Compounding the Risk: Improper Use of Compounded Drugs



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Compounded medications can be valuable when an FDA-approved drug is unavailable or unsuitable for a specific patient. However, they present added risks because they generally do not receive the same pre-market FDA review for safety, effectiveness, and manufacturing quality as FDA-approved drugs.

Physician-prescribed compounded medications are typically intended for individual patients whose specific medical needs cannot be met by a commercially manufactured, FDA-approved drug. For example, when a patient is allergic to an inactive ingredient in an approved medication, a physician may prescribe a compounded version that omits that ingredient while maintaining the intended therapeutic effect.

Section 503A of the Federal Food, Drug, and Cosmetic Act governs compounding pharmacies that prepare personalized, patient-specific medications in small batches under state board oversight and require a valid prescription for an individual patient before compounding. By contrast, Section 503B permits bulk compounding without individual prescriptions, but those pharmacies must register with and be directly regulated by the

FDA and comply with Current Good Manufacturing Practice requirements.

Improperly prescribing compounded medications may expose physicians to significant civil malpractice risk and, in some circumstances, criminal liability. Even when the underlying problem involves the compounding or manufacturing process, such as sterility, a physician may be named in a lawsuit against the pharmacy or manufacturer if the physician did not take reasonable steps to confirm compliance with applicable state and federal laws, including Sections 503A and 503B.

Key risks include:

Contamination: Poor sterile-compounding practices may introduce bacteria, fungi, or other contaminants, creating risk of infection and serious injury.

Potency and dosing errors: The medication may contain too much or too little active ingredients, increasing the risk of treatment failure, toxicity, or overdose.

Batch variability: Concentration, purity, stability, or consistency may differ from one preparation to another.

Drug-selection or formulation errors: Errors involving the ingredient, concentration, dosage form, or route of administration can cause significant patient harm.

Stability and storage issues: Some compounded preparations may have shorter or less certain beyond-use dates and may be sensitive to temperature, light, or other storage conditions.

Lack of FDA-approved labeling: Prescribers and patients may have less standardized information about indications, contraindications, dosing, adverse effects, and interactions.

Quality-control concerns: Oversight and testing may vary depending on the type of compound and the facility preparing it.

Counterfeit or fraudulent products: Products obtained from inappropriate or unlicensed sources may pose additional risks involving identity, potency, sterility, and authenticity.

Documentation and communication risks: Inadequate documentation of the formulation, source, dose, instructions, or patient counseling can increase medication-error risk and complicate later care.

Patient confusion about the source: Patients should be told that the medication is compounded by an entity other than a drug manufacturer, is not FDA-approved, carries potential risks, and is being used for a specific clinical reason. Potential adverse effects should also be discussed.

Fraud, misrepresentation, deceptive practices, or unethical conduct: If a compounded drug is used instead of a common FDA-approved alternative for profit-driven reasons, the

conduct may support criminal, regulatory, and/or ethical violations, resulting in sanctions, fines, statutory penalties, and medical negligence claims.

From the physician's perspective, the primary concern is not simply whether compounded medications are unsafe, although they may present that risk in some cases. The broader issue is that their use introduces additional variables requiring careful attention. Before prescribing or administering a compounded drug, clinicians should evaluate the clinical necessity, the compounder's source and regulatory status, formulation and concentration, sterility when applicable, labeling and storage requirements, and appropriate patient counseling. Clear documentation of the clinical rationale, product prescribed, source, dosage, instructions, and patient communication, including informed consent to use an alternative medication, is especially important when the medication falls outside the FDA-approved drug pathway. This documentation may be critical if the patient experiences an adverse event related to the compounded drug.

Best practices to mitigate risk:

Establish medical necessity: Prescribe compounded medications only when a specific patient need—such as a documented allergy to an inactive commercial ingredient or a unique dosage form—cannot be met by an FDA-approved commercial product.

Document thoroughly: Clearly record the clinical rationale, medical necessity, and potential risks in the medical record.

Obtain informed consent: Discuss and document that the medication is compounded, is not FDA-approved, and that the patient consented to its use. If the compounded medication presents a risk of significant harm, use a written consent form signed by the patient that addresses the risks, benefits, and alternatives and confirms the patient had an opportunity to ask questions and receive answers.

Vet the compounding pharmacy: Carefully select and verify that the pharmacy operates either as a state-regulated 503A pharmacy or as an FDA-regulated 503B outsourcing facility that follows Current Good Manufacturing Practice requirements. **Do not use any pharmacy or manufacturer that raises concerns.**

For more information on this topic, contact the Risk Education department or a Claims Attorney.

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