Report of the Task Force on Best Practices for Veterinary Compounding

Members Present:

Mark Hardy (ND), *chair;* Jillian Foster (MS); Diane Halvorson (ND); Brenda McCrady (AR); William Mixon (NC); Patti Smeelink Keim (MI); Krystal Brashears Stefanyk (NC); Jennifer Yoakum (TX); Anita Young (MA).

Others Present:

Timothy D. Fensky, *Executive Committee liaison;* Julie Dohm (FDA*)*; Diana Link (FDA); Kent McClure (AVMA); Jim Penrod (AAVSB), *guests;* Gigi Davidson, *Subject Matter Expert*; Melissa Halvorson, *PharmD Candidate;* Carmen Catizone; Melissa Madigan; Eileen Lewalski; Maureen Schanck; Romy Schafer, *NABP staff*.

Introduction:

The Task Force met on August 14-15, 2017, at NABP Headquarters in Mount Prospect, IL. This task force was established in response to Resolution 113-1-17, Best Practices for Veterinary Compounding, which was approved by the NABP membership at the Association's 113th Annual Meeting in May 2017.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing state laws and regulations addressing compounding of animal (non-food-producing) products.
2. Review existing federal laws and regulations pertaining to the compounding of animal (non-food-producing) products.
3. Determine the applicable role of state boards of pharmacy in regulating the compounding of animal (non-food-producing) products and develop model regulations to amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* accordingly.

Recommendation 1: NABP Should Amend the *Model Act*

The task force recommends that NABP amend the *Model Act*. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

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Section 105. Definitions.

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(x) "Compounding" means the preparation, mixing, assembling, altering, packaging, and Labeling of a Drug, Drug-Delivery Device, or Device, unless performed in a Food and Drug Administration (FDA)-registered Outsourcing Facility in conformance with Federal law, are in accordance with a licensed Practitioner's prescription, medication order, or initiative based on the Practitioner/patient/Pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

(1) preparation of Drug dosage forms for both human and animal patients;

(2) preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns[7]; and

(3) ~~reconstitution or~~ manipulation of commercial Products ~~that may require the addition of one or more ingredients~~ for patient-specific needs beyond the manufacturer's labeling[1].

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(t2) "Drug" means:

(1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;[2]

(2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and

(4) articles intended for use as a Component of any articles specified in clause (1), (2), or (3) of this definition.

[7] Anticipatorily Compounded Drugs may not be dispensed until receipt of a patient-specific Prescription Drug Order.

[1] Reconstitution of an FDA-approved Drug according to the FDA-approved Labeling is not Compounding.

[2] The official compendium recognized by Food and Drug Administration (FDA) and many State Boards of Pharmacy is the USP-NF.

(m4) "Outsourcing Facility"[3] means a facility at one geographic location or address that[4]:
(1) is engaged in the Compounding of sterile drugs for human use;
(2) is registered as an Outsourcing Facility with FDA; and
(3) complies with all of the requirements of Section 503B of the Federal FD&C Act.

(dd6) "Veterinary Dispensing" means the interpretation, evaluation, and implementation of a veterinary Prescription Drug Order, including the preparation, final Verification, and Delivery of a Drug for a veterinary patient in a suitable container appropriately labeled for the client for subsequent Administration.

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National Association of Boards of Pharmacy Model Rules

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Model Rules for Compounded or Repackaged Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure Compounded Pharmaceuticals are prepared and Dispensed according to practice and quality standards through the provision of: (1) Pharmacist Care Services; and (2) the preparation, Labeling, and Distribution of Compounded or Repackaged Pharmaceuticals by Pharmacies. These standards are intended to apply to all Sterile and nonsterile Compounded Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor's office). All facilities and Practitioners engaging in Sterile and nonsterile Compounding or Repackaging shall practice in accordance with Federal law, these Rules, and the current United States Pharmacopeia–National Formulary (USP-NF), including but not limited to General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations,* General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations,* General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings,* and other applicable referenced general chapters. The procedures contained herein are considered to be the minimum current good compounding practices for the Compounding of Drug Products by State-licensed Pharmacies for Dispensing and/or Administration to humans or animals.[5]

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Section 9. Compounded Drug Preparations For Veterinary Use[6]

(a) The use of bulk drug substances for Compounded preparations is prohibited except when:
(1) There is no marketed-approved, conditionally-approved, or index-listed animal Drug that can be used as labeled to treat the condition.
(2) There is no marketed-approved animal or human Drug that can be used to treat the condition through off-label Drug use.

[3] Outsourcing Facilities may engage in Compounding for animal use.
[4] Boards may choose to license an Outsourcing Facility as a Pharmacy; however, if a Pharmacy and an Outsourcing Facility are located at the same geographic location or address, or are located adjacent to said location or address, there must be a clear delineation between the two entities and both must comply with current Good Manufacturing Practices as defined by the Federal FD&C Act.
[5] The Compounding of Drugs for animals must be done in accordance with the algorithm contained in Animal Medicinal Drug Use Clarification Act of 1994 and associated FDA Guidances.
[6] This section is intended for non-food-producing animals. For food-producing animals, refer to Federal and State laws and rules.

(3) The Drug cannot be appropriately Compounded from an approved animal or human Drug.
(4) Immediate treatment with the Compounded drug is necessary to avoid animal suffering or death, and
(5) FDA has not identified a significant veterinary safety concern with the use of the bulk Drug substance for Compounding.

(b) It is acceptable for any licensed Pharmacy to Compound veterinary Drug preparations to be used by veterinarians in their office for Administration to client's animals.

(c) Compounded office use preparations may be Dispensed by a veterinarian to clients only in an urgent or emergency situation for use in a single course of treatment, not to exceed 120-hour supply.

(d) Prohibition on wholesaling
The Compounded veterinary preparations will not be Distributed by an entity other than the Pharmacy that Compounded such veterinary Drug preparations. This does not prohibit Administration of a Compounded Drug in a veterinary health care setting or Dispensing a Compounded Drug preparation pursuant to a Prescription Drug Order executed in accordance with Federal and State law. Providing samples of Compounded veterinary preparations is prohibited.

Background:
The task force members reviewed the United States Food and Drug Administration (FDA) policy enumerated in its guidance document regarding compounding for veterinary use. The discussion included the fact that FDA, generally, will use enforcement discretion and not take action against pharmacies that compound using approved human or veterinary drugs. This discussion also detailed FDA's position that pharmacy compounding from bulk drug substances should be pursuant to a patient-specific prescription. Furthermore, the task force members were informed that FDA will also use enforcement discretion when it comes to FDA-registered outsourcing facilities that compound using bulk drug substances for veterinary office use if the outsourcing facilities use bulk drug substances that appear on FDA's approved list and have not been identified as a safety concern, as FDA is still seeking nominations for bulk drug substances to be included in this list.

The members concluded that a new definition of veterinary dispensing should be added to the *Model Act* to recognize the importance of this emerging role in pharmacist care services. Furthermore, the members also recommended that a new section be added to the Model Rules for Compounded or Repackaged Pharmaceuticals to incorporate FDA's current position and identify appropriate instances for compounding for office use by veterinarians, and subsequent dispensing for emergency situations.

Recommendation #2: NABP to Collaborate With Stakeholders to Assist Them in Developing Model Language on Veterinary Compounding.

The task force recommends that NABP collaborate with stakeholders such as the American Association of Veterinary State Boards (AAVSB), the American Veterinary Medical Association (AVMA), and state veterinary associations to assist them in developing model language on veterinary compounding to provide regulatory boards with the framework to enhance regulation.

Background:

The task force members pondered about the medical need for compounded preparations from bulk drug substances and with the fact that FDA does not authorize this practice and exercises regulatory enforcement discretion. Furthermore, the members also noted that compounding regulatory language is often written in human terms.

Members reviewed state laws and rules that authorize pharmacies to compound and dispense a limited supply for office use to meet an unmet need. This does not seem to conflict with the Drug Quality and Security Act since FDA has clearly delineated this law to be for human drugs. The task force members expressed concern about pharmacists who compound indiscriminately to increase profit without regard to patient safety.

Representatives from AVMA and AAVSB discussed the value of collaboration between NABP and stakeholders to align regulatory language and further clarify and understand the issues of concern. Stakeholders await updates from FDA regarding its guidance document and will monitor for any FDA enforcement action.

Recommendation #3: NABP to Collaborate With Stakeholders to Encourage Veterinary Drug Education in Schools and Colleges of Pharmacy and CPE Activities.

The task force members recommend that NABP collaborate with the American Association of Colleges of Pharmacy (AACP), the Accreditation Council for Pharmacy Education (ACPE), and other stakeholders to encourage veterinary drug education in schools and colleges of pharmacy and continuing pharmacy education (CPE) activities to educate pharmacists to better serve veterinary patients.

Background:

The task force members supported NABP collaborating with other pharmacy education stakeholders, such as AACP and ACPE, to educate pharmacists and pharmacy students on veterinary dispensing. It is through this education that the task force members felt safety concerns for veterinary dispensing may be addressed.

The members and guests discussed several issues related to prescribing practices for animals as opposed to prescribing practices for humans that may lead to medication errors. One such issue involves the use of abbreviations, as certain abbreviations in animal medicine may differ in meaning from those in human medicine or may not exist as abbreviations at all. Additionally, lack of appropriate drug dosing knowledge was identified as a large potential for error as dosing ranges can vary greatly from human-use dosing. The last major gap in prescribing practices discussed was the use of the phrase “brand necessary”; while commonly used in communication of human prescriptions, veterinarians do not currently use this phrase in their prescribing or effectively convey this message.

The members agreed that continuing education may be helpful in solving immediate safety concerns for veterinary dispensing, but determined that the use of a universal language should be considered in pharmacy and veterinary curricula to facilitate accurate communication among practitioners.

Recommendation #4: NABP to Distribute Information to Pharmacists via NABP Publication Vehicles.

NABP to distribute information to pharmacists via NABP publication vehicles, including the national news section of the NABP state newsletters, to keep pharmacists and pharmacy boards apprised of veterinary compounding issues.

Background:

The task force members agreed that NABP should continue to provide educational opportunities for pharmacists through the *Innovations* newsletter and other publications, such as the quarterly *National Pharmacy Compliance News.* Suggested areas of content include: differences in prescribing practices, common dosing ranges for common animals, ways pharmacokinetics may differ in animals compared to humans, etc.

Recommendation #5: NABP to Collaborate With Stakeholders to Determine Appropriate Entities to Develop a Veterinary Pharmaceutical Care Certification Program for Pharmacists.

NABP to collaborate with stakeholders to determine appropriate entities to develop a veterinary pharmaceutical care certification program for pharmacists to demonstrate competency in veterinary compounding.

Background:

Task force members determined that specialty knowledge and maintenance of that knowledge is very important for pharmacists who routinely compound veterinary medications. Additionally, several task force members voiced concern that many pharmacies call themselves veterinary pharmacies without the staff or facility having any certification or accreditation to support their claims. Therefore, task force members supported the development of an optional certification for pharmacists to demonstrate competency in veterinary compounding. This will assist veterinarians and their clients in identifying the safest places to obtain medication. Task force members who compound veterinary medications affirmed they would obtain such certification, if available.