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Facts about Compounding Pharmacies and Accreditation

What are Compounded Medications?

Compounded medications are prescriptions that are written by a physician, veterinarian or other legally authorized prescriber and prepared for an individual patient. They are not commercially available; rather, they are prepared by a pharmacist to meet an individual's unique needs as determined by the prescriber.

Compounded medications are necessary for a variety of reasons. Examples include:

- When a child needs a dose smaller than the manufactured dose.
- When a patient cannot tolerate an inactive ingredient in a manufactured medicine.
- When a doctor believes a medicine is needed for his or her patient, but a manufacturer has discontinued the medicine for economic reasons.

Compounded medications are safe and effective treatment options for patients. Prescribers customize prescriptions for patients when they believe compounded medications are that patient's best treatment option.

Why is Accreditation Important?

Compounding medications is an integral part of the practice of pharmacy, and with the demand of patient-specific compounded medications increasing each year, there is a need for an enhanced, profession-wide system of standards by which each compounding pharmacy can test its quality processes. While compounding pharmacy is regulated by the state, accreditation is an even more comprehensive way to ensure a compounding pharmacy is meeting the highest quality and safety standards.

Pharmacists also want to give patients and prescribers a way to select a quality pharmacy. The pharmacies seeking PCAB™ Accreditation want to be able to demonstrate that they are "the best."

The Pharmacy Compounding Accreditation Board Process

The Pharmacy Compounding Accreditation Board (PCAB) is a not-for-profit corporation formed by eight national pharmacy organizations that recognized the need for a national standards organization for compounding pharmacy. Together, these leading organizations developed the industry principles, policies and standards for the practice of compounding pharmacy, as well as the PCAB Accreditation criteria and processes.

Examples of specific quality and safety standards include:

Pharmacy Compounding Accreditation Board™
Fact Sheet

- PCAB™ Accredited compounding pharmacies can use only certain chemicals from highly reliable suppliers.
- PCAB Accredited compounding pharmacists and their technicians must receive regular, specialized training.
- PCAB Accredited compounding pharmacy facilities must meet design and other related standards to help ensure the area is clear and free of contamination.
- PCAB Accredited compounding pharmacies must meet or exceed USP <795> standards for non-sterile compounding and/or USP <797> standards for sterile compounding.
- PCAB Accredited compounding pharmacies agree to adhere to the PCAB “Principles of Compounding”

Pharmacies seeking accreditation must submit documented proof that they meet PCAB quality standards, submit their policies and procedures for regular review, and open their doors to regular physical inspections.

PCAB was founded by the American College of Apothecaries, American Pharmacists Association, International Academy of Compounding Pharmacists, National Alliance of State Pharmacy Associations, National Association of Boards of Pharmacy National Community Pharmacists Association, National Home Infusion Association and United States Pharmacopeia.

More detailed information about PCAB™ and the PCAB™ Accreditation process can be found on its Web site at www.pcab.org.