

Baxa Corporation

Outsourcing & USP <797> Compliance

Technical Paper

The limitations of outsourcing pharmacy IV admixture services to comply with USP <797> requirements for sterile compounding



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Abstract

January 2008¹ was the initial target date the Joint Commission set for full compliance with USP <797>. However most US pharmacies are still scrambling to meet the deadline. Outsourcing of pharmacy IV admixtures is one compounding option that has been considered to 'fast-track' compliance. While this option may work in some niche applications, this paper concludes that outsourcing alone, or in combination with immediate-use mixing and ready-to-use doses, is not the answer to USP <797> compliance for comprehensive and appropriate pharmacy services.

Outsourcing Overview

Outsourcing pharmacy services is an extremely complicated decision on many levels and too broad of a topic for elaboration in this paper. An excellent objective overview of the concept and process is available through the American Society of Health-System Pharmacists.² This easy-to-read, seven-page document is full of summarized bullets, contract provisions and suggested reading that is sure to stimulate the thought process of anyone contemplating outsourcing.

The "ASHP Guidelines on Outsourcing Pharmaceutical Services" was approved by the ASHP Board of Directors in 1998. It was reviewed in 2002 by the same group and found to be still appropriate. The information continues to be relevant today and should be required reading by anyone desiring to learn more about the topic of outsourcing pharmacy services.

Impact of USP <797>

The Joint Commission's January 2008 deadline for full compliance with USP <797> seemed like a long time away when the document first released in January 2004. But the time did pass and that deadline is now at hand. Most US health-system pharmacies agree that they will not achieve full compliance on time.³

Lack of compliance to industry and regulatory standards brings pressure on the non-compliant and inevitably stimulates the search for solutions. One obvious solution is simply to get out of the business of compounding sterile products altogether. Pharmacies that do not compound sterile IV admixtures would no longer need to comply to USP <797>.

There are probably only a few practical ways for typical hospital pharmacies to leave the IV compounding business. Refusal to make the doses is one option, but probably not a viable one for continued operation and employment.

The proposed revision to USP <797>⁴ offers a small window of non-compliance through the production of doses for 'immediate use.' This exemption was accepted by the Joint Commission in 2004.⁵

One alternative for compliance is the use of ready-to-use unit dose medications such as ADD-Vantage[®], Add-a-Vial[®], etc. Another alternative is to have someone else make the doses, by outsourcing the work. These options are explored in greater depth below.

Immediate Use

The immediate use exemption offered in the revised USP <797> guidelines is extremely narrow and clearly not intended to provide institutions with a means to bypass the entire standard. The requirements to hang doses within one hour of mixing is deliberately restrictive. Boards of Pharmacies also expect providers to comply to a limited administration time for completion of doses, as it is relevant to the stability and sterility of the dose. 'Immediate use,' for example, cannot include routine and known doses and IV chemotherapy doses are excluded. No typical healthcare provider could accomplish comprehensive state-of-the-art IV therapy under these restrictions.

There are also bigger issues involved in this approach. Expanding immediate-use mixing virtually implies shifting mixing activities to the patient care areas. There is a good argument to be made that pharmacy would abdicate its professional responsibilities by shifting this critical function to nursing. Pharmacy IV admixture services were developed and flourished for sound patient safety and economic reasons. Turning back the clock on decades of progress to circumvent new (and necessary...) quality requirements does not seem appropriate or in the best interests of the patient.

Ready-to-Use

Ready-to-Use, or premixed IV admixtures, are an important component of the IV therapy system. Examples like standardized concentrations of potassium chloride in liters of solutions have provided efficiency, safety and many other benefits for decades. Unfortunately, premixed IVs alone will not meet the needs of every clinical situation. USP <797> compliance will still be required for the inevitable additional compounding required to meet the needs of any comprehensive IV admixture service.

Outsourcing

The third option is outsourcing. Outsourcing the production of IV admixtures has been available to some extent for at least 20 years. This option usually is limited to major metropolitan areas, although niche providers also exist throughout the country. There are good reasons to outsource some IV products that are documented in the literature.^{2, 6-8} Some of the most viable choices for IV outsourcing are high-risk admixtures, batch products mixed in anticipation of future doses, and some patient-specific IVs that can be ordered well enough in advance to overcome the logistical issues (order timing, travel, etc.) for the outsourcing operation.

For pharmacy managers, the hard truth is that pharmacies cannot fully meet the USP <797> requirements through outsourcing. Any pharmacy providing any level of IV therapy will still need to make first doses, doses that are subject to change and many short-expiration doses. Certain anti-neoplastic drugs, and other expensive doses that are subject to change, based on patient response or current labs, are difficult to outsource. While some of the aforementioned doses fall under the definition of 'immediate use,' it is clear that sterile compounding requirements can be reduced by outsourcing, but cannot practically be eliminated. Even if a pharmacy outsources most of their doses, they will still have to comply with USP <797> for the remaining admixtures that are not 'immediate use' under the USP definition.

With outsourcing, there are other issues to consider beyond regulatory compliance. Pharmacies should use extreme caution in getting too far removed from the compounding business. If their outsourcing vendor closes, raises prices sky high, encounters service or quality problems etc., the pharmacies now have placed their hospitals in a potentially catastrophic situation. Business failures can come from either economic or regulatory pressures and can happen overnight. Outsourcing operations are very susceptible to these pressures. For health systems (and patients), IVs are life and death. There are significant risks to hospitals in walking away from one of pharmacy's fundamental responsibilities by outsourcing more than they can quickly recover.

Other intangibles about outsourcing to circumvent USP <797> compliance is that the pharmacy likely will be required to give up full-time-equivalent labor positions to justify the outsourcing costs. Such steps may undermine pharmacy influence within the organization over the long term and merit serious consideration in the decision-making process. For the most part, USP <797> contains many procedural, training and quality assurance requirements that are not unreasonable for quality IV operations. Many of these lessons are transferable to the running of the entire pharmacy operation, such as distribution and clinical functions.

Responsibility

The final point is that while it may be possible to outsource *labor*, it is not possible to outsource the *responsibility* for the quality and sterility of CSPs. Regardless of the source, the pharmacy department is still responsible for the IVs administered in their facilities. Outsourcing operations also use human capital and make mistakes. While an outsourcing company may have superior IV compounding quality to an operation that is not USP <797> compliant, it's naive to believe that errors will be completely eliminated. Pharmacies are required to comply with USP <797> regardless of their balance of labor and source of supply (in-house, outsourced, regional compounding). Individual pharmacy managers should determine how much additional responsibility they are willing to accept without control.

Summary

For the profession of pharmacy, the requirements to comply with USP <797> may seem difficult and unnecessary. However, it's important to remember that the pharmacy industry self-regulated sterile compounding practice for many years. The American Society of Health-System Pharmacists noted in two studies⁹⁻¹⁰ that self-regulation failed to achieve compliance to the minimum requirements for safe practice. The reality is that today, USP <797> sets the baseline for pharmacy practice and that responsibility cannot be outsourced completely. Although free-standing clinics and other service providers may be able to find alternative solutions for compounding sterile products; for hospital pharmacy, there is no viable long-term option other than compliance to USP <797>. Immediate-use mixing, and even outsourcing, play a role in this process, but do not permit hospitals to abdicate their responsibility for adherence to USP <797>.

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