



Ensuring Quality Pharmacy Compounding: Implications for Pharmaceutics Education

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What is PCAB?

- Founded by:

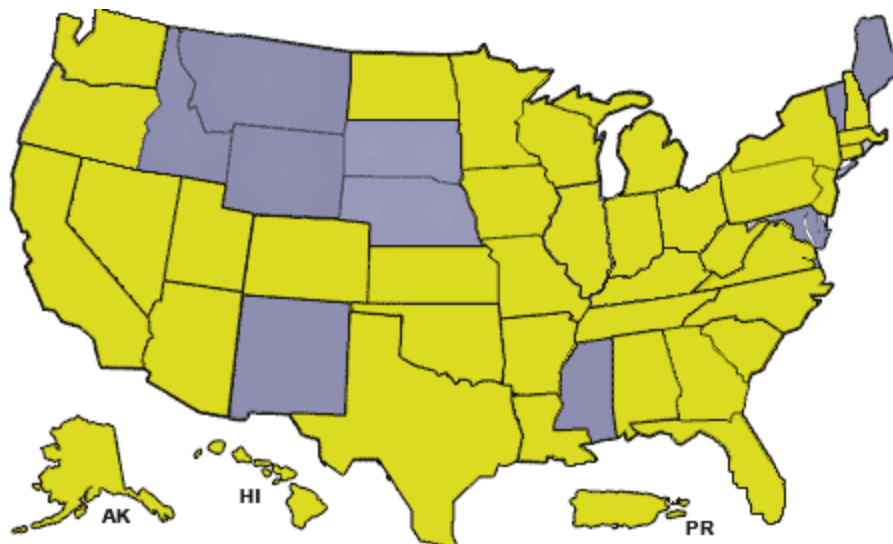


U.S. PHARMACOPEIA

Numbers



- 204 applicants from 40 states
- Of these, 61 pharmacies are accredited from 27 states (as of 8 JUL 2009)





AMA policy 120.945 (2006)

States in part,

Our AMA

2. recognizes the accreditation program of the Pharmacy Compounding Accreditation Board (PCABTM) and the PCABTM Seal of Accreditation as a means to identify compounding pharmacies that adhere to quality and practice standards, including those set forth in the USP-NF, for the preparation of individualized medications for specific patients;
3. encourages all state boards of pharmacy to require compounding pharmacies in their states to obtain the PCABTM Seal of Accreditation or, alternatively, to satisfy comparable standards that have been promulgated by the state in its laws and regulations governing pharmacy practice



2008 APhA policy

States in part:

5. APhA supports accreditation of compounding sites by PCAB to ensure patient safety. APhA encourages state boards of pharmacy to recommend accreditation for those sites that engage in more than basic non sterile compounding as defined by PCAB.
6. APhA supports the development of education, training and recognition programs that enhance pharmacist and student pharmacist knowledge and skills to engage in compounding beyond basic, non sterile preparations as defined by PCAB.
7. APhA encourages the exploration of a specialty certification in the area of compounding through the Board of Pharmaceutical Specialties (BPS)

American Veterinary Medical Association Compounding policy statement

AVMA

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Issues

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AVMA policy

Compounding

(Oversight: COBTA; EB approved 11/00; revised 03/05; 04/09)

Compounding is the manipulation of a drug, other than in accordance with the FDA approved label, to make a different formulation of the drug to meet the needs of a specific patient.

Veterinarians need to be aware that compounding, including formulation in a novel drug delivery system (e.g. transdermal), may impact the absorption and depletion of a drug. This may result in drug concentrations that are above or below the therapeutic range and lead to the development of an adverse drug event, including therapeutic failure. In order to minimize the risk of adverse events associated with compounded drugs, the following actions are recommended:

1. The decision to use a compounded drug should be veterinarian (not pharmacist) driven, based on a veterinarian-client-patient relationship. Whenever possible the veterinarian should make that decision utilizing evidence-based medicine.
2. Compounding must be implemented in compliance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Compliance Policy Guide 608.400 titled Compounding of Drugs for Use in Animals. Use of compounded drugs in food animals is accompanied by food safety concerns that preclude their use unless information exists to assure a voidance of illegal tissue residues.
3. Use of a compounded drug should be limited to:
 - a. Those drugs for which both safety and efficacy have been demonstrated in the compounded form in the target species;
 - b. Disease conditions for which response to therapy or drug concentration can be monitored; or
 - c. Those individual patients for which no other method or route of drug delivery is practical.
4. Use of a compounded drug should be accompanied by the same precautions followed when using an approved drug, including counseling of the client regarding potential adverse reactions and attention to the potential for unintended human or animal exposure to the drug.

One element in evaluating the quality of a compounding pharmacy is whether the pharmacy is accredited by an independent accreditation body. For example, the Pharmacy Compounding Accreditation Board (PCAB) offers accreditation to compounding pharmacies that meet high quality and practice standards. Further information and a listing of PCAB-accredited pharmacies are available at www.pcab.org. Be aware that independent accreditation is different from association or professional

Search within Policies, Positions, Guide Lines.

= AVMA/SAVMA Members Only

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American Animal Hospital Association (AAHA)

- AAHA Board of Directors passed the following motion at its June 2009 meeting:
- **THAT AAHA ENDORSE THE ACCREDITATION PROGRAM OF THE PHARMACY COMPOUNDING ACCREDITATION BOARD (PCAB) AND RECOMMEND THAT VETERINARIANS ACQUIRE COMPOUNDED MEDICATIONS FROM PCAB ACCREDITED PHARMACIES WHENEVER FEASIBLE.**

Steps in PCAB Accreditation Process

- Application
 - Licensure info; SOPs
- Pre-survey review
 - Licensure verification; SOP & website review
- On-site survey
- Post-survey review
- Accreditation Committee

PCAB ACCREDITED™



Example of onsite procedure

Review 10-20 completed compounded preparations

- pull original Rx
- ask for Master Formulation Record
- look at labeling and patient education
- ask about recalls and have staff demonstrate process
- ask about BUDs and any accompanying documentation
- if shipping – review shipping process and follow-up post delivery
- appropriate storage if in Fridge & how does it get to patient (verification)
- QA checks (QC; particulates; etc)



PCAB Accreditation Committee

- Five members
- Chair – National Association of Boards of Pharmacy
- Vice-chair – United States Pharmacopeia
- Two pharmacists that own PCAB Accredited pharmacies
- Physician



Create user account

- Click on “Apply to PCAB”
- Submit demographic information
- Receive periodic updates from PCAB
- *FREE*
- First step in accreditation process



W I I F M



- Up to 15% credit from Pharmacists Mutual
- Marketing kit created by national PR firm
- Business generation (e.g. JCAHO-accredited hospitals seeking PCAB-Accredited pharmacies)
- More efficient operation (e.g. fewer throw-aways)



PCAB Standards

- PCAB requires compliance with USP <795> and USP <797>
 - See PCAB Standard 3
- PCAB Standard 2 deals directly with personnel competence

PCAB Standard 2.10

General

- *A pharmacy must document that all relevant personnel are competent to perform their assigned duties and must establish procedures for assessing that competency on an ongoing basis. Specific duties and responsibilities shall be clearly defined and described. A pharmacy shall retain documentation of current and ongoing education, training, and competency of all personnel involved in the compounding of preparations. Supervision of personnel shall be sufficient to assure preparation integrity and safety.*

PCAB Standard 2.20

Responsible Pharmacist

- *A pharmacy must provide documentation of education and training of the pharmacist responsible for the compounding activities. The pharmacist responsible for the compounding activities shall establish the scope of compounding practice of the pharmacy based upon the education and training of the personnel and the facilities and equipment of the pharmacy. The pharmacist responsible for the compounding activities shall be knowledgeable about the compounding processes of the pharmacy and shall be responsible for adherence to regulatory and accreditation standards.*

PCAB Standard 2.21

Compounding Pharmacist

- *The compounding pharmacist is responsible for ensuring that the compounded preparation has been prepared, labeled, stored, and properly packaged for dispensing. This shall include ensuring the stability and sterility of the preparation consistent with its preparation, labeling, and intended use. The compounding pharmacist is responsible for the completed compounded preparation, including in-process and end-process preparation verification.*

PCAB Standard 2.30

Compounding Personnel

- *A pharmacy must provide documentation of an education program that demonstrates and verifies that personnel responsible for the compounding of preparations are knowledgeable about the processes and procedures they employ. The pharmacy shall only utilize personnel that have been properly trained and educated, and that have demonstrated minimum competency in these areas. Pharmacies that engage in sterile compounding shall document and verify adequate didactic education and training in aseptic technique by those personnel authorized to assist and prepare sterile compounded preparations.*

Next steps for academia

- Revised standards – available for public comment this month
- Compounding pharmacy rotation sites using PCAB-Accredited pharmacies
 - PCAB has sample materials for setting up a compounding pharmacy rotation (e.g. learning objectives, etc.)
- PCAB-Accredited practice labs

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