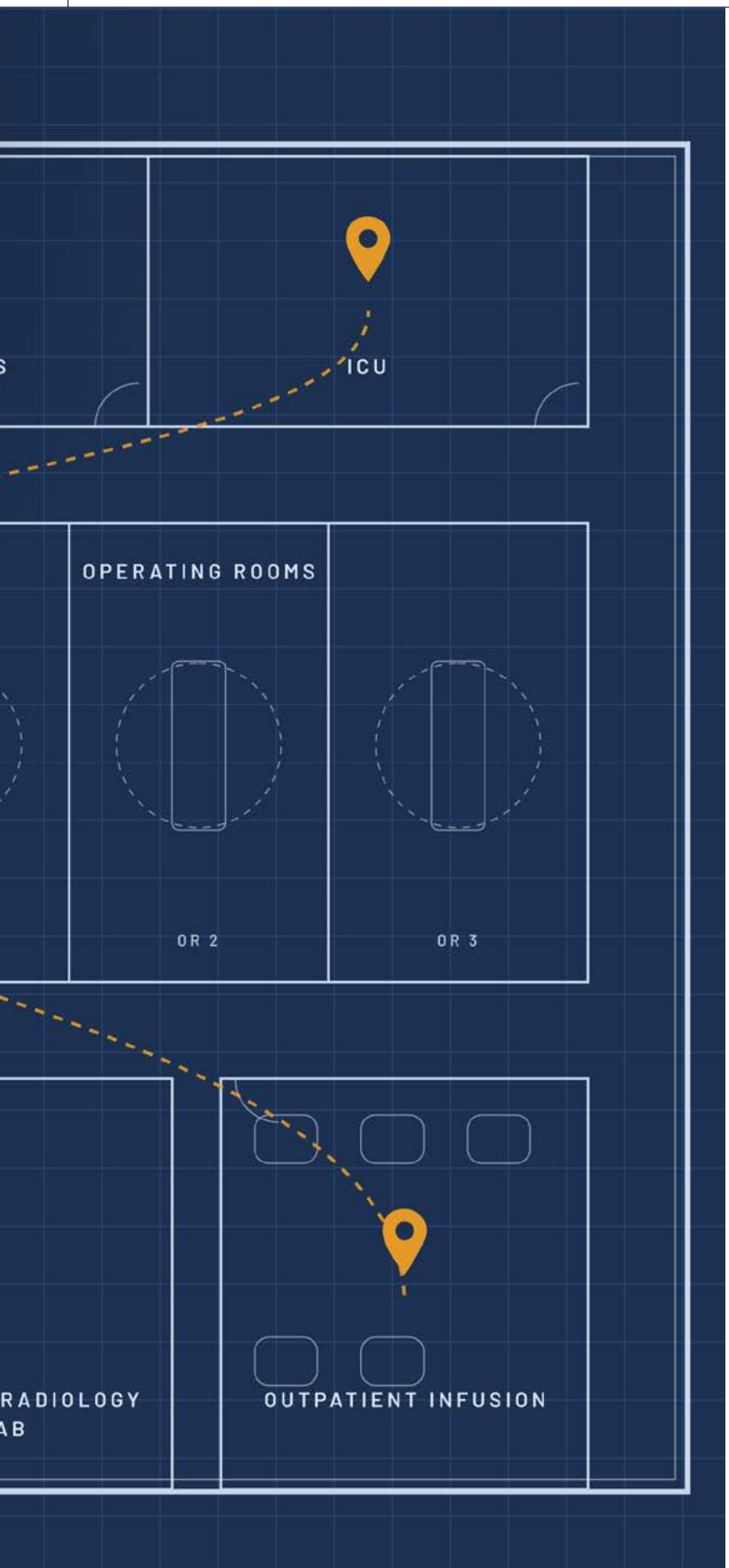
Hospital Compounding:
More Than a Pharmacy Issue

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Overview

Hospitals may procure finished pharmaceutical products from drug manufacturers and wholesalers. For a wide variety of patient care settings, however, clinicians may need to alter the standard dosage, dosage form, route of administration, or other features of a manufactured drug therapy. These changes to drug products, which involve interacting with the finished drug substance in a way that changes its final form prior to administration, typically implicate diverse state, federal, and accreditation body regulations on pharmaceutical compounding.

Most health care providers are familiar with pharmaceutical compounding mainly through their interactions with pharmacies and outsourcing facilities. Because providers operate some distance from the activity of compounding and its associated regulatory burdens, they view compounding regulations primarily through the lens of business-to-business transactions. Because of their unique position as primary sites of care and medical administration, hospitals are more directly impacted by compounding regulations.

> *"Crucially, having the ingredients and even the ability to prepare a compounded therapy does not imply that the compounding activity is permitted."*

Compounding happens well beyond the pharmacy: operating rooms, emergency departments, ICUs, obstetrics, interventional radiology and outpatient infusion.

Hospitals sit at the intersection of overlapping and sometimes conflicting regulatory agencies that govern the preparation of pharmaceutical compounds. Who prepares a drug, who receives it, the type of medical care being provided, the specialized clinical needs of patients, the route of administration, and the location of administration are all questions, the answers to which may greatly alter what regulations are implicated by these therapies. Developing and implementing compliant compounding policies and procedures requires a comprehensive institutional assessment. The purpose of this article is to provide a framework to help hospitals to identify the regulatory standards that apply to these practices and, through this framework, to evaluate and, where needed, to improve their internal compounding practices.

Introduction

I. HOSPITAL COMPOUNDING AS AN INSTITUTION-WIDE ACTIVITY

Pharmaceutical compounding and analogous drug mixing procedures occur throughout hospitals. Hospital compounding is seldom limited to licensed pharmacists and physicians. Sterile and nonsterile compounding routinely occurs in operating rooms (mixing local anesthetics, irrigation solutions with epinephrine, cardioplegia solutions), emergency departments (code-cart preparations, diluted drips for pediatric dosing), ICUs (titrated infusions), obstetrics wards, interventional radiology/cath labs, and outpatient infusion clinics.

Given the diversity of settings, regulatory complexity is unavoidable. Compliance with applicable compounding standards depends significantly on the "who, what, when, where, and how" of the specific compounding activity. Although practitioners rarely need encyclopedic knowledge of the regulatory infrastructure at play, recognizing the broad implications of different answers to these questions is vital to a hospital's effective development of compliant compounding policies and procedures.

Importantly, actions that are permitted in one context may be forbidden in another. Details matter. Some examples are easy to spot. Preparing a sterile compound in a properly sterilized environment is far less risky than preparing the same compound at a patient's bedside. Compounding by a pharmacist or physician is regulated differently than compounding by a technician or a nurse.[1,12,13] The differences can be subtle. Compounding a drug commonly used by Emergency Department staff to be held as office stock on a code-cart is regulated differently from the production of the same drug by an outsourcing facility. Crucially, having the ingredients and even the ability to prepare a compounded therapy does not imply that the compounding activity is permitted. Knowing the basic limits of permissible compounding can help minimize a hospital's related regulatory liabilities. Recognizing these limits requires some working knowledge of the different sources and sites of regulation.

II. OVERLAPPING SOURCES OF HOSPITAL COMPOUNDING OVERSIGHT

To appreciate the regulatory complexity of hospital compounding, consider, by contrast, the typical 503a pharmacy. Compliance there focuses on a relatively small set of standards: the FD&C Act, applicable state pharmacy rules and regulations, USP standards and any voluntary or required accreditation standards. These standards sit squarely within the scope of practice for pharmacies and pharmacists.

Hospital compounding is different. Hospitals typically feature both in-pharmacy compounding—for hospitals with institutional pharmacies—and a variety of out-of-pharmacy compounding activities performed by an array of different licensed health professionals. As a result, pharmacy rules are not the only standards that must be considered. Each regulatory

WHO
Are providers other than physicians and pharmacists engaging in or assisting with compounding?

WHAT
Are patient prescriptions required before compounding, or are stock drug products being compounded?

WHEN
Is this a true emergency, "in which a delay could harm the patient"?

WHERE
Does the hospital maintain a current inventory of all the locations in the hospital where compounding is taking place?

HOW
Is sterile compounding only being conducted in compliant clean rooms, or if not, under what circumstances?

agency oversees different aspects of the activity. CMS sets rules for administration, coverage, and reimbursement; state professional licensing boards set rules for different licensed providers, including defining each discipline's scope of practice and permissible supervision and delegation structures; private accreditation bodies set standards for auditing and ensuring the main components of compliance for an array of different business and professional services.

Making Sense of the Web of Providers and Rules

I. THE FEDERAL LAW OF COMPOUNDING: THE FD&C ACT AND SECTIONS 503A/503B

The Federal Food, Drug & Cosmetics Act (the "FD&C Act" or "the Act") is the touchstone for pharmaceutical compliance—the overarching standard that all providers must comply with regarding questions of the production of drug products, including compounded drug products. However, drug products compounded in compliance with 21 USC 353a ("Section 503a") or 21 USC § 353b ("Section 503b") are exempt from certain requirements of the Act. Products compounded under Section 503a are exempt from the current good manufacturing practices ("cGMP"), the Act's requirements regarding labeling, and the Act's new drug approval requirements. In other words, drug products that do not meet the requirements of Section 503a or Section 503b must satisfy these requirements, even if they are compounded.[1]

The practical impact of this for hospitals is that drug compounding must satisfy the requirements and limitations of either Section 503a or Section 503b, including the following:

Another important question is how compounding is defined. Although—unlike many state pharmacy acts—the Act does not provide an affirmative definition of compounding, it does specify what compounding is not:

> *As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.*[1]

Because the Act includes only this narrow exception, it is prudent to consider compounding as a fairly broad term, including any acts involving the combining, mixing, or creation of a new product from various drugs or drug ingredients. To the extent a drug preparation falls outside manufacturer-approved labeling, it likely constitutes pharmaceutical compounding.

While the Act leaves several significant questions unanswered, these requirements must be kept in mind. Compliance with the Act is a baseline requirement for other compounding activities; the institution and implementation of policies and procedures covering other governing rules and standards must maintain compliance with the Act.

TABLE 1. COMPARISON OF SECTION 503A AND SECTION 503B COMPOUNDING

	SECTION 503A	SECTION 503B
Who may compound	Pharmacists and physicians	Registered outsourcing facilities
Prescription requirements	Prescription required prior to compounding with limited exception for anticipatory compounding	No prescription required and compounded drug products can be used as office stock
Manufacturing standards	Not treated as manufacturing—cGMP standards enforced on registered manufacturers providing compounding ingredients; typically subject to state licensing and inspection	current Good Manufacturing Practice (cGMP)
"Essentially a copy" compounding	Prohibited except under limited exceptions	Prohibited except under limited exceptions

II. FILLING IN THE GAPS: WHAT STANDARDS REGULATE HOSPITALS DAY-TO-DAY

The FD&C Act provides a basic framework for compounding. But within this framework, compounding is also governed by various other regulatory agencies and their associated regulations and standards. These agencies and associated regulations typically include at least:

- State boards of pharmacy, medicine, and nursing and the regulations promulgated by each;
- The Centers for Medicare & Medicaid Services Conditions of Participation and related coding coverage, and administrative regulations;
- Accreditation agencies for both licensed professionals and associated business and facility accreditation, e.g., the Joint Commission;[3]
- State public health agencies or other hospital-licensing or registration boards and their promulgated rules;
- USP standards incorporated by law, regulation, accreditation, or professional practice requirements;
- Medical staff rules; and
- Local hospital rules and policies, including compliance programs.

Successfully navigating these various sources of oversight requires communication and collaboration between multiple stakeholders within a hospital system, including administration, compliance, pharmacists, physicians, and associated medical and nursing staff.

USP Standards: Hospital Compounding Requirements Through Boards of Pharmacy and the Joint Commission

The U.S. Pharmacopeia's ("USP") objective is to improve public health through the setting of standards in compounding, biologics, pharmaceutical manufacturing, and other fields. Most relevant to the area of compounding are USP chapters <797> (Sterile Preparations), <795> (Nonsterile Preparations), and <800> (Hazardous Drugs) (note however that facilities registered with FDA as Section 503b outsourcing facilities are subject to applicable current good manufacturing practice requirements rather than USP standards).[2]

While the specifics vary from state to state, hospital pharmacies are generally licensed and regulated by the state boards of pharmacy as institutional pharmacies. While the adoption and application of more recent USP updates have been inconsistent, most state boards have adopted some version of the USP standards.

However, with some exceptions state boards of pharmacy seldom regulate activities outside the setting of licensed pharmacies and pharmacists. Other professional or institutional licensing agencies will typically oversee the activity of non-pharmacy providers and associated licensed facilities. Consequently—though state boards of pharmacy often regulate the pathways by which drug products reach sites beyond licensed pharmacy facilities—compounding activity in a hospital but outside a pharmacy or the work of licensed pharmacists are typically most proximately regulated by agencies other than the pharmacy board.

For hospitals, although there are federal and local boards of health and other related agencies, the main "governing" body is not a government agency at all, but a private non-profit organization recognized by CMS as having "deemed status" authority. The Joint Commission and other accreditation organizations approved by CMS (collectively referred to as "Joint Commission") exercise this authority through the Medicare Conditions of Participation.[3,4]

The Medicare Conditions of Participation are the "baseline health and safety requirements that hospitals must meet to be eligible for participation in Medicare."[3] The Conditions of Participations require that "[p]harmaceutical services must be administered in accordance with accepted professional principles."[5] These include "applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations, such as those found in the U.S. Pharmacopeia/National Formulary (USP/NF)." By way of example, the Joint Commission, in the exercise of its role, has adopted the USP standards—including the updated USP Chapters <797> and <800>.[5,6]

Issues to Consider in Developing a Compliant Hospital Drug Compounding System

A hospital compliance team must be able to identify the "who, what, when, where, and how" of compounding in its hospital under the standards and regulations applicable to the hospital system. Does the hospital maintain a current inventory of all the locations in the hospital where compounding is taking place? Are providers other than physicians and pharmacists engaging in or assisting with compounding? Are patient prescriptions required before compounding, or are stock drug products being compounded? Is sterile compounding only being conducted in compliant clean rooms, or if not, under what circumstances?

Patients seek hospital care for a wide and ever more complex range of conditions and associated therapies. While it may be impossible to imagine every scenario in which a compounded drug product might be needed or the context in which that compounding may take place, hospitals can still work to implement policies and procedures to answer everyday questions about permissible drug compounding. Moreover, planning for more unusual, but foreseeable, situations enables a hospital to prepare for more difficult regulatory questions and challenges as they arise.

I. PHARMACIST LEADERSHIP

Compliance in this area requires coordination between multiple disciplines and departments, but pharmacists must be central to these efforts.[7] In its guidance on preventing medication errors in hospitals, the American Society of Health-System Pharmacists ("ASHP") notes:

> *Safe medication practices begin with placing medication safety as an organizational and departmental priority, and implementing a system that will support these practices...In order to ensure overall success, a medication safety leader, preferably a pharmacist should lead the medication safety efforts throughout the organization.*[8]



As part of its overall compounding compliance efforts, ASHP further notes that the hospital's pharmacy department should implement, review, and, as needed, update SOPs addressing the following general categories:[9]

- *Personnel* – training, education, skills, competency evaluations, and responsibilities.
- *Facilities* – access, cleaning, maintenance, use, monitoring, and testing.
- *Equipment* – calibration, maintenance, cleaning, certification, verification, and use.
- *Supplies* – ordering, storing, certification, inspection, and disposal.
- *Compounding procedures* – preparation of various sterile compounded medications, formulas, assigning BUDs, handling and packaging.
- *Safety* – injuries, hazardous spills, and accidental exposures (although outside the scope of this article, this standard and USP Chapter <800> provides a useful reminder that compounding compliance involves hospital personnel outside administration and clinical providers, including facilities and occupational-health personnel).
- *Quality assurance* – inspection of compounded drug products, testing of compounded drug products, BUDs, delivery and storage of final compounded drug products, patient monitoring and adverse event reporting, and personnel and environmental monitoring.
- *Administration* – record keeping and management.

II. HOSPITAL ADMINISTRATION AND OVERSIGHT

Hospital administration must be active in ensuring that compliance in this area is maintained.

- Has the hospital administration implemented a medication safety team and appointed a medication safety leader?
- Is the administration supporting the efforts of this team, including removing obstacles to compliance efforts and encouraging coordination not only among the health care providers, but also within other departments in the hospital—such as facilities, safety, and HR?

> *"Regardless of a staffer's organizational title, any individual involved in drug compounding…is 'compounding personnel.'"*

III. AREAS OF POTENTIAL COMPOUNDING ACTIVITY

While industry leaders such as ASHP recommend that to the extent possible drug compounding, particularly sterile drug preparations, take place within the hospital's pharmacy, the reality is this is not always possible. Hospitals sometimes provide localized, designated compounding spaces in key departments for more efficient delivery of formulas—particularly those formulas relevant to that clinical setting. Compounding also occurs in clinical settings, such as emergency departments and operating rooms where compounded therapies may need to be prepared and administered on site for immediate use. Hospitals must take special care to ensure these additional spaces meet the applicable standards. Because of this, hospitals must know where compounding is expected to take place and ensure it satisfies these requirements. Consider:[10,11]

- Are these areas well-suited for the types of compounding that is most needed in this clinical situation?
- For example, if sterile compounds are expected to be used, is the location set up for sterile compounding?
- As ASHP notes, compounded drug products "shall be prepared by appropriately trained personnel in accordance with applicable practice standards and regulations." Do the personnel compounding the medication have appropriate training?[11]
- If hazardous drugs are involved, does the compounding location comply with the requirements of USP <800>?
- Is the clinical environment well-suited to maintain prepared medication in usable form?

- Is the location being used to store ingredients, finished compounded drug products, or compounding equipment?
- Does it meet the environmental and security requirements to satisfy the requirements for these uses as well?
- If not, what processes are in place for transporting these items to ensure the final compounded drug product is not compromised in some way?

IV. PROVIDER QUALIFICATION AND COMPETENCY VERIFICATION

Regardless of a staffer's organizational title, any individual involved in drug compounding—particularly sterile preparation drug compounding—is "compounding personnel." It is critical that hospitals identify all such individuals and ensure that they are not only qualified but also competent to engage in or assist with drug compounding.

- Are compounding personnel—in whatever capacity—initially qualified, continually trained, and periodically subject to quality assessments and competency evaluations?
- Are the requirements and limitations of drug compounding clearly set forth in the hospital's policies, procedures, and other guidance so that compounding personnel are clearly instructed on what they may and may not do? For example, are nurses engaged in independent compounding activity, or are they properly directed and supervised by an individual authorized to engage in drug compounding?
- Has the hospital clearly identified what activities are not classified as compounding under Section 503a—mixing, diluting, and other acts pursuant to the manufacturer's label direction?
- Has the hospital trained the providers in recognizing the difference between compounding and these activities such that they know when compounding standards apply and when they do not?

The major categories of providers whose roles may intersect with perform or assist in compounding in the hospital setting include:

- Pharmacists;
- Physicians;
- Advanced practice providers;
- Pharmacy technicians; and
- Nurses.

In all activities that relate to compounding, these providers are governed by their professional licensing bodies, delegation and oversight responsibilities, individual scope of practice regulations, and Section 503a. Under Section 503a, only pharmacists and physicians may engage in compounding.[1] But as a matter of practice, other providers—such as pharmacy technicians and nurses—engage in activities which relate to or involve compounding and are explicitly acknowledged and regulated by the states.[12,13]

Hospitals should review who is engaging in compounding and compounding-related activities to ensure that the following questions are considered and appropriately addressed:

- Are all the providers operating within their scopes of practice, including permissible delegation, under applicable state law?
- Are the hospital's compounding practices in compliance with Section 503a's requirements?
- Do the hospital's rules, procedures, and processes account for the locations, circumstances and personnel involved in drug compounding?
- Is the hospital—or the relevant department or practice within it—providing the necessary and documented training and oversight to all providers that are engaged in or assisting with compounding?

V. IMMEDIATE USE AND EMERGENCY COMPOUNDING

Regulatory requirements and industry standards are consistent in requiring that all sterile compounding be confined to a proper environment, with environmental controls, including air exchange and ventilation requirements, consistent with ISO classifications; viable testing; and cleaning and disinfecting protocols.[14] The one exception to these requirements is immediate-use compounding in emergent care situations. Luis Hernandez, a certified sterile compounding pharmacist, summarized the issues this way:

> *In hospital settings, particularly within critical care units, the role of the pharmacist is crucial in ensuring the timely administration of life-saving medications. The preparation and delivery of compounded sterile preparations (CSPs) often determines the outcome of patients whose conditions are rapidly deteriorating. However, the traditional process of compounding, especially when handled through the standard IV room workflow, can introduce delays that are costly in emergency situations.*[15]

IMMEDIATE-USE SOP ESSENTIALS

Four topics hospitals should address, per Hernandez[15,17]

1 Setting clear criteria for qualifying emergencies

2 Designating safe compounding areas

3 Establishing training and competency standards

4 Establishing compliant labeling and administration procedures

Industry standards recognize that in certain circumstances, optimal patient care is better served by prioritizing efficiency in delivery over the quality of the compounding process. In other words, on balance the risks of contamination or mistake inherent to compounding outside the standard sterile preparation processes and environment are acceptable in cases where the delay of the administration of the drug product to the patient carries a greater relative risk of harm. In these situations, the standards and the requirements related to pharmacist involvement, compounding environment, and compounding processes relax.

This, however, does not mean there are no standards. First, this type of compounding should be rare. The Joint Commission describes it as taking place in "urgent situations in which a delay could harm the patient."[16] Meaning this exception is meant for true emergencies, not simply practitioner convenience. Second, while the standards are relaxed, USP <797> still requires the use



BY THE NUMBERS

~7,500
compounding pharmacies in the U.S., by one recent estimate

97
outsourcing facilities on the FDA's official registry

4 hrs
window to begin administering an immediate-use compound

24 hrs
to use or discard "stock" compounds after they leave the pharmacy

of aseptic techniques, processes, and procedures, the establishment of written SOPs, personnel training, and that the administration of the compounded product begin within four hours following the start of the preparation. In his discussion of these issue, Hernandez distinguished four broad topics that hospitals should address to develop specific SOPs for immediate-use compounding including (1) setting clear criteria for qualifying emergencies; (2) designating safe compounding areas; (3) establishing training and competency standards; and (4) establishing compliant labeling and administration procedures.[15,17]

VI. PRESCRIPTION REQUIREMENTS AND STOCK USE COMPOUNDED DRUG PRODUCTS

Because hospitals very rarely operate outsourcing facilities, virtually all compounding in a hospital falls under Section 503a, which requires that compounding be in response to a specific patient prescription or in limited quantities based upon a history of receipt of valid prescriptions for the compounded drug product.[18]

The Food & Drug Administration ("FDA") has acknowledged that within the hospital context, certain allowances may need to be made for circumstances in which neither prong of Section 503a's prescription requirement can be met: "For example, a hospital or health system may maintain a supply of certain compounded drug products within the hospital or health system but outside of the pharmacy (e.g., in an emergency department, operating room, or automated dispensing machine) in anticipation of a patient presenting with a critical need for the drug when there is no time for the patient to wait for the hospital pharmacy to receive a prescription or order for that patient before providing the drug."[19]

Whenever possible, the FDA recommends that hospitals obtain these "stock" compounded drug products from registered outsourcing facilities. But, in cases where that is not possible, the FDA's Draft Guidance outlines its current enforcement priorities. In cases where a patient is administered a compounded drug product that does not meet the Section 503a prescription requirement, the FDA does not intend to take action so long as the following conditions are met:[20]

- The compounded drug products are only administered to patients within the hospital or health system;
- The compounded drug products are used or discarded within 24 hours of transfer out of the pharmacy; and
- The drug products are compounded in accordance with all other applicable requirements of the FD&C Act and FDA regulations.



If the hospital's compounding of "stock" drug products does not meet these criteria, the FDA exercises enforcement discretion. In describing its priorities, the FDA has focused on the following considerations:[19]

- Evidence of poor compounding practices or lack of sterility assurances;
- Non-patient specific compounded drug products not for emergency use;
- Routine, large amounts of non-patient specific compounded drug products;
- Routine interstate distribution of large amounts of non-patient-specific compounded drug products; and
- No procedures to obtain non-patient-specific compounded drug products from an outsourcing facility.

VII. THIRD-PARTY COMPOUNDING SUPPLIERS AND SUPPLY-CHAIN CONTINUITY

While some hospitals may prefer to supply the bulk of their compounded drug products internally, for other hospitals this may not be possible, practical, or desirable. Many hospitals lack adequate facilities or staff or sufficient patient or physician demand to justify a dedicated drug compounding program. But all hospitals, from time to time, will likely need to acquire compounded drug products from some third-party. The two primary sources for these products are 503a compounding pharmacies and 503b outsourcing facilities.

While the FDA has expressed a clear preference that hospitals source compounded drug products from outsourcing facilities, there are practical, and in some cases, regulatory reasons why this may not be possible. Understanding the capabilities and limitations of the two types of drug compounders will allow hospitals to properly assess which is the best option under various circumstances.

503a Compounding Pharmacies

From a regulatory perspective, the major limitation of compounding pharmacies as sources of compounded products to hospitals is that they are subject to the Section 503a prescription-specific compounding requirements. This means that a standalone pharmacy cannot supply "stock" compounded drug products. Also, from a practical perspective, while a 503a pharmacy is subject to the same compounding standards as the hospital itself, the hospital does not have direct oversight and control of the pharmacy. Obtaining compounded drug products from outsourcing facilities, which are under direct FDA oversight and subject to cGMP production standards, may afford hospitals greater confidence in the quality of the drug products supplied.

The major benefits of working with 503a pharmacies include enhanced product availability and operational flexibility. The practice of compounding by pharmacies stretches far back into history—with pharmacists and their predecessors in effect serving as the original drug manufacturers. While drug manufacturing has replaced much of this historical practice, drug compounding remains a vital piece of the overall drug supply chain, with one recent estimate putting the number of compounding pharmacies in the United States at approximately 7,500. Pharmacies also have greater flexibility in what products they can compound. Under Section 503a, they are authorized to compound with, among other ingredients, any substances "that are components of drugs approved by the [FDA]."[1,20]

503b Outsourcing Facilities

The key strengths of outsourcing facilities include their ability to provide stock compounded drug products to licensed health providers and the requirement that they prepare compounds according to cGMP standards. From a quality and compliance standpoint, these are both attractive benefits.

However, the supply of compounded drug products from outsourcing facilities is constrained by both the relative rarity of outsourcing facilities and the regulatory constraints on what they may produce. First recognized in 2013, outsourcing facilities are still a comparatively novel part of the drug supply infrastructure. As this article goes to press, only 97 outsourcing facilities are listed on the FDA's official registry. Furthermore, the FDA tightly restricts the types of drug substances that outsourcing facilities are allowed to use in compounded products. Unlike 503a pharmacies, which can compound using any component of an approved drug, outsourcing facilities can only compound using substances on the approved 503b bulk substances list or drug products that are currently in shortage. As a result, even where a hospital may need a supply of compounded drug products, outsourcing facilities may not be able to produce them.

Because each option has its own strengths and limitations, hospitals should consider developing arrangements with suppliers from both categories. Hospital procurement personnel must maintain awareness of its suppliers' strengths and

limitations in order to adapt to the changing demands of the hospital's component divisions.

VIII. SURVEY READINESS - MAJOR AREAS OF REGULATORY RISKS AND ENFORCEMENT

In Standard MM 15.01.01, the Joint Commission outlines the elements it reviews in evaluating whether a hospital safely prepares medications in compliance with the law and applicable compounding standards. This standard is broken into the following general requirements:

- A pharmacist supervises all compounding activity—except in emergent situations.
- The hospital develops and implements SOPs for sterile medication compounding.
- The hospital assesses competency of staff who conduct sterile medication compounding.
- The hospital conducts sterile medication compounding within a proper environment.
- The hospital properly stores compounded sterile preparations and labels them with appropriate and compliant beyond-use dates.
- The hospital conducts quality assurance of compounded sterile preparations.
- And for hospitals that use Joint Commission accreditation for deemed status purposes, an appropriately trained registered pharmacist or doctor of medicine or osteopathy performs or supervises in-house preparation of radiopharmaceuticals.

At the ASHP Pharmacy Futures 2025 meeting, Dr. Jeannel Mansur, a specialty principal consultant for medication management for Joint Commission Resources, gave a report on hospitals' progress with the expectations set forth in Joint Commission Standard MM 05.01.07. While she noted that hospitals have made significant progress in meeting those expectations, areas of confusion and weakness still exist. For example, regarding immediate-use compounding, she noted that areas of weakness were typically the result of unclear ownership, inconsistent staff training, gaps in competency validation, and policies that did not align with actual practice. Considering the issue more broadly, she noted several persistent problem areas:[21]

PERSISTENT PROBLEM AREAS

Areas of confusion and weakness reported at ASHP Pharmacy Futures 2025

1. **Nurses compounding in clinical areas for nonurgent needs**
2. **Improper compounding technique, hand-washing process, and storage of materials used in compounding**
3. **Noncompliant immediate-use compounding**
4. **Inadequate competency documentation**
5. **Failure to implement new competency requirements**
6. **Failure to maintain or implement proper cleaning protocols, environmental controls, and improper storage of hazardous drugs**
7. **Improper labeling, including specifically incorrect beyond-use dating**



The experts at the ASHP meeting noted that they have seen and are encouraged by improvements at hospitals they are reviewing. But a common thread throughout their observations was that compliance in this area must extend beyond the basic training and documentation. Regular reviews, inspections, trainings, competency evaluations, and basic practice vigilance are critical to ensure that compounding personnel and support staff maintain the high standards required to provide safe and effective compounded therapies to medically vulnerable patients in their hospitals' diverse care settings.[8,21]

Conclusion

Hospital compounding compliance turns not only on what is prepared, but also on who prepares it, where it is prepared, the clinical settings at play, and the particular set of regulatory organizations overseeing the preparation. Maintaining compliance requires that hospitals identify compounding and medication-preparation activities across all clinical departments and align those activities with the applicable regulatory frameworks.

To accomplish this, hospitals must identify every location and category of professional involved in compounding or medication preparation. They must then determine the legal standards applicable to each activity and align institutional policies with current USP, accreditation, and regulatory expectations and requirements. When necessary or beneficial, hospitals should establish relationships with qualified outside compounding pharmacies and outsourcing facilities.

Developing and acting in accordance with these policies and procedures will set a hospital up for success at maintaining a consistent, safe, and effective supply of compounded drug therapies.

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