



PCAB[®] Required Labeling for Medications Compounded

When dispensing compounded medications, compounding pharmacists have a responsibility for ensuring that their patients know what they are taking; how to take it; and basic safety information about their medicines. Proper and consistent labeling of compounded medicines is an important tool in providing patients with this essential information. PCAB requires that PCAB Accredited[™] compounding pharmacies adopt the following labeling system for medications compounded.

I. Required Compounded Prescription Statement

Pursuant to PCAB Standard 8.20, the primary label of each compounded medication prepared in response to a prescription for a specific patient shall include a statement notifying the patient that the medication has been compounded. If space limitations or clinical reasons preclude inclusion on the primary label, the information may be affixed through auxiliary labeling.¹ For all such prescriptions, the statement shall be prominently displayed in the medication labeling. The following statement complies with Standard 8.20:

“This medicine was specially compounded in our pharmacy for you at the direction of your prescriber.”²

II. Required Label Information

In addition, the following items of information, or a reasonable alternative, shall be included on all compounded prescription labels:³

- (1) Patient's name;
- (2) Prescriber's name;
- (3) Name, address, phone number of the pharmacy preparing the medicine;
- (4) Prescription number;
- (5) The medication's established or distinct common name;
- (6) Strength;
- (7) Statement of quantity;
- (8) Directions for use;
- (9) Date prescription filled;
- (10) Beyond-use date
- (11) Storage instructions; and
- (12) All state labeling requirements.

III. Required Accompanying Information

The following information, or a reasonable alternative, shall be included with all compounded medication:

¹ For example, when there is concern that a label applied directly to the primary container may affect the quality of the compounded medication. In such cases, the pharmacist may decide, in the pharmacist's professional judgment, that the label and statement be applied in another manner, such as to exterior packaging

² Alternate language providing a clear designation that the medication has been compounded may be used, where, in the pharmacist's professional judgment, the welfare of the patient requires and the information is adequately and prominently communicated.

³ Label must be in conformity with law and state board of pharmacy regulations. Alternative placement may be acceptable if determined necessary because of space requirement or, in the pharmacist's professional judgment for the needs of the patient.



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This medicine was compounded specifically for you in a pharmacy to fill the prescription your doctor wrote for you. It was specially made to meet your individual needs. For this reason, no standardized information or literature is available with your prescription. If you have not done so, please discuss this medicine with your doctor to ensure that you understand (1) why you have been prescribed a compounded medicine, (2) how to properly take this medicine, and (3) the interactions, if any, this medicine may have with any other medicines you are taking.

Compounding is a long-standing pharmacy practice that allows doctors to treat their patients' individual needs without being restricted only to off-the-shelf medicines or devices. This medicine was prepared in a compounding pharmacy to meet the specifications ordered by your doctor.

1. Call your doctor if:

- ◆ You experience any side effects.*
- ◆ You are taking additional medicines that may interact with this compounded medicine.*
- ◆ You have allergies or other medical conditions that should be noted.*

2. Call our pharmacists if:

- ◆ Information on the label is not clear to you.*
- ◆ You have any concerns regarding precautions, ingredients, or proper storage.*

Our pharmacists are available to address any additional questions or concerns.

IV. Labeling for Office Use Preparations

PCAB Principles of Compounding recognizes the need for the preparation of non-patient specific compounded medications for office use by licensed institutions and practitioners. Physicians and institutions occasionally request pharmacists to compound medications that are not commercially available and that must be administered by the prescriber. In some instances, the FDA even requires that certain medications be administered by the prescriber. In other cases, office-use compounds must be compounded in advance and available for immediate use by the physician in emergencies. The purpose of this requirement is to help ensure (1) that the medication is administered properly and (2) that the prescriber and the patient are aware that the medication has been compounded

Pursuant to PCAB Standard 8.10, the following language shall be included on the primary label of each package compounded for use in the prescriber's office. If space limitations or clinical reasons⁴ preclude inclusion on primary labeling, the information may be affixed through auxiliary labeling. In either case, the statement should be prominently displayed in the medication labeling. The following statement complies with Standard 8.10:

“This medicine was compounded in our pharmacy for use by a licensed professional only. This compounded preparation may not be resold.”

⁴ For example, when there is concern that a label applied directly to the primary container may affect the quality of the compounded medication. In such cases, the label and statement should instead be applied to exterior packaging.