



Pharmacy's Legal Liability and USP <797> Risk Reduction Strategies

“To improve is to change;
to be perfect is to change often.”

-Winston Churchill

An introduction to a pharmacy law course may sound something like this: “Welcome to one of – if not the most – legally regulated professions in society. Welcome to pharmacy.” Due to the large number of regulations, pharmacy rules are dynamic and frequently change. This observation takes on additional meaning as pharmacists become more involved in patient care and their legal liabilities increase exponentially. Over the past four years, USP Chapter <797> has moved from a background position of something we “should” comply with, to a forefront position as a standard we “must” comply with when producing compounded sterile preparations (CSPs) for patient use. Today, it is nearly impossible to go through a shift without hearing the term USP <797>, leaving many pharmacy practitioners to ask, “How will the chapter be enforced, and how can I comply with it?” The landscape has shifted from one of “best practice” advice to the reality of enforceable “minimum standard” regulations.

This article will discuss the legal responsibilities resulting from a turbo-charged USP <797> and summarize the shifts in public policy and liability issues resulting from two primary sources of enforcement: federal and state administrative regulations, and civil litigation. Strategies for minimizing liability risks will also be discussed.

Public Policy Changes and the Basis for USP <797>

Recent medication errors have received much public attention. These examples are tragic, although most are unintentional – and sometimes avoidable – errors involving a variety of pharmaceuticals, including heparin, cardioplegia, proteins, and other compounded medications. Rarely are such misadventures intentional; however, with sadness, we mark seven years since Robert Ray Courtney’s reprehensible dilution of chemotherapy agents.

Health system errors are currently a hot button issue. The media highlights areas where change may be required, but most often does so by identifying fault rather than a solution. Other organizations, such as the Institute of Medicine (IOM) and the Institute for Safe Medication Practices (ISMP), seek to promote process improvements.

The USP is an independent, not-for-profit, science-based research organization that sets quality standards for pharmaceuticals. USP is not an “official” body of federal or state governments. Guidelines issued by USP, in the form of “chapters”, have been largely regarded as aspirational in nature. In other words, USP establishes reference standards, which can become enforceable if adopted into federal or state laws, statutes, or regulations.

All three branches of the U.S. government give great deference to USP guidelines and advice. For example, judges have used USP standards in formulating

court opinions; legislative bodies have incorporated USP standards into federal and state statutes; and administrative agencies often rely on USP standards as indicators of acceptable practices. In addition, independent accrediting organizations, such as The Joint Commission (TJC), have incorporated USP standards into certification qualifications.

Regulations and associated enforcement actions function as deterrents to non-conforming behavior. Enforcement may be administrative (levied by agency sanc-



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tions), criminal (levied by law enforcement agencies), or civil (through civil litigation). Governmental bodies must incorporate these standards into accredited laws and vest enforcement authority with the appropriate agencies. In addition, certifications and other credentialing may be denied if mandated compliance with USP <797> cannot be demonstrated. For example, failure to achieve Joint Commission accreditation could have a substantial impact on an institution qualifying for reimbursement from the Centers for Medicare and Medicaid Services (CMS).

Federal and State Enforcement of USP <797>

As a general rule, administrative agencies at both the federal and state government levels share the same mission: the protection of the health, safety, and welfare of the population they help to govern. The jurisdictions of federal and state administrative agencies in health care tend to adhere to the following dichotomy: Federal agencies are concerned with regulating the research, manufacture, production, and market-



ing of pharmaceuticals, whereas state agencies are concerned with regulating the professional practice of pharmacy.

■ Federal Enforcement

Several administrative agencies have various levels of jurisdiction over pharmaceuticals. A sub-division of the Department of Health and Human Services (DHHS), the FDA is the largest administrative agency in the U.S. government. CMS is also a division of the DHHS. The DEA, FBI, and Federal Trade Commission (FTC) are all divisions of the Department of Justice (DOJ). The Office of Civil Rights (OCR) also falls within the DOJ and has responsibility for enforcing patient privacy and confidentiality under HIPAA. These federal agencies' enforcement mechanisms are meant to ensure the quality of industrial manufacturing and supply chain integrity for pharmaceutical distribution. The Food, Drug, and Cosmetic Act and the ability of the federal government to regulate interstate commerce are the legal basis for these agencies' enforcement actions. Recent U.S. Congress and FDA efforts to regulate pharmaceutical compounding exposed some gaps in the perceived jurisdiction over individual pharmacy practice. For example, in the '90s, Congress and the FDA undertook efforts to regulate extemporaneous compounding activities by pharmacists. Legal challenges directed at freedom of speech in this matter were heard before the U.S. Supreme Court, and ultimately, the restrictions imposed on pharmacy practitioners were found to be unconstitutional.

■ State/Local Enforcement

Enforcement of USP <797> at the state and local level is likely more important to individual pharmacy practitioners than federal enforcement. At least 12 states have incorporated all of the USP standards into their pharmacy practice acts and other health care statutes (To learn more about your state board of pharmacy's position on USP <797>, visit www.clinicaliq.com/component/option,com_google_maps/Itemid,111), and momentum is gaining for more states to incorporate <797>.

In most related state and local statutes, non-compliance with USP <797> may lead to an administrative penalty as simple as a citation and monetary fine, or as severe as the denial, suspension, or revocation of an individual or organizational license to practice pharmacy. In Utah's pharmacy practice statutes and regulations, non-compliance is deemed unlawful or unprofessional conduct, and a finding of such conduct may result in administrative penalty of \$500 to \$10,000.

The NABP is leading an effort to assist individual state boards of pharmacy to systematically and rationally incorporate USP <797> standards to promote public health, safety, and welfare. The NABP is also in the process of changing their set of model rules for pharmacy practice to incorporate USP <797> guidelines.

Risk of Civil Litigation from Non-Compliance

Civil litigation may commence when one party (the plaintiff) believes it was harmed by another party (the defendant) because a duty (standard of care) was breached. In these situations, civil litigation may be labeled as a malpractice action or as professional negligence, and these actions are almost exclusively handled in state court systems. There are four basic elements to a malpractice case: duty/standard of care; breach; proximate cause; and harm (damage). To be successful in civil litigation, the plaintiff must prove each of the four elements.



Documentation of activities is essential to avoiding an administrative or civil action, and keeps your facility on target for optimizing patient safety

Photo courtesy of Hardy Diagnostics

■ Defining the Standard of Care

In malpractice cases, the legal battle starts with defining the standard of care to be applied. In a general negligence case, this standard is: What would a reasonable person have done in the same situation? In a professional malpractice case, the standard is: What would a pharmacist with similar training have done in the same situation? The standard of care is established through expert testimony. If the defendant is a generalist in the profession, the standard of care is typically based on a local or community standard. However, if the defendant is practicing in a large metropolitan area or involved in a specialty practice, the standard will be a "national" standard. In situations involving CSPs, a reasonable argument may be made that national standards should be applied. In other words, the practice is sufficiently specialized so that most pharmacists cannot work with CSPs without receiving specific additional training beyond any entry-level requirements. This implies that USP <797> is likely to be viewed as a national civil liability standard for producing CSPs.

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■ Negligence Per Se and Res Ipsa Loquitur

In the involved jurisdiction, specific statutes may prescribe compliance with USP <797>. In those situations, a pharmacy professional failing to produce the appropriate compliance documentation may be found liable on a negligence per se basis. In other words, if a specific state law requires compliance with USP, and non-compliance with USP resulted in harm to a party, a defendant may be found negligent on a per se basis. When USP guidelines are violated by manufacturers and others who compound CSPs, they may be subjected to negligence per se reasoning and the principles of product liability. Under product liability circumstances, defendants may be held liable even if they were not professionally negligent. As USP <797> is more widely incorporated into state pharmacy practice acts, an administrative action against a pharmacy for non-compliance with USP may also serve to support a legal action if harm comes to a patient.

Finally, a plaintiff who suffers damage, and who may not be able to otherwise prove the standard four elements of negligence, may be able to assert an argument of negligence res ipsa loquitur (Translation: the thing speaks for itself.). Negligence res ipsa loquitur requires an inference that harm specifically resulted from failure to comply with USP guidelines. If this legal argument is utilized, there would have to be widespread acknowledgement that USP <797> is the standard of care. Although this is the direction in which USP appears to be heading, it will take a substantial majority of practitioners to accept USP <797> as the standard of care before a res ipsa loquitur challenge is possible. This legal pathway should be recognized as a future enforcement tool against practitioners who do not respect USP <797> guidelines.

As more state boards of pharmacy begin to develop specific statutes for USP <797> compliance, the opportunity for civil litigation may be substantially enhanced. Incorporation of USP <797> into statutes will greatly impact definitions of standards of care and the resulting assessments of civil liability.

Strategies to Reduce Litigation Risk and Demonstrate Compliance

Given the legal liability risks associated with non-compliance, pharmacists should take steps to demonstrate their adherence to USP <797> requirements. The following guidelines are suggestions for minimizing risk, but should not be legally relied upon as a complete list of risk-minimization strategies.



Cover Story

Identify all CSP-related activities. For every instance in which CSPs are produced, identify the location (central admixture area, OR satellite, outpatient infusion pharmacy, pharmacy satellite, compounding aseptic isolator, nuclear pharmacy, etc.) and all of the staff members responsible for or involved in producing CSPs.

Demonstrate an understanding of USP <797> and maintain competence in compounding activities. All staff involved in CSP activities should read and understand USP Chapter <797> and stay informed of federal and state statutes and regulations. Staff understanding should be evaluated at regular intervals and quantified using media-fill tests. Continuing education and specialized training programs are available to assist pharmacies in maintaining competence and compliance.

Develop USP <797>-specific policies and procedures. Review your institutional and/or departmental policies and procedures involving CSPs. Facilities should have specific policies related to CSP preparation and cleanroom procedures and the training of staff involved in preparing CSPs.

Designate a CSP “Czar” or committee. Vest responsibility for compliance with USP in a staff member or group to ensure “ownership” of compliance-related issues.

Document, document, document. Documentation of activities is essential to avoiding an administrative or civil action, and keeps your facility on target for optimizing patient safety. Adopt the mantra: If it is not documented, it was not done. Organize and maintain complete files.

Collect references and resources on CSPs. Pharmacies should maintain a library of references related to CSP activities.

Cultivate communication on USP requirements. Medical, nursing, respiratory, and medical technology staff, as well as facility administration and other professionals who may be involved in producing or utilizing CSPs should be kept abreast of USP <797> requirements and any changes to related federal and state statutes.

Consider a gap analysis. Numerous consulting firms can assist your pharmacy in

performing a gap analysis. An action plan should be contemplated and undertaken for each of the points of non-compliance identified in the gap analysis.

Perform diligent environmental monitoring. Develop an environmental monitoring program pursuant to <797> guidelines for each area where CSPs are produced.

Incorporate external quality control mechanisms. To the highest degree that is financially possible, utilize outside companies for the design, implementation, or validation of your primary and secondary engineering controls, environmental monitoring program, and staff competency requirements.

Review out-of-state pharmacy activities. Those pharmacies that prepare and dispense prescriptions under out-of-state licenses to non-residents should remain current in their knowledge of USP requirements in out-of-state licensed jurisdictions.

Summary

The principles set forth in USP <797> are of great importance to health care professionals and their patients. The chapter is used by administrative agencies to govern activities related to CSPs and to signal practices that jeopardize the health, safety, and welfare of society. The enforcement of USP <797> may be accomplished administratively and through civil court proceedings, the possibility of which may give some pharmacists angst. However, USP <797> should be viewed as roadmap for promoting patient safety in health care and, by implementing its recommended guidelines and other strategies to reduce risk, as a means for minimizing the pharmacy professional’s legal liability. ■



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Disclaimer: The content of this article is provided only as a general introduction and should not be relied upon for specific legal situations. Please consult an attorney for counsel on legal risks associated with USP <797> compliance.

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