

## Scope of Compounding Practice

Compounding pharmacies often specialize in its 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 Summary page in the pharmacy's Compounding Accreditation Report.

While all prescriptions must be free of contamination, most oral and topical medications, whether compounded or manufactured, 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.