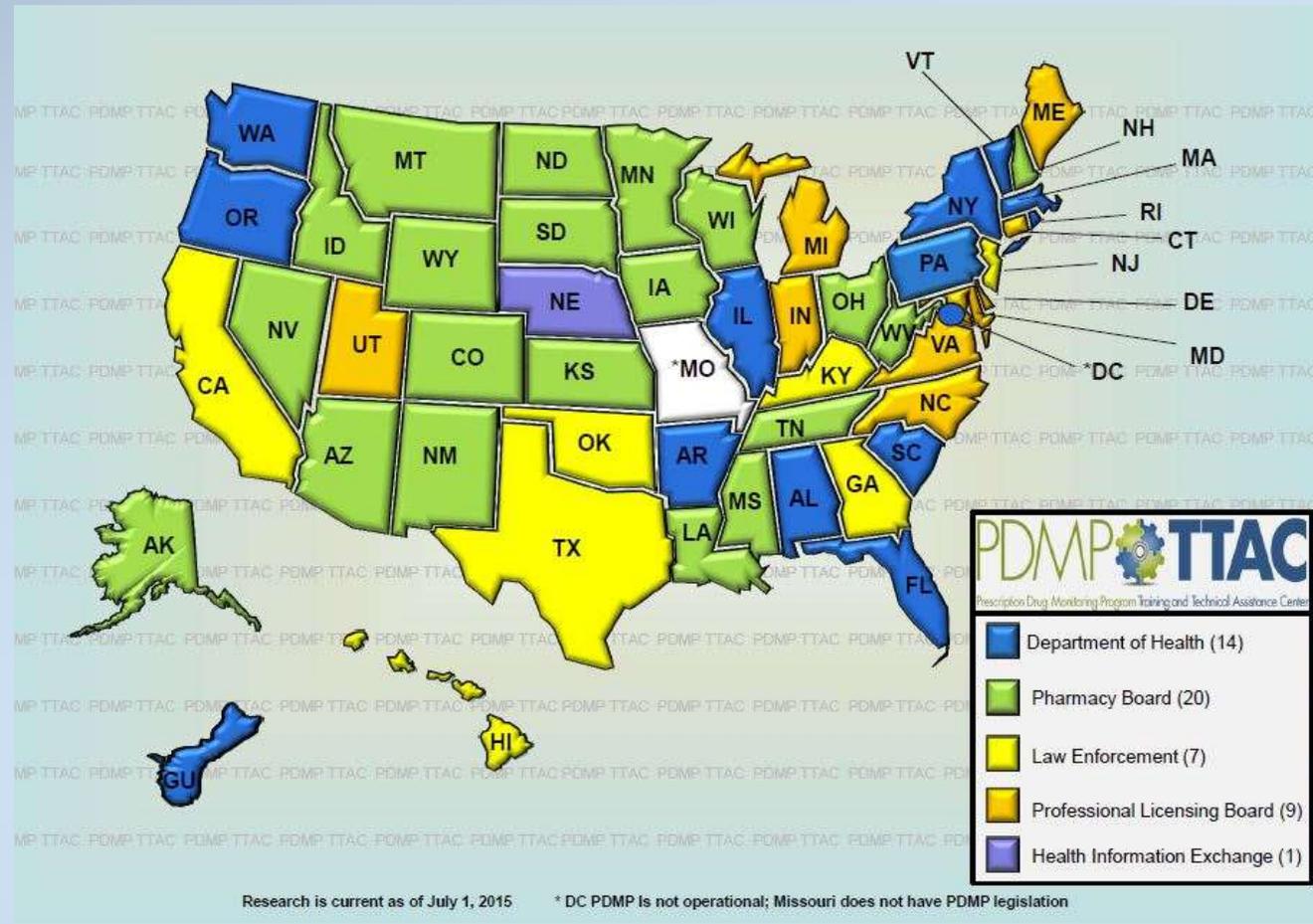
Oklahoma (1990) First electronic PDMP/PMP

- Federal grants – plan, establish, enhance, improve
  - Harold Rogers PMP Grants 2003-2014
  - Substance Abuse and Mental Health Services Administration (SAMHSA)
  - Office of National Coordinator for Health Information (ONC)
- Health care and law enforcement purposes

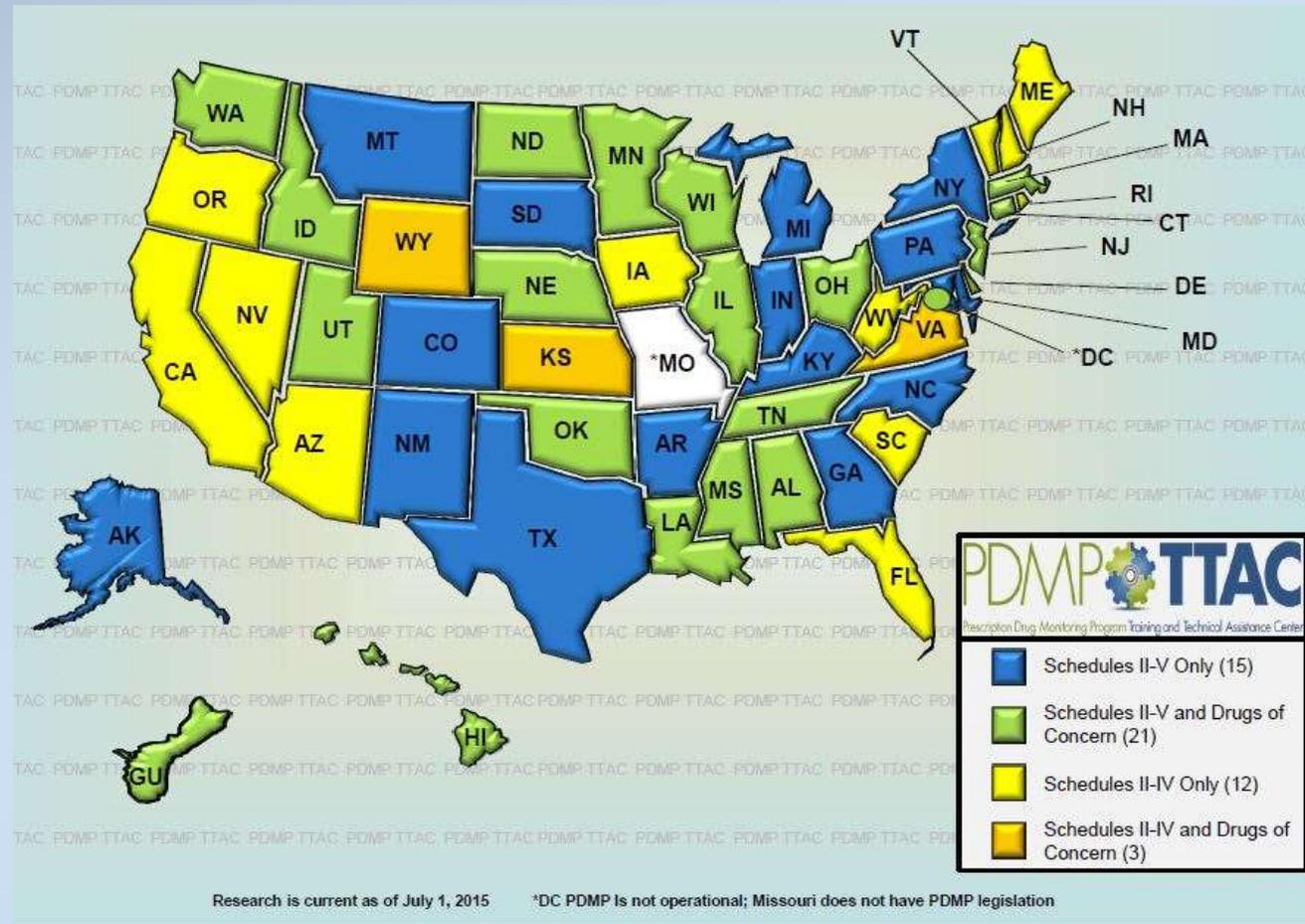
# Status of PDMPs



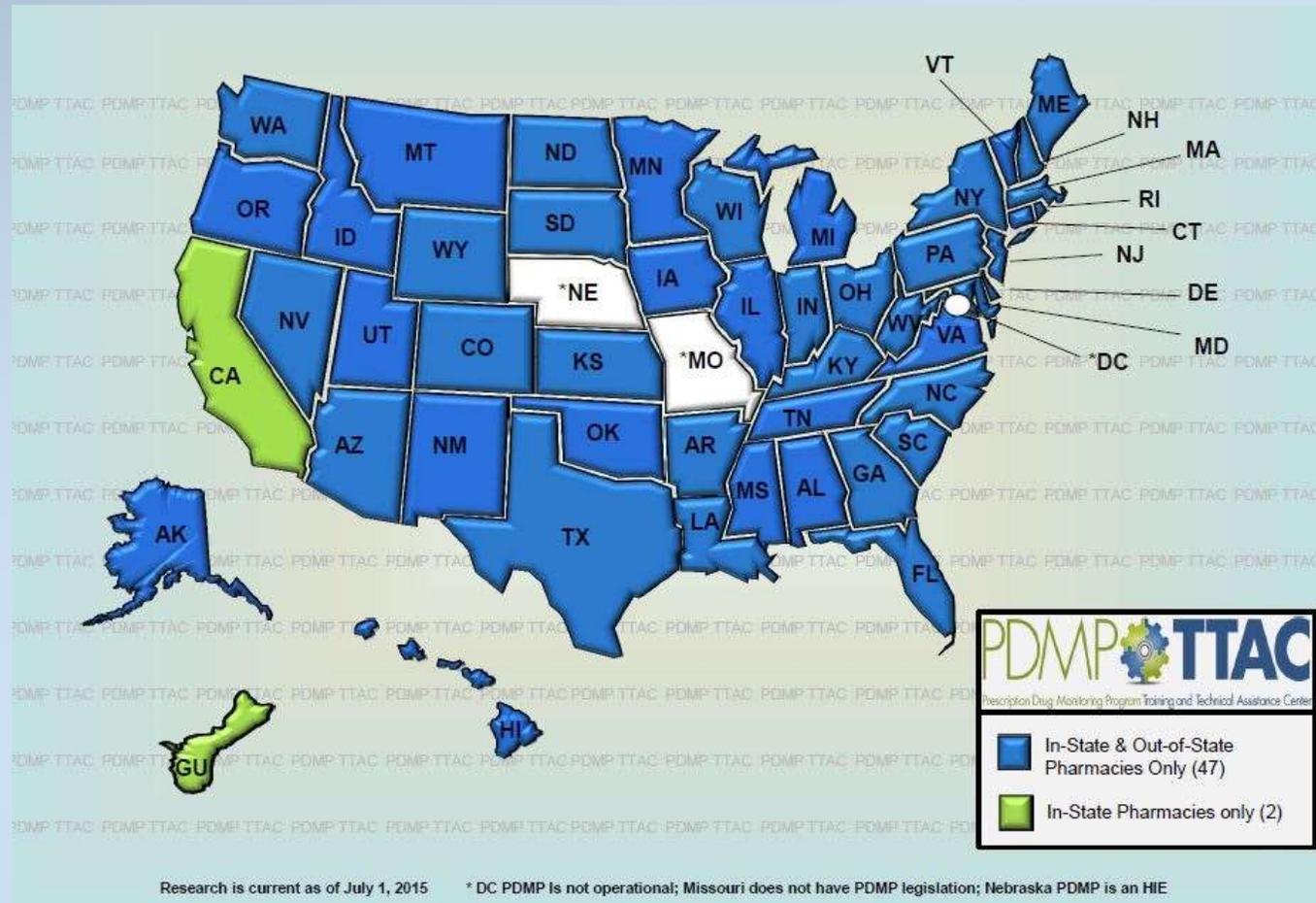
# Where is the PDMP housed?



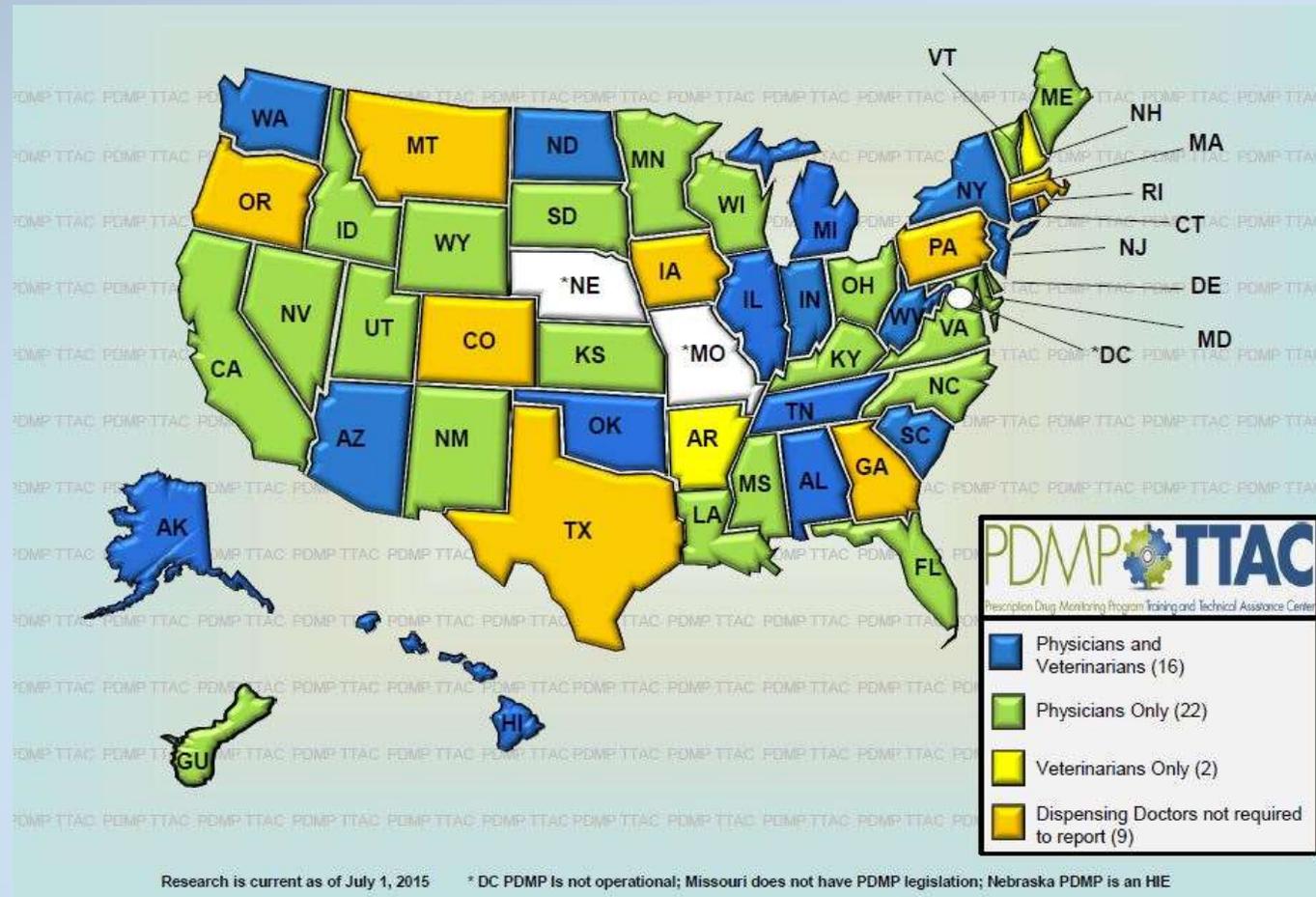
# Drugs Monitored



# Who reports the data?

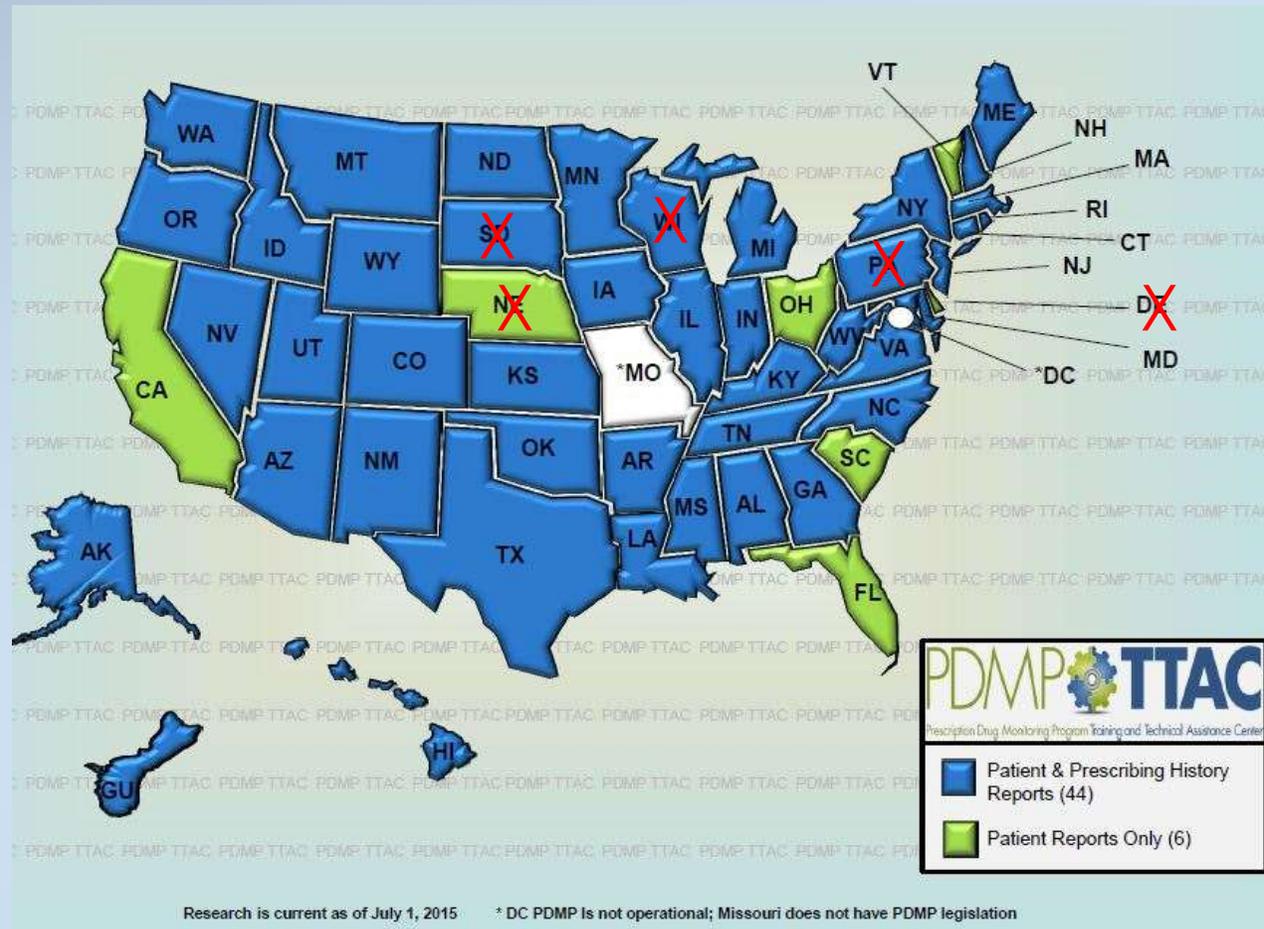


# Veterinarian Reporting

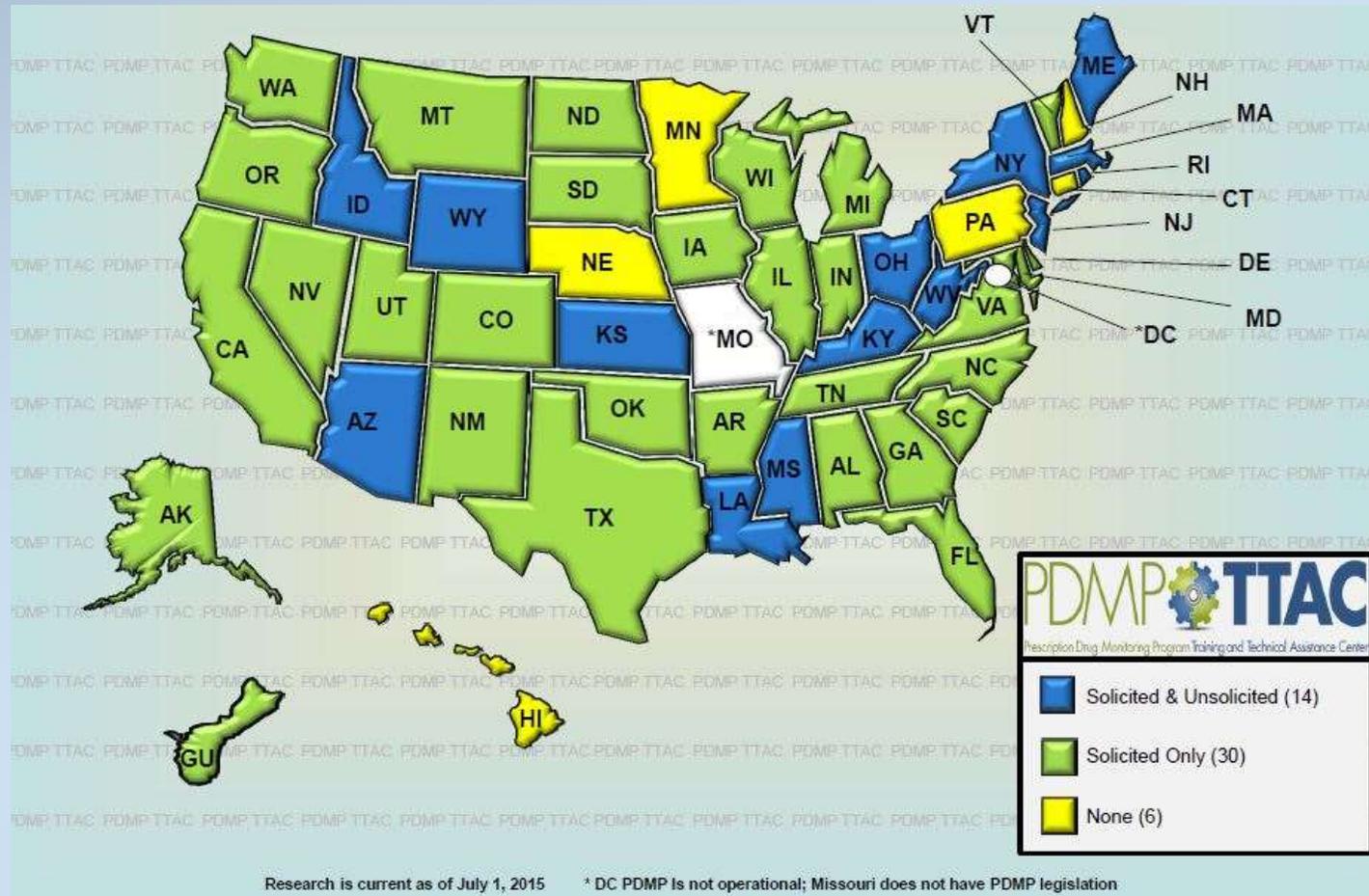




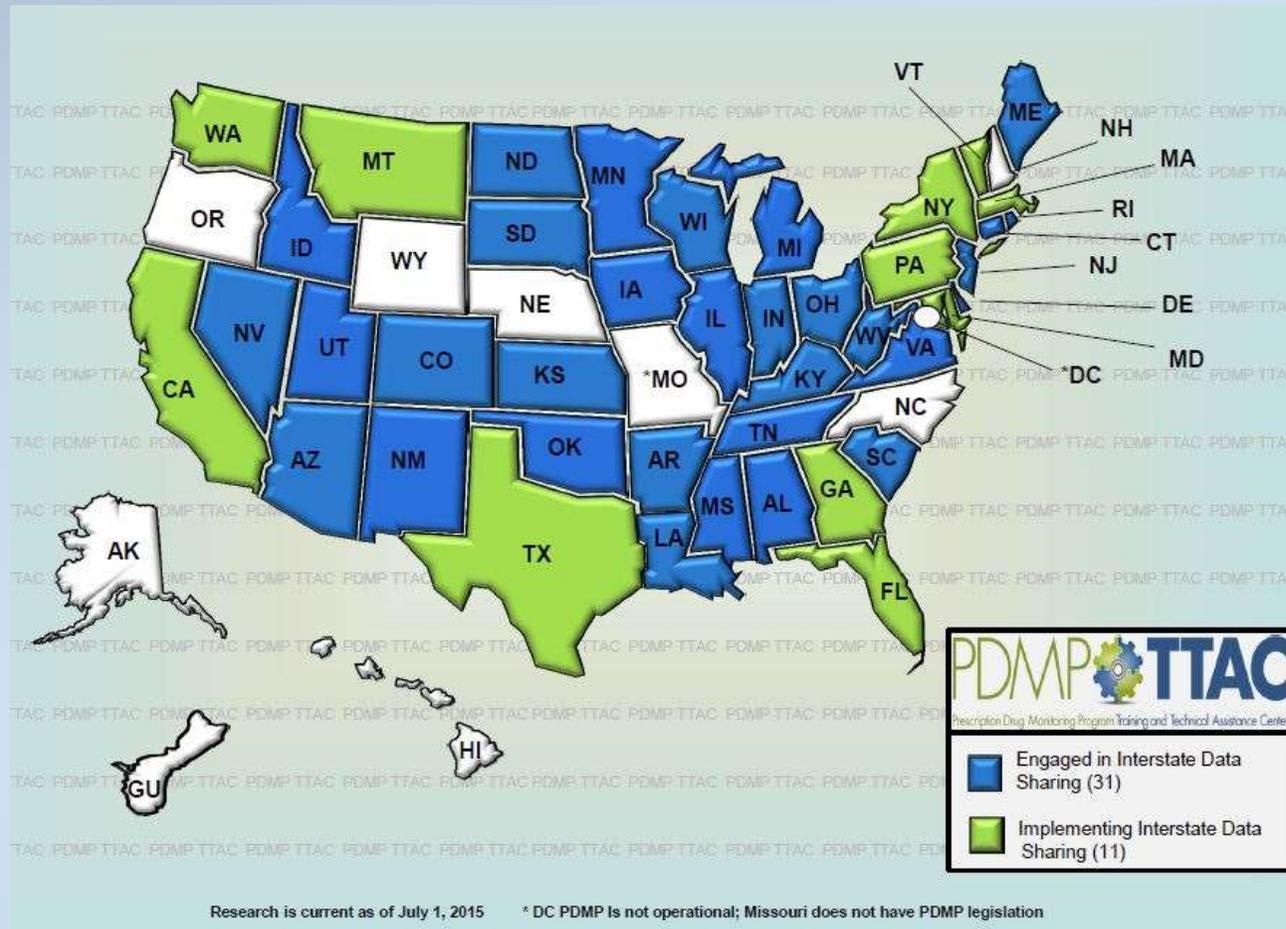
# Who has access to the data?



# Use by Licensing/Regulatory Agencies



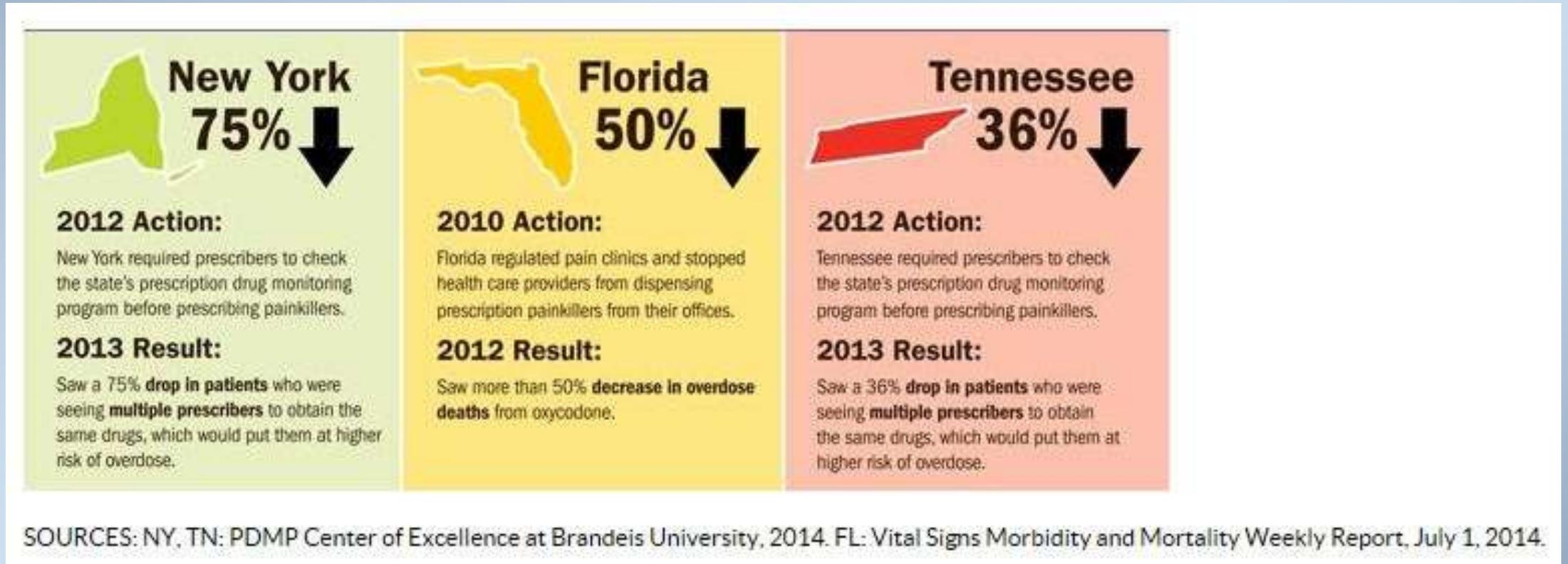
# Interstate Data Sharing



# Proactive/Unsolicited Alerts & Reports

- 45 states + D.C.
- PMP Administrator gives notice of unusual or “suspicious” activity
- Common triggers for alert
  - Reason to believe violation of law/standards
  - Patient visits certain number of prescriber/pharmacies within specific period of time
- Criteria for triggers vary by jurisdiction
  - Peer review committees
  - PMP capacity to send reports and alerts
  - Indicators of abuse/diversion
- Prescribers and dispensers – most common recipients of alerts

# Do PDMPs make a difference?



# What can you do?

- Timely reporting of prescriptions dispensed
- Use the PDMP
- Avoid overprescribing
- Properly dispose of unused medications
- Educate

# Veterinary Hospital-New York

- Controlled substances are medications that have been declared by federal or state law to be illegal for sale or use, except when dispensed under a physician's or veterinarian's prescription. The basis for control and regulation is the danger of addiction, abuse, physical and mental harm (including death), the trafficking by illegal means, and the dangers from actions of those who have used the substances.
- **A signed "CONTROLLED-SUBSTANCE AND NARCOTIC POLICY" is required if narcotic/controlled medications are prescribed for your pet.**
- Controlled-substances/narcotic prescriptions for your pet **require** a follow up appointment and examination every 30-90 days.
- Medications are for the prescribed pet's use only. You should not "share" your pet's medicine.

# PDMP Resources & Information

- National Association of State Controlled Substance Authorities

[www.nascsa.org](http://www.nascsa.org)

- National Alliance for Model State Drug Laws

[www.namsdl.org](http://www.namsdl.org)

- PDMP Training and Technical Assistance Center

[www.pdmpassist.org](http://www.pdmpassist.org)

Q & A



THANK YOU

