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Alliance for Pharmacy Compounding

Compounding the Joy of Living

BEST PRACTICES FOR DISPENSING COMPOUNDED THERAPIES

This document is not specific to particular indications or dosage forms for compounded medications, and it is not intended to be an exhaustive statement on the practice of pharmacy. It should not be relied upon as advice. Pharmacies should seek legal counsel before dispensing compounded medications.

INTRODUCTION

Pharmacists play a vital role in ensuring that compounded medications are prepared and dispensed in a way that supports patient safety, therapeutic efficacy, and regulatory compliance. Compounded drugs are not FDA-approved, so they are exempt from the FD&C Act's "adequate directions for use" requirement (Section 502(f)(1)). As a result, they don't need package inserts and Medication Guides that accompany commercial drugs. As a result, the responsibility for proper documentation, patient education, and safe dispensing lies heavily with the pharmacy team.

This document outlines best practices for dispensing compounded medications, drawing from USP standards, state board regulations, and the collective experience of pharmacy professionals. These practices apply primarily to 503A compounding pharmacies but may also support internal dispensing and counseling practices for 503B facilities.

To ensure consistent quality and compliance with regulatory requirements, pharmacies must develop and maintain standard operating procedures specific to the dispensing of compounded medications. These SOPs should clearly outline the labeling, verification, patient counseling, and documentation processes described below. Equally important, the SOPs should be a part of staff training upon hire and at regular intervals thereafter, and the pharmacy should maintain documentation of training. This helps ensure all personnel understand and follow established protocols, supporting patient safety and regulatory readiness.

1. PACKAGING REQUIREMENTS

Child-resistant packaging is required for most orally administered compounded drugs under the Poison Prevention Packaging Act , unless an exemption applies or the patient formally opts out. This includes preparations such as troches, gummies, and sublingual lozenges. While there are exceptions – for example, certain hormone therapies or medications dispensed to institutionalized patients – the exceptions must be carefully documented. Pharmacies should use packaging options that are both child-resistant and appropriate for the dosage form, such as CR troche molds with locking lids, push-and-turn vials, or certified CR zipper pouches.

When a patient or prescriber requests non-CR packaging, this waiver must be documented in writing and maintained in the pharmacy's records. Opt-out waivers should be renewed annually, and a notation should be made in the patient's profile. For remote or delivery patients, this request may be captured electronically or during counseling calls. When dispensing without CR packaging (as in the case of transdermal creams or injectables), the pharmacy must include a warning label indicating that the medication is not child-resistant and should be kept out of the reach of children.

2. LABELING REQUIREMENTS

Labeling is a critical safety function and must meet both regulatory requirements and professional standards for clarity, legibility, and accuracy. Each compounded medication label should include the pharmacy's name, address, and contact information; the patient's full name; the prescribing provider's name; the date dispensed; the drug's name and strength; dosage form and route of administration; quantity dispensed; and clear directions for use. For comprehensive guidance on labeling standards, pharmacies should refer to USP Chapter <7>. The beyond-use date must be listed, supported by USP <795> or <797> standards or applicable stability data and compliant with state-specific regulatory requirements. A lot number and/or prescription number must also appear for traceability. Additionally, the label must contain a statement such as, "This medication has been compounded for dispensing to an individual patient and has not been approved by the FDA." to indicate that the product is not FDA-approved. Veterinary compounds must include the statement on the labeling: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; this is a compounded drug, not an FDA-approved or indexed drug, not for use in food-producing animals. Report suspected adverse events online using FDA Form 1932a."

Compounding pharmacies should avoid the use of abbreviations, brand-like terminology, or vague proprietary names. Terms like "Bi-Est" or "All-Purpose Nipple Ointment" obscure the ingredients and purpose of the medication and should be replaced with full, descriptive names that include all active ingredients and concentrations. Pharmacists should also avoid dosing abbreviations like "qd" or "cc" in favor of clear, unambiguous language. Pharmacies should refer to United States Pharmacopeia's General Notices, which has lengthy chart on abbreviations under 8.240 Weights and Measures.

Importantly, pharmacies should not use the specific terms “SR” (sustained release), “ER” (extended release), or “XR” (extended-release), unless they have conducted appropriate dissolution and release-profile studies to support those claims. In place of these unsupported terms, descriptive compounding language should be used, for example, “modified release” or “slow release,” which accurately reflects that an excipient was used to influence release properties without implying a validated pharmacokinetic profile.

State-specific formatting requirements must also be considered. For example, California and New York mandate that patient-facing label content be printed in at least 12-point font. Across all states, labels should be formatted in high-contrast, easy-to-read typefaces, free of unnecessary jargon or clutter. Storage instructions such as “Refrigerate. Do not freeze.” must be included where applicable. Auxiliary labels, such as “Shake well,” “For external use only,” or “Hazardous drug – handle with care,” should be affixed when clinically or legally appropriate. For controlled substances, DEA-required cautionary statements must be present. When a product is dispensed in an outer container like a plastic resealable pouch, such as during refrigerated shipping, duplicate labels should be affixed to the exterior of the pouch to ensure the BUD, storage conditions, and product identity are clearly visible at the point of receipt.

3. PATIENT EDUCATION MATERIALS

Because compounded medications are not FDA-approved and do not come with standardized drug monographs, pharmacies should develop and distribute their own patient education materials based on their state-specific requirements. These materials may include specifics like the drug name and active ingredients, as well as clear instructions for dosage and administration. Guidance should be included for missed doses, storage conditions, drug or food interactions, and what to do in the event of an overdose. If abrupt discontinuation could lead to withdrawal effects, this should also be noted. Proper disposal instructions should be included, along with contact information for the dispensing pharmacy. Commercial patient leaflets should not be used, as they do not reflect the actual compounded formulation. Written materials should be concise, readable at a 6th- to 8th-grade level and provided in addition to verbal counseling. When dispensing remotely, these materials should be shipped with the prescription and referenced during follow-up communication with the patient. Educational materials should not make any claims as to the safety or efficacy of compounded medications.

4. DISPENSING LOGISTICS AND SUPPORT MATERIALS

Dispensing compounded medications often requires tools and packaging beyond the label and container. When a compounded preparation requires refrigeration, pharmacies must maintain proper cold chain management from preparation through delivery. This includes verified temperature-controlled storage, validated packaging materials such as insulated shippers and gel packs, and clear labeling of the shipping container to indicate that refrigeration is required. Pharmacies should periodically validate shipping protocols under real-world conditions to ensure the preparation's drug concentration is maintained during transit.

Additionally, pharmacies should dispense appropriate administration tools with medications when needed. Oral suspensions should be provided with marked oral syringes or spoons that reflect the prescribed dose unit, and topical preparations may require applicators or syringes to ensure consistent administration. The selection of the proper dosing tool should be based on the formulation's route, viscosity, and dosage volume. Tools must align with the instructions on the label, both in terms of units and intended use.

5. RIGHT DRUG, RIGHT PATIENT: IDENTITY VERIFICATION AND PICKUP PROCEDURES

Ensuring that the correct medication is dispensed to the correct patient is a fundamental aspect of pharmacy practice. Pharmacists can be disciplined by their state board of pharmacy if they dispense the wrong medication to the wrong patient. In the context of compounded medications, many of which are customized or for medications that have narrow therapeutic windows, verifying patient identity at the point of pickup or delivery is particularly important.

At the time of prescription pickup, pharmacy staff should always verify the patient's name and date of birth, and if needed other identifiers like patient address, and confirm that it matches the prescription and patient profile. For minors or when a caregiver is picking up the medication, the identity of the authorized person should also be verified. Pharmacies should develop and train staff on clear verbal verification scripts, like asking open-ended questions, to avoid assumptions or shortcuts during busy dispensing hours.

When dispensing controlled substances, additional safeguards must be followed. In most jurisdictions, the recipient, whether the patient or a designated pickup person, must present a valid government-issued photo ID. Depending on state regulations, the pharmacy should record the name and, when required, the ID number and issuing agency. For scheduled medications, particularly those subject to state prescription drug monitoring programs (PDMPs), these steps are not only best practice but also required under state law.

For mailed or couriered prescriptions, pharmacies should take reasonable steps to confirm delivery to the intended recipient. This may include signature confirmation, secure delivery packaging with tamper-evident seals, and documented shipping logs. When delivering controlled substances, additional tracking and documentation may be required, and pharmacies should consult both state and DEA guidance. Additionally, the pharmacy must have a system for alerting individuals in the event of unsuccessful deliveries.

In all cases, pharmacists should be trained to slow down and verify the "Five Rights" before handing over any compounded medication: right patient, right drug, right strength, right route, and right time. Verifying identity and confirming these core dispensing elements helps prevent misfills, ensures proper administration, and reinforces patient trust.

6. PATIENT COUNSELING AND VERIFICATION

Patient counseling plays a vital role in supporting proper use and adherence to compounded therapies. Pharmacists must offer to counsel the patient or their caregiver at each new dispense, and this offer should be documented. Counseling should include the name and purpose of the compounded drug, proper storage, dosing instructions, potential side effects, interactions, and a review of any administration tools or devices provided. It should also include an explanation of the compounded nature of the medication and why a custom formulation was used. Some states have different requirements for counseling, including but not limited to who is allowed to offer, whether counseling must be offered for refills, and how to document refusal of counseling. Check specific state requirements and incorporate those into the pharmacy's SOPs.

For mail-order or delivery patients, counseling may be conducted via telephone. Pharmacists must make a good-faith effort to reach the patient and document these attempts. If contact cannot be made, a voice message should be left (where permitted by law), and printed counseling materials should be included with the shipment. All counseling efforts and outcomes, whether completed, declined, or unsuccessful, should be recorded in the patient profile or dispensing system.

7. RETURNS, DESTRUCTION, AND DISPOSAL

Because prescription medications are not subject to resale or redistribution, they are generally not eligible for return once dispensed. The only exceptions may be for documented pharmacy errors or product damage during shipment. In these cases, pharmacies should have clear protocols in place for documentation, retrieval, and safe destruction of returned products. Previously dispensed compounded products may not be re-dispensed after return.

Expired compounded medications must be segregated from active inventory and disposed of in accordance with state and federal law. If the product contains hazardous ingredients, such as hormones or chemotherapeutics, the destruction method must comply with applicable hazardous waste requirements. Pharmacies may use a licensed medical waste disposal company or a DEA-compliant reverse distributor for controlled substances. Documentation of destruction must be retained.

Patients should be provided with guidance on how to dispose of unused compounded medications safely. Instructions should discourage flushing and direct patients to authorized drug take-back programs or pharmacy-based disposal services where available. Pharmacies may also direct patients to resources on safe medication disposal, such as:

https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines or ***https://www.dea.gov/everyday-takeback-day.***

9. QUALITY ASSURANCE AND DOCUMENTATION WORKFLOWS

A strong quality assurance (QA) program is essential for verifying that compounded prescriptions are dispensed correctly, labeled appropriately, and accompanied by the correct tools and documentation. Pharmacists should complete a final product check for every prescription, verifying the drug name and strength, quantity, label accuracy, auxiliary labels, BUD, and inclusion of the appropriate packaging and patient education. A visual inspection of the compounded preparation should be performed prior to dispensing to check for potential defects, integrity of container system, or damage. Final verification should be documented with the initials or signature of the verifying pharmacist.

Comprehensive documentation should be maintained for all comp ounded prescriptions. This includes the original prescription, the compounding log or worksheet, a copy of the label, any waivers for CR packaging, and records of counseling or shipping. Records should be kept in accordance with applicable state requirements, typically for a minimum of five years (ten years if the pharmacies perform third-party billing to Medicare or Medicaid programs). Pharmacies should also audit their dispensing process regularly, especially for high-risk or high-volume preparations, and use these findings to identify areas for improvement. Trends in documentation errors, labeling issues, or patient complaints should be tracked and addressed via documented strategies.

10. ADVERSE EVENT REPORTING

Pharmacies dispensing compounded medications may have a regulatory obligation to monitor and report adverse events or quality complaints associated with their preparations. Although compounded drugs are not FDA-approved, adverse event reporting can play a vital role in protecting patients, improving compounding practices, and demonstrating pharmacist accountability.

When a pharmacy becomes aware of a possible adverse drug event, whether reported by the patient, caregiver, or prescriber, it should initiate a structured internal review. This includes gathering details about the event, the formulation and lot dispensed, patient demographics, and any concurrent medications or conditions that could be relevant. Documentation should include specifics like the timeline of symptom onset, how the drug was stored and administered, whether the symptoms resolved upon discontinuation or persisted, and other details relevant to the medication.

Compounded drugs dispensed under Section 503B must include the FDA's MedWatch reporting statement, which reads: "Adverse events associated with this compounded drug may be reported to the FDA's MedWatch program: 1-800-FDA-1088." FDA does not require this statement in labeling of 503A compounded products, but some states may. Patients and prescribers may report directly to FDA, but pharmacies also have the option to report voluntarily. While not mandatory, reporting known or suspected adverse events to MedWatch reflects a commitment to transparency and public health.

In addition to federal reporting, pharmacies should follow their state board's requirements related to adverse event documentation. Some states require notification to the board within a certain timeframe, especially in cases of hospitalization or serious harm. Internal QA systems should include a procedure for identifying, documenting, and escalating reports of ADEs, including clear guidance for pharmacy staff on how to recognize and respond to potential events.

Pharmacies should also evaluate whether the event was potentially related to a formulation issue, compounding error, inappropriate dosing instructions, or product degradation. If a product defect or formulation concern is identified, the pharmacy must assess whether a recall or notification to other patients or prescribers is warranted. In such cases, pharmacies should document all actions taken and review the incident during internal QA meetings to identify systemic improvements or training needs.
Ultimately, adverse event reporting, whether to FDA, state boards, or internally, supports the safe use of compounded medications and contributes to a culture of continuous quality improvement. Pharmacies should train all staff on the importance of reporting, encourage open communication about potential errors or events, and treat reporting as a patient safety tool rather than a punitive process.

10. PRODUCT RECALLS AND NOTIFICATIONS

Compounded medications, while patient-specific, are not immune to quality-related concerns that may require a recall or targeted notification. Unless the FDA is overseeing a recall of a compounded drug, the responsibility for initiating and managing recalls rests entirely with the compounding pharmacy. A well-defined recall policy is essential to ensure swift action in the event of contamination, potency issues, incorrect ingredients, or labeling errors.

Recalls may be voluntary or required by a state board of pharmacy or another regulatory body following an inspection or report. Regardless of the trigger, pharmacies should have an internal recall SOP that outlines roles, responsibilities, and timelines for action. At a minimum, recall procedures should include:

- ***Immediate identification*** *of the affected lot, batch, or prescription records*
- ***Notification of affected patients and/or prescribers****, with clear instructions on whether the product should be discontinued, returned, or replaced*
- ***Quarantine and segregation*** *of any remaining in-stock product to prevent further dispensing*
- ***Documentation*** *of the reason for the recall, the scope of affected prescriptions, and the actions taken*
- ***Investigation*** *into the root cause, including review of formulation, labeling, QA logs, and compounding procedures*
- ***Corrective action*** *and training to prevent recurrence, which may include formulation revision, updated SOPs, or staff re-education*

For recalls involving controlled substances, pharmacies may need to notify the DEA or follow reverse distribution procedures depending on whether the recalled material is returned. In some states, certain recalls, particularly those involving sterility failures or patient harm, must be reported to the board of pharmacy or public health authority.

Pharmacies are encouraged to maintain up-to-date contact logs that allow rapid identification and outreach to all patients or providers associated with a recalled batch. Dispensing software, if used, should include functionality to generate a list of prescriptions linked to a particular lot or ingredient.

Communication to patients should be clear and factual. It should describe the reason for the recall, potential risks (if known), what actions the patient should take, and a contact number for follow-up questions. Even when patient risk is low, transparency helps maintain trust and ensures appropriate action is taken.

CONCLUSION

The dispensing of compounded medications demands precision, care, and professional judgment at every step, from verifying the patient's identity to providing appropriate packaging, labeling, education, and follow-up. While this document outlines many of the practical and regulatory best practices for safe dispensing, it is not exhaustive. Additional critical responsibilities such as drug utilization review (DUR), prescriber credential verification, calculation checks, ingredient sourcing, and clinical appropriateness assessments are integral to the compounding process but are outside the scope of this dispensing-focused guidance. Pharmacies are encouraged to integrate these dispensing practices into broader quality systems and to tailor their policies based on their scope of services, patient populations, and regulatory environment.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses — including compounding pharmacists and technicians in both 503A and 503B settings — as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.