



PCAB[®] Compounding Accreditation
Accreditation Summary



Leiter's Pharmacy
1700 Park Ave. Suite 30
San Jose, California 95126
(800) 292-6773
www.LeiterRx.com

Date of Last In-Pharmacy Survey: November 2008

Next Scheduled In-Pharmacy Survey: June 2012

Pharmacy Compounding Accreditation Board
Washington, D. C.
www.pcab.org

About this Accreditation Summary

This Pharmacy Accreditation Summary is composed of the following three separate reports:

1. Accreditation Abbreviated Report (1 page)
2. Accreditation Full Summary Report (4 pages)
3. Compounding Scope of Practice Report (1 page)

Additional information can be found following the reports:

- About Compounding Scope of Practice
- Frequently Asked Questions About Compounding
- About PCAB and its Mission
- PCAB Principles of Compounding
- Code of Ethics for Pharmacists

The Compounding Scope of Practice Report provides information regarding the pharmacy's accreditation. It indicates the accreditation status of the pharmacy; the date on which the pharmacy was first accredited; the date of the last review and the last survey (an in-pharmacy inspection); and the next scheduled review and survey.

Scope of compounding practice is particularly important. A pharmacy may change its scope of compounding after the survey. If it does so, it must report the changes must be in accordance with PCAB Rules to which the pharmacy agreed at the time it applied for accreditation. The rule governing changes, states: *"If at any time an Accredited Pharmacy expands its Compounding Scope of Practice, the Accredited Pharmacy shall:*

- a. Meet the Standards applicable to the expanded Compounding Scope of Practice prior to dispensing;*
- b. Notify PCAB™ within thirty (30) days of expanding;*
- c. Submit an abbreviated application within sixty (60) days of expanding its Compounding Scope of Practice; and*
- d. Be fully accredited by PCAB™ for its entire Compounding Scope of Practice within six (6) months."*

Should any questions arise regarding a pharmacy's accreditation summary please speak to one of the pharmacists at your compounding pharmacy or contact PCAB.

Accreditation Abbreviated Report

Accredited Since: June 2009

Date Last In-Pharmacy Survey: November 2008

By review and survey pharmacy met or exceeded the required standards for its compounding practice. The findings are reported as follows*:

Standard	Quality Finding
Standard 1.00 - Regulatory Compliance	✓ Passed
Standard 2.00 - Personnel	✓ Passed
Standard 3.00 - Facilities and Equipment	✓ Passed
Standard 4.00 - Chemicals, Components, and Completed Compounded Preparations	✓ Passed
Standard 5.00 - Compounding Process	✓ Passed
Standard 6.00 - Beyond-Use Dating, Stability, Sterility	✓ Passed
Standard 7.00 - Completed Compounded Preparations	✓ Passed
Standard 8.00 - Practitioner and Patient Education	✓ Passed
Standard 9.00 - Quality Assurance Plan and Continuous Quality Improvement	✓ Passed
Standard 10.00 - Self Assessment	✓ Passed

* Refer to full report for Pharmacy's Scope of Compounding Practice at the time of Review and Survey. Only those areas of practice performed at the time of the Review and Survey are tested and reported.

Next Scheduled In-Pharmacy Survey: June 2012

Status: PCAB Accredited™ compounding pharmacy

Pharmacy Standards Accreditation Summary Report

PCAB standards are comprised of ten general categories. Under each general category are one or more sub-parts. To be accredited a pharmacy must pass each standard applicable to its scope of practice. The following report will list each sub-part of each standard and will indicate "Passed" or "not applicable", meaning this area was not in the pharmacy's compounding scope of practice at the time of the review and survey. *(see Compounding Scope of Practice and Report)*

Standard 1.00 Regulatory Compliance

Standard	Quality Finding
Standard 1.10 Facility	✓ Passed
Standard 1.20 Personnel	✓ Passed
Standard 1.30 External Standards	✓ Passed
Standard 1.40 Policies and Procedures	✓ Passed

Standard 2.00 Personnel

Standard	Quality Finding
Standard 2.10 General	✓ Passed
Standard 2.20 Responsible Pharmacist	✓ Passed
Standard 2.21 Compounding Pharmacist	✓ Passed
Standard 2.22 Dispensing Pharmacist	✓ Passed
Standard 2.30 Compounding Personnel	✓ Passed

Pharmacy Standards Accreditation Summary Report continued

Standard 3.00 Facilities and Equipment

Standard	Quality Finding
Standard 3.10 General	✓ Passed
Standard 3.11 References	✓ Passed
Standard 3.20 Non-Sterile Compounding	✓ Passed
Standard 3.30 Sterile Compounding	✓ Passed

Standard 4.00 Chemicals, Components, and Completed Compounded Preparations

Standard	Quality Finding
Standard 4.10 General	✓ Passed
Standard 4.20 Storage	✓ Passed

Standard 5.00 Compounding Process

Standard	Quality Finding
Standard 5.10 General	✓ Passed
Standard 5.20 Master Formulation Record	✓ Passed
Standard 5.30 Compounding Process Record	✓ Passed
Standard 5.40 Records	✓ Passed

Pharmacy Standards Accreditation Summary Report continued

Standard 6.00 Beyond-Use Dating, Stability, Sterility

Standard	Quality Finding
Standard 6.10 Beyond-Use Date	✓ Passed
Standard 6.20 Stability and Sterility	✓ Passed

Standard 7.00 Completed Compounded Preparations

Standard	Quality Finding
Standard 7.10 Packaging, Labeling, Delivery for Administration, Dispensing	✓ Passed
Standard 7.20 Internal and External Recalls	✓ Passed

Standard 8.00 Practitioner and Patient Education

Standard	Quality Finding
Standard 8.10 Practitioner Education	✓ Passed
Standard 8.20 Patient Education	✓ Passed

Pharmacy Standards Accreditation Summary Report continued

Standard 9.00 Quality Assurance Plan and Continuous Quality Improvement

Standard	Quality Finding
Standard 9.10 Quality Assurance Plan	✓ Passed
Standard 9.20 Continuous Quality Improvement	✓ Passed

Standard 10.00 Self Assessment

Standard	Quality Finding
Standard 10.00 Self Assessment	✓ Passed

Next Scheduled In-Pharmacy Survey: June 2012

Status: **PCAB Accredited™** compounding pharmacy

Compounding Scope of Practice Report

Accredited Since: June 2009

Date Last In-Pharmacy Survey: November 2008

By review and survey pharmacy met or exceeded the required standards for its compounding practice. The findings are reported as follows*:

At the time of the review and survey, the pharmacy's practice included the types of compounding noted on the chart below.

	Non-Sterile Basic	Non-Sterile Complex	Sterile Low/Medium	Sterile High
Tested Against following Quality Standards	✓	✓	✓	✓
Passed the following Quality Standards	✓	✓	✓	✓

Next Scheduled In-Pharmacy Survey: June 2012

Status: **PCAB Accredited™** compounding pharmacy

About Compounding Scope of Practice

Compounding pharmacies often specialize in areas of compounding. We refer to this as the pharmacy's "compounding scope of practice." When PCAB conducts a review and survey for accreditation, it must determine the compounding scope of practice for the pharmacy. There are four levels of compounding practice recognized by PCAB. This determination is important when testing the pharmacy's practices against the PCAB Standards. The differences involve the equipment and procedures needed for compounding.

The scopes of practice are divided into two parts—sterile and non-sterile. Each of these categories are further divided depending upon the complexity of the process and the measures that must be taken during compounding. It is important that patients understand and appreciate where their compounded prescription fits in these levels and what standards the pharmacy was tested against. This information can be found on the Scope of Compounding Practice Report in the pharmacy's Compounding Accreditation Report.

While all prescriptions must be free of contamination, most oral and topical medications, whether compounded by a pharmacist or manufactured by a pharmaceutical company, are not sterile. There are two categories of non-sterile compounded prescriptions—basic and complex.

Non-Sterile Basic

A Non-Sterile Basic compounded preparation uses two or more medications combined into a prescription as ordered by the prescriber. While the prescription will require pharmacist training, knowledge, and skill to compound, it is, relatively speaking, a standard preparation. It will also be non-sterile, meaning it will not require special handling or equipment.

Non-Sterile Complex

Some prescriptions, called Non-Sterile Complex, are more difficult to compound or the medications used require special handling during the compounding process. It may be that the calculations are more difficult or exacting. The medications used may be more potent than those used in basic, thus requiring special care. Sometimes, as with hormone replacement preparations, special handling is required to protect the pharmacists or technicians from repeated exposure over time. Special, often expensive, equipment will be required for pharmacies filling non-sterile complex prescriptions.

Sterile, Low and Medium

Pharmacies preparing sterile preparations must meet special requirements as part of PCAB™ quality accreditation testing. There are two levels of sterile compounding recognized for the purpose of accreditation. Sterile, Low and Medium, refers to prescriptions prepared from sterile ingredients. Special handling is required to maintain sterility. The final prescription must remain sterile when it is delivered to the patient.

Sterile, High

The Sterile, High category are preparations required to be compounded out of medications or chemicals that start out as non-sterile. These preparations require that the pharmacy use special equipment to destroy disease causing organisms before the prescription can be delivered to the patient.

Frequent Questions About Compounding

What are compounded medications?

Compounded medications are prescriptions that are written by physicians and prepared by pharmacists – often specially trained pharmacists – for individual patients. They are not commercially available; rather, they are prescribed by a physician, dentist, veterinarian or other legally authorized prescriber and prepared by a pharmacist to meet an individual's unique needs. Compounded medications are necessary for a variety of reasons.

Commonly compounded medicines include hormone-replacement therapy; pain medication for hospice patients and pediatric formulations of a variety of drugs.

How are they different from manufactured medications?

Compounded prescriptions may differ from manufactured medications in several ways:

- They are customized, meaning they are prescribed to meet the needs of a particular patient, whereas manufactured medications are formulated to meet the needs of a large “average” population. A compounded medication does not exist until it is ordered for a particular patient.
- In the one case, the medication is matched to the patient, whereas in the other, the patient is matched to the medication that is available.
- Manufactured medications are manufactured under federal law, and thus are subject to FDA regulations. In contrast, the practice of pharmacy (as with the practice of all healthcare professions) is controlled by state. Because compounding is a part of the practice of pharmacy, it is regulated at the state level.
- A compounded medication is not manufacturing, but is the practice of pharmacy. The practice of pharmacy is controlled by the state government. Within the state, the agency usually responsible for the regulation of the profession of pharmacy is the board of pharmacy.

Why do physicians and veterinarians prescribe compounded medications?

There are many reasons for prescribing compounded medicines. These reasons include:

- Standard treatments have failed and an alternative is needed.
- The dosage forms available may be unusable by some patients. (For example, a product that is only available as a tablet may need to be formulated so that it can be absorbed through the skin or taken as a suppository for a patient who cannot swallow.)
- The manufactured version of a medication is discontinued for economic reasons, but the prescriber believes that medicine is still the best solution for the patient.

Frequent Questions About Compounding

Who takes/needs compounded medications?

Examples of people who benefit from compounded medications include:

- The young patient who will not take the “bad”-tasting medicine or who needs a child-sized dosage of a medicine that is manufactured in adult doses.
- The patient who is allergic to the dye or other inactive ingredients in manufactured medicines.
- The patient who responds better to bio-identical hormones than the manufactured forms of hormonal drugs.

What are the advantages of compounded medications?

The advantage is the same as every treatment alternative the prescriber has at hand. The prescriber will search for the best way to treat a patient's healthcare problem. Compounded medication is one possible answer.

There are no perfect medications. The medicine or dosage form that works well on one patient for one particular condition may not work well for another patient or a different condition. This is why the physician, or other prescriber, needs options. With each patient and each treatment, the prescriber must consider and assess the risks and benefits among all alternatives – including the choice of doing nothing.

Do most pharmacies provide compounded medications, or do only specialized pharmacies do this?

Many pharmacies will provide some compounding. Most will perform basic compounding – for example, combining two ointments into one preparation. The more complicated and time-consuming the procedure, the more likely it is to be performed only in specialized pharmacies.

Often, the equipment needed for complicated or sensitive compounding is expensive. For example, if the resulting compounded preparation must be sterile, a special air-filtering system will probably be required. In the case of higher-level sterile products, an entire room designed to meet special requirements as a “clean room” will be necessary.

Are all pharmacists trained to prepare compounded prescriptions?

Pharmacists are trained in pharmacy school to compound; the depth of that training may depend on when a student graduated and from what pharmacy school. As the preparations become more difficult or complicated, the amount of training needed increases, sometimes above that taught in many colleges of pharmacy.

PCAB Accredited compounding pharmacies are required to have specific training in the art and science of compounding on a regular basis.

About PCAB®

Pharmacy Compounding Accreditation Board (PCAB®) is a not-for-profit, voluntary accreditation body formed by pharmacy organizations to establish high quality standards for compounding pharmacies. These organizations, and the pharmacists they represent, believe that standards against which compounding pharmacies can be tested are not only good for the patient, but also good for the practice of pharmacy. The founding organizations are:

- American College of Apothecaries
- National Community Pharmacists Association
- American Pharmacists Association
- National Alliance of State Pharmacy Associations
- International Academy of Compounding Pharmacists
- National Home Infusion Association
- National Association of Boards of Pharmacy
- United States Pharmacopeia (USP)

PCAB® is a 501(c) 3 tax-exempt organization under the IRS Code. Contributions to PCAB may be deductible for federal income tax purposes.

The Mission of PCAB:

- To organize and carryout a comprehensive program of voluntary accreditation in the practice of pharmacy compounding.
- To promote, develop and maintain principles, policies and standards for the practice of pharmacy compounding in the public interest and to apply these in the accreditation of pharmacies that offer pharmacy compounding to improve the quality and safety of pharmacy compounding provided to the general public.
- To offer to the public and prescribers a way to identify the pharmacies that satisfy accreditation criteria.
- To provide a public forum for information on the practice of pharmacy compounding, and to educate the public on the importance of pharmacy compounding.

PCAB™ Principles of Compounding

In any profession, principles are an important criteria by which to judge a person or a business. PCAB adopted “Principles of compounding” as a guide to pharmacy, patients and prescribers when dealing with compounded prescriptions. Below are the those Principles. This pharmacy, in its application, has pledged to abide by the PCAB™ Principles of Compounding.

- **Compounding is the preparation of components into a drug product** either as the result of a practitioner's prescription drug order based on a valid **practitioner/patient/pharmacist relationship** in the course of professional practice, or for the purpose of, or as an incident to, research, teaching, or chemical analysis that are not for sale or dispensing. Compounding is a part of the practice of pharmacy subject to regulation and oversight from the state boards of pharmacy.
- **Compounded medication may be dispensed to prescribers for office use**, where applicable state law permits. Office use does not include prescribers reselling compounded medications.
- **Compounding may be conducted in anticipation** of receiving prescription orders when based on routine, regularly observed prescribing patterns. Anticipatory compounding is limited to reasonable quantities, based on such patterns.
- **Compounding does not include** the preparation of copies of commercially available drug products. Compounded preparations that produce, for the patient, a **significant difference** between the compounded drug and the comparable commercially available drug product or are determined, by the prescriber, as necessary for the medical best interest of the patient are not copies of commercially available products. "Significant" differences may include, for example, the removal of a dye for a medical reason (such as an allergic reaction), changes in strength, and changes in dosage form or delivery mechanism. Price differences are not a "significant" difference to justify compounding.
- **Both the prescriber** (via the prescription) **and the patient** (via the label) should be aware that a compounded preparation is dispensed.
- **The pharmacy may advertise** or otherwise promote that it provides prescription drug compounding services. Such advertising should include only those claims, assertions, or inference of professional superiority in the compounding of drug products that can be independently and scientifically substantiated.

Code of Ethics for Pharmacists

PCAB Board of Directors has endorsed and adopted the Code of Ethics for Pharmacists, as previously adopted by the membership of the American Pharmacists Association. PCAB encourages all pharmacists to do the same.

PREAMBLE

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

I. A pharmacist respects the covenantal relationship between the patient and pharmacist.

Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.

II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.

A pharmacist places concern for the well-being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.

III. A pharmacist respects the autonomy and dignity of each patient.

A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.

IV. A pharmacist acts with honesty and integrity in professional relationships.

A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.

V. A pharmacist maintains professional competence.

A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

VI. A pharmacist respects the values and abilities of colleagues and other health professionals.

When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.

VII. A pharmacist serves individual, community, and societal needs.

The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.

VIII. A pharmacist seeks justice in the distribution of health resources.

When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.

Adopted by the American Pharmacists Association membership, October 27, 1994.

Endorsed and adopted by the Pharmacy Compounding Accreditation Board, November 2, 2005