



Pharmacy Law Update

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Disclosures

Brian E. Dickerson “declare(s) no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.”



The American College of Apothecaries is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.



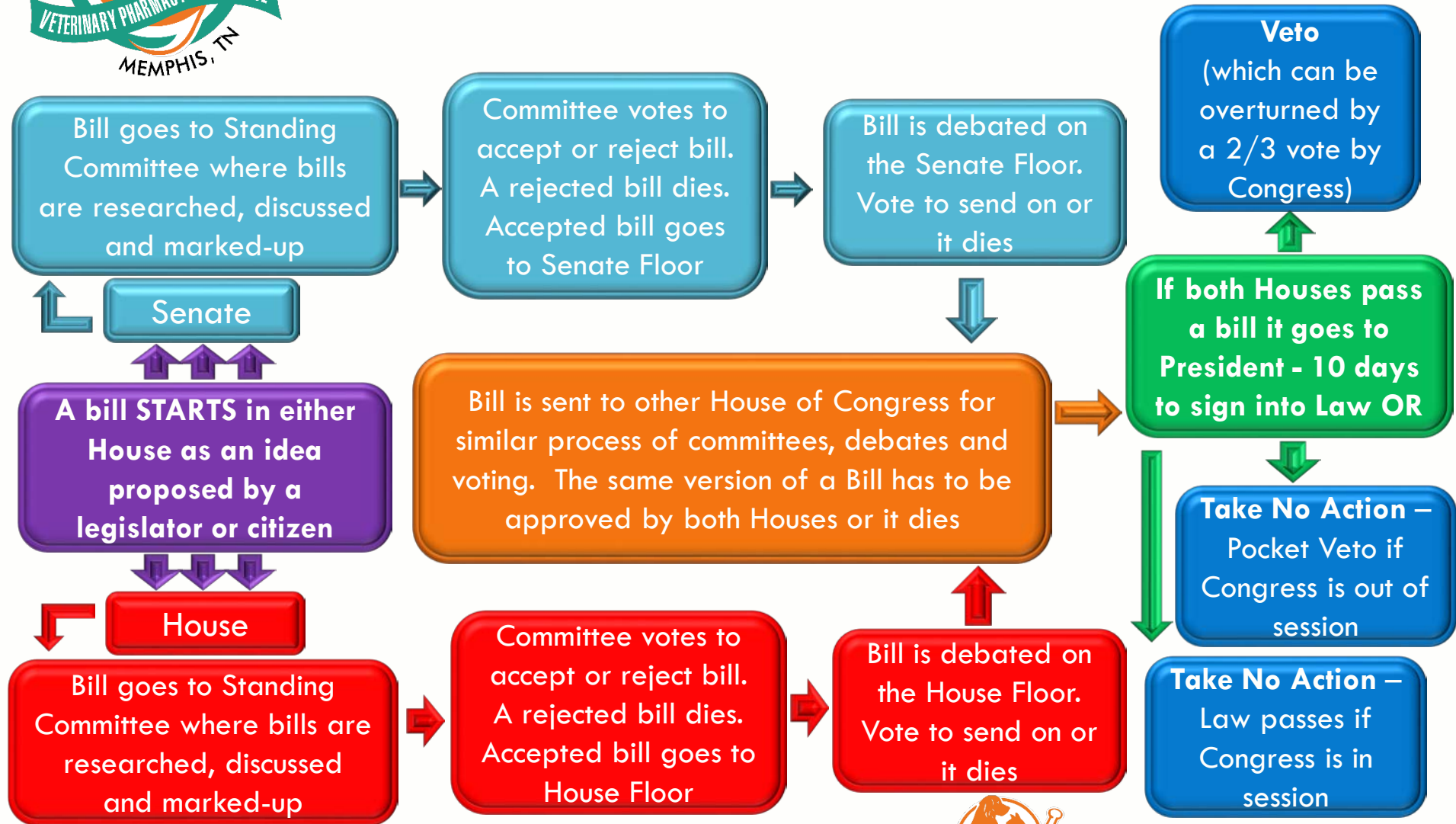
Learning Objectives

At the conclusion of this program, the participating pharmacist or technician will be able to:

- Outline the process for the law to become effective and implemented
- Define the most recent veterinary laws in effect now
- Identify the current veterinary bills being considered



How a Federal Bill Becomes a Law





What is a Lobbyist

- Lobbying is any attempt by individuals or private interest groups to influence the decisions of government.
- Lobbying takes place at every level of government, including federal, state, county, municipal, and even local governments.
- The practice of lobbying is regulated by the Federal Regulation of Lobbying Act of 1946, the Lobbying Disclosure Act of 1995 and is protected under the First Amendment.



Lobbying Takes Many Forms

- Group representatives may appear before legislative committees.
- Public officials may be “buttonholed” in legislative offices, hotels, or private homes.
- Letters and telephone calls to public officials.
- Organizations may provide candidates with money and services.
- Massive public-relations campaigns may be launched to influence public opinion.
- Extensive research into complex legislative proposals may be supplied to legislative committees by advocates of various and often conflicting interests.
- Substantial election campaign contributions or other assistance may be supplied to legislators or executives. The persons who lobby in these ways may be full-time officials of a powerful trade or agricultural association or labor union, individual professional lobbyists, or ordinary citizens.



How do Lobbyists Influence Federal Public Policy Decisions

- Lobbying efforts that are directed primarily at the national level include:
 1. Congressional Committees
 2. Regulation Agencies
 3. Executive departments.
- Lobbyists depend on their personal relationships with members of Congress and the executive branch. Many lobbyists have served in government themselves and have worked with the people they are now lobbying, which some would say gives them an advantage.
- Lobbyists testify at committee hearings and can also write the proposed legislation.
- Lobbyists also testify before regulatory agency administrative hearings, submit comments or file briefs, and draft the regulations their clients are required to operate under.





State Lobbying

- Companies and interest groups also concentrate their efforts at the State level.
- Legislation can be considered more effective at the State level compared to the Federal level with a higher percentage of bills introduced being passed.
- Each state has its own rules and policies governing lobbyists.



Executive Order 13771

Reducing Regulation and Controlling Regulatory Costs

- Issued January 30, 2017
- It is required that executive branch be financially responsible from both public and private sources.
- It is essential to manage the costs of private expenditures required to comply with Federal regulations.
- Therefore, for every one regulation issued at least two prior regulations are to be identified for elimination.
- Furthermore, the cost of planned regulations are to be prudently managed and controlled – adhere to a budget.





Executive Order 13777

Enforcing the Regulatory Reform Agenda

- Issued February 24, 2017
- It is the United States policy to alleviate unnecessary regulatory burdens placed on the American people.
- Within 60 days, the head of each agency (except those receiving waivers) shall designate an agency official as its Regulatory Reform Officer (RRO)
- Each RRO shall oversee implementation of regulatory reform initiatives and policies to ensure agencies carry out regulatory reforms.





Link

Draft Guidance for the Industry #230 Compounding Animal Drugs from Bulk Drug Substances

[http://www.fda.gov/downloads/animalveterinary/
guidancecomplianceenforcement/guidanceforindust
ry/ucm446862.pdf](http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm446862.pdf)



Compounding Governing Law

- Federal

- Federal Food Drug and Cosmetic Act (Enforcing Agency is the FDA)

- **Draft** Guidance for Industry #230 – “Compounding Animal Drugs from Bulk Drug Substances”

- Issued in 2015 – STILL NOT FINAL

- State

- Pharmacy Rules





Compounding Federal Requirements

- Two types of compounding
 - Approved drug products
 - Manipulating a product that has already been through the FDA approval process - follow Extra Label Drug Use Rules (no changes on the horizon)
 - Bulk drug substances – currently ALL outside of the rules according to the FDA





Compounding Federal Requirements

- Guidance for Industry #230 (GFI 230)
 - Issued in *May 2015* as Draft
 - **To date, not issued in Final form – no indication as to when or if final guidance is forthcoming from FDA**
 - Addresses the compounding of animal drugs from bulk drug substances
 - Guidance for pharmacists, veterinarians and outsourcing facilities



Compounding Federal Requirements

- GFI 230 set out policy on when FDA WILL NOT take action under FD&C Act for bulk compounding
 - Policy for pharmacists is set out in Section III.A
 - Policy for veterinarians is set out in Section III.B
 - Policy for outsourcing facilities is set out in Section III.C





Compounding Federal Requirements

- Bulk Compounding by Pharmacists – Conditions
 - Keep adequate records to demonstrate compliance!
 - 1. compounding performed by or under supervision of licensed pharmacist
 - 2. drug dispensed after receipt of valid prescription for individually identified animal patient (check state rules on valid prescriptions and note quantity limitations)
 - 3. species of animal identified on prescription and statement that compounded drug cannot be made from FDA approved drug.





Compounding Federal Requirements

- 4. label identifies species of animal patient, name of animal patient and name of owner/caretaker
- 5. compounding ONLY for non-food animals
- 6. bulk drug must be acquired from FDA registered supplier with valid certificate of analysis
- 7. drug must be compounded in compliance with USP chapters 795 and 797
- 8. drug cannot be sold or transferred – can only be dispensed to identified animal patient
- 9. adverse affects reported to FDA within 15 days





Compounding Federal Requirements

- Bulk Compounding by Vets
 - 1. compounded and dispensed by vet to treat individually identified animal patient under his or her care
 - 2. no compounding for food producing animals
 - 3. note change between compounded drug and FDA-approved drug that produces clinical difference
 - 4. no available FDA approved drug
 - 5. no sale or transfer of drug by compounding vet
 - 6. other requirements as for pharmacist





Compounding Federal Requirements

- Bulk compounding by outsourcing facilities
 - 1. only from bulk substances appearing in Appendix A (no Appendix A ever finalized!)
 - 2. compounding only by licensed pharmacist or under direct supervision
 - 3. drug compounded under current good manufacturing practice requirements
 - 4. bulk drug substance obtained from FDA registered supplier and have valid certificate of analysis





Compounding Federal Requirements

- 6. Adverse affects reported to FDA within 15 days
- 7. No sale or transfer by any entity other than outsourcing facility
- 8. All drugs compounded must be included in 503B report to FDA twice yearly
- 9. Vet prescription or order verifies that drug is intended to treat species and condition for which substance is listed in Appendix A
- 10. No compounding for food-producing animals verified in prescription
- 11. Lengthy list of labeling requirements





Compounding State Requirements

- Various state laws exist regarding compounding by veterinarians – can run counter to or reinforce FDA guidance. Some jurisdictions are silent.
- American Veterinary Medical Association provides a breakdown of states laws and regs by category.



Compounding State Requirements

- State laws and regs that allow veterinary offices to *administer* compounded products and *dispense* the products to clients but may be subject to conditions or limitations:
 - California, Colorado, Florida, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, Ohio, Tennessee, Texas, Virginia





Compounding State Requirements

- State laws and regs that allow veterinary offices to *administer* compounded products but do not specifically address or *the law is not clear regarding dispensing products compounded by a pharmacy*:
 - Idaho, Illinois, Mississippi, Montana, Nevada, New Hampshire, New Jersey, Oregon, South Carolina





Compounding State Requirements

- State laws and regs that allow veterinary offices to administer compounded products but specifically prohibit them from dispensing or reselling products compounded by a pharmacy:
 - Alabama, Alaska, Arizona, Arkansas, Connecticut, Georgia, Iowa, Kentucky, Louisiana, Missouri, North Carolina, North Dakota, Oklahoma, Rhode Island, Utah, Vermont, Washington, West Virginia, Wyoming





Compounding State Requirements

- States that prohibit compounding for office use:
 - Delaware, New Mexico, New York
- No laws or regs addressing compounding:
 - Hawaii, Indiana, Kansas, Pennsylvania, South Dakota, Wisconsin





Compounding State Requirements

- States with recent changes or proposed changes
 - **Maryland** – Change in state law effective 10/1/2016. SB 614, “provides an exception to state pharmacy law, specifying that it does not prohibit a licensed veterinarian from dispensing compounded preparations, provided by pharmacy, for use in a companion animal, under specified circumstances. A pharmacy would be authorized to provide certain preparations without a patient-specific prescription to a licensed veterinarian.”





Compounding State Requirements

- **Colorado** - HB 1324 effective 8/10/2016. The law now authorizes a compounding pharmacy to compound and distribute a drug to a veterinarian without a specific patient indicated to receive the compounded drug; and a veterinarian to dispense a compounded drug, maintained as part of the veterinarian's office stock, in an amount not to exceed 5 days' worth of doses, if a patient has an emergency condition that the compounded drug is necessary to treat and the veterinarian cannot access, in a timely manner, the compounded drug through a compounding pharmacy.





Compounding State Requirements

- **Delaware** – Delaware revised its Board of Pharmacy regulations in March 2016 by adding the following:

5.1.7 Compounded medications for office use

5.1.7.1. Non-patient specific compounded products may not be sold to the practitioner for use in his or her office to administer to patients unless authorized by Federal authority.



Compounding State Requirements

- **Ohio** – Effective 2/22/16, new Board of Pharmacy regs include provisions under which drugs may be compounded by a pharmacy for use by a veterinarian. A pharmacist may provide, without a prescription, a non-patient specific drug for the purpose of the direct administration to patients. Veterinarians may dispense up to a 7-day supply of the medication





Compounding State Requirements

- Measures that failed:
 - Massachusetts HB 3989 died in chamber. The bill would have permitted a veterinarian to dispense a compounded drug, that is not prepared from bulk supplies, to the veterinarian's patient under limited circumstances.
 - New York A08167 would permit veterinarians to keep an inventory of certain compounded drugs for emergency use. The bill died in committee.



Other Veterinary Pharmaceutical Bills - Federal

- In the 114th Congress that just ended on Jan. 3, 2017, a number of bills were circulating related to pharmaceutical issues and the veterinary industry. **NONE** of the following were enacted, but they may be reintroduced in the 115th Congress.



Other Veterinary Pharmaceutical Bills - Federal

- **Fairness to Pet Owners Act** – Veterinarians would be required to provide pet owners with a copy of their pet's prescriptions, whether or not requested and prior to offering to fill or dispense the medication. The veterinarian may not require payment for the prescription or require the pet owner to sign a waiver or disclaim liability.



Other Veterinary Pharmaceutical Bills - Federal

- **Preservation of Antibiotics for Medical Treatment Act -**
The bill would have amended the FD&C Act to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases.
- **Preventing Antibiotic Resistance Act –** A bill to amend the FD&C Act to require FDA to refuse a new animal drug application if the drug is a medically important antimicrobial (used to treat humans) and the applicant fails to demonstrate that the drug meets specified criteria for use in animals.





Other Veterinary Pharmaceutical Bills - State

- Colorado – Effective 7/1/2016 Colorado created a 3-person veterinary pharmaceutical advisory committee to which the board of pharmacy refers matters concerning veterinary pharmaceuticals.
- Mississippi – Board of Pharmacy - final rule change provides that dispensing by a veterinarian is exempt from required reporting to the Prescription Drug Monitoring Program effective 2/10/2016
- New Hampshire – Veterinarians must report dispensing controlled substances within 7 business days. Eff. 1/26/2016





Need More Information?

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