

## Frequently Asked Questions with Answers

### Why is PCAB uniquely qualified to accredit compounding pharmacies?

PCAB brings together the expertise of the leading pharmacy organizations in the United States in the field of compounding pharmacy. Through these organizations, PCAB is able to assemble **THE** experts in the field. For example, PCAB's Standards Committee includes some of the nation's leading compounding pharmacists, as well as some who literally "wrote the book" on compounding. No one is more dedicated to protecting patients and the profession than the pharmacists represented by these organizations. They know what to look for, what can be done and what should not be done – and are determined to accept into their ranks only the best.

In addition, the National Association of Boards of Pharmacy (a PCAB member organization) represents all 50 state pharmacy regulatory boards, as well as those from the U.S. territories and most Canadian provinces. These boards of pharmacy represent not the pharmacies in their states, but the citizens (patients) of the state.

Finally, PCAB member the United States Pharmacopeia, formed in 1817, is the premier drug and chemical standards organization in the world (and sets standards for the pharmaceutical industry). The U.S. government recognizes USP standards as official.

### Which organizations are members of the PCAB Board of Directors?

- American College of Apothecaries
- National Community Pharmacists Association
- American Pharmacists Association
- National Council of State Pharmacy Association Executives
- International Academy of Compounding Pharmacists
- National Home Infusion Association
- National Association of Boards of Pharmacy
- United States Pharmacopeia

### Is PCAB Accreditation mandatory for every compounding pharmacy?

No, PCAB Accreditation is voluntary.

### What are the necessary steps to obtain PCAB Accreditation?

- Agree to the rules and terms of accreditation set by PCAB
- Agree to abide by the PCAB Principles of Compounding
- Submit documented proof that it meets the PCAB standards of quality
- Agree to a review of that proof
- Open the pharmacy to a physical inspection by experts who must verify that the pharmacy meets all of PCAB's stringent standards

- Pay an annual fee

### **Why is compounding pharmacy accreditation necessary?**

Accreditation is necessary to:

- Protect our patients by providing the finest-quality compounding services possible
- Provide high-quality compounding pharmacies with a way to demonstrate their high standards to patients and prescribers
- Give the high-quality pharmacies a competitive advantage in the market place
- Raise the quality of all compounding pharmacies by pushing pharmacies with less-stringent practices to adopt higher standards or leave the market
- Protect pharmacists and their patients from the errors and resulting injuries caused by any slip in quality

### **How will accreditation be good for my business?**

Accreditation will provide assurance to patients and prescribers that your pharmacy is among the best. It will allow you to differentiate your pharmacy and your compounding practice from others that have not earned the PCAB Accreditation Seal

### **What happens if my pharmacy does not receive PCAB Accreditation on our first attempt?**

No pharmacy “fails,” but some may not pass on the first review. The pharmacy will be provided with comments and information about its deficient areas, and encouraged to correct them.

### **How can we be sure that accreditation will improve the quality of compounding pharmacies?**

The question is not whether the quality of compounding will improve. The question is does your pharmacy meet the highest standards for quality in the pharmacy profession? Pharmacies that already meet those standards may not improve, but you will know that your practice has been tested against tough standards. In that way, your pharmacy has a plan designed to assure that high quality. All other pharmacies will be encouraged by competition to be just as good as you.

### **Will accreditation lower my risk of liability as a prescribing physician/vet?**

A pharmacy that compounds a prescription to the highest standards will have fewer errors. Fewer errors equals a reduced risk of harm to the patient – and in turn, lowers your risk of liability.

Also, remember why you went into a healthcare profession: to help people. You should insist that your patients receive the highest-quality service available. Accreditation gives you a way to provide it.

### **How will PCAB Accreditation minimize the risks associated with compounding?**

The risk of any professional service is minimized by a quality process. PCAB Accreditation provides the testing against quality standards that allows all to judge where the risks are most minimized.

**What quality standards does PCAB use for accreditation?**

PCAB standards have been written by a Standards Committee of compounding pharmacists, academics and experts. The complete standards can be seen on our Web site at [www.pcab.info](http://www.pcab.info).

Examples of specific quality and safety standards include:

- Accredited pharmacies can use only high-quality chemicals and equipment
- Compounding pharmacists and their technicians must receive regular, specialized training.
- Compounding pharmacy facilities must meet certain design standards to help ensure quality.
- Pharmacies must employ a system of continuous quality improvement

**Who performs the PCAB Accreditation quality surveys?**

The PCAB has contracted with the National Association of Boards of Pharmacy to perform the surveys. NABP possesses the skills and knowledge for this important task.

**How often must a pharmacy undergo a quality survey to maintain accreditation?**

Each pharmacy is reviewed annually, and every three years, the review includes a physical inspection.

**Will accreditation help keep the FDA from moving in and regulating our industry?**

The FDA wants the public to be protected, and this goal is shared by the profession of pharmacy. We believe the FDA wants PCAB to succeed. Like all governmental agencies, FDA has limited resources and very important duties regarding the 99% of the prescriptions that are manufactured under its authority and control. While there remains a disagreement concerning regulatory authority, PCAB believes the FDA wants to leave the regulation of the vast majority of compounding in the hands of state boards of pharmacy.

**I'm running a safe and ethical business, do I really need to worry about bad reports that have nothing to do with me?**

Unfortunately, every pharmacist is tainted by reports of errors and injuries that result from preventable causes. Bad reports tar the reputation of every member of the profession.

Even if that were not the case, every pharmacist has an obligation to provide his or her patients with the highest-quality level of practice. Patients have the right to know that the pharmacy they have chosen is

among the best. And every pharmacist has the obligation to assist in elevating the quality of all pharmacy practice to the highest level possible.

We can do this through identifying the pharmacies that practice according to the highest standards, which in turn pressures others to ensure they are meeting high-quality standards.

**Why does NASPA think it is important to support PCAB?**

*This question needs to be answered by your organization.*