Committee News

ASA Champions Safety and Workflows with USP <797> Policy Victory

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In November 2022, United States Pharmacopeia (USP) announced revisions to its General Chapter <797>, a standard for sterile pharmaceutical compounding that plays a major role in guiding regulatory bodies and accrediting organizations (asamonitor.pub/3iUbtDn). These revisions included a clear distinction between administration and compounding, and effectively ended the "one-hour rule," a restrictive standard stating that all immediate-use sterile products must be administered within one-hour after the start of preparation. Within this revised guidance, USP made clear that administration is officially outside the scope of Chapter <797>. Altogether, the revisions will resolve confusion and workflow disruptions our members have faced for years.

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Shortly after the publication of USP's revised guidance and based on the USP <797> Frequently Asked Questions, The Joint Commission (TJC) also released a statement clarifying that the pre-spiking of I.V. bag also falls outside the scope of Chapter <797> (asamonitor.pub/3YjPVAp). This development will further prevent misinterpretation of USP's guideline. In 2022, the ASA House of Delegates approved the Statement on Intravenous Fluid Bag Spiking. The statement described both USP and TJC misinterpretations prior to November 2022, and asserted, "Based on our understanding of the definitions and guidance put forth by the [Food and Drug Administration] and USP, as well as the available evidence in the published literature to date, not substantiating any risk of infection or contamination, spiking I.V. fluid bags and using them within 24 hours for surgery/procedure appears to be an appropriate and safe practice." Both the ASA Statement on Intravenous Fluid Bag Spiking and revisions from USP <797> will contribute to reducing clinical burden, reducing waste, and streamlining workflow in the perioperative environment while maintaining utmost patient safety.

ASA Advocacy on USP <797>

The United States Pharmacopeial Convention is a scientific nonprofit organization that sets standards for the identity, purity, manufacturing, and handling of medications that are recognized worldwide. These standards are published in the USP chapters, those numbered below 1,000 are standards while those numbered above 1,000 are recommendations. In most U.S. jurisdictions, USP chapters are incorporated into statute by reference. That makes these chapters enforceable by the Centers for Medicare & Medicaid Services (CMS) and those accrediting agencies that have been granted deemed status by CMS. To maintain compliance with TJC and CMS, physicians, pharmacists, and other health care workers are required to meet the standards of USP chapters. USP has no enforcement role.

Since the version of USP <797> that included the "one-hour rule" was published in 2004 and revised in 2008, ASA member liaisons have worked tirelessly with members of the USP Compounding Expert Committee to provide input regarding the "one-hour rule" that required the administration of all immediate-use compounded sterile products (CSPs) begin within one-hour after the start of preparation. ASA also submitted numerous comments to USP describing how the one-hour rule jeopardized patient safety, led to drug wastage, and was unnecessary in its application to anesthesiologist workflows. ASA also asked federal regulators for assistance in reducing administrative and clinical burden. The new changes to USP <797> are the result of years-long advocacy and our relationships with USP, TJC, and other regulatory and accrediting bodies.

Knowing that USP <797> was not only misapplied but gave anesthesiologists little room to negotiate changes to local policies and procedures, the ASA Committee on Quality Management and Departmental Administration (QMDA) proposed, and the ASA House of Delegates approved, a statement further clarifying anesthesiologist responsibilities on administering drugs in the OR and proactively preparing intravenous bags for patients. The ASA Statement on Administration of Medications, approved in 2020, affirmed, "Administration of medications includes the preparation of the medication from the packaged form into a form suitable as individually required by the needs of patients, including aseptically drawing up fluid medications into syringes, reconstituting and diluting sterile products, as well as preparing fluids in bags or bottles by attaching tubing for patient use." The statement clarifies that "these activities are distinct from compounding and not subject to compounding regulatory guidance."

In 2019, it appeared that USP had finalized their changes to USP <797>

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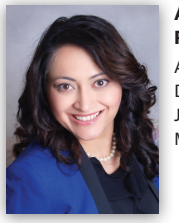

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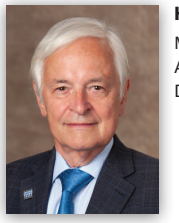

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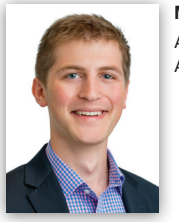

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that aligned with ASA and anesthesiologist priorities. However, in 2020, USP rescinded their revisions based upon non-OR concerns associated with compounding. The ASA advocacy efforts continued, ultimately resulting in the distinction between compounding and administration in 2022.

Where do we go from here? What can members do to remain compliant with accreditation requirements?

The Joint Commission has stated that their surveyors' approach to USP <797>, the administration of medications, and the spiking of I.V. bags will solely evaluate compliance with local/institution policy. Members should advise their department chairs and facility administrators to develop clear policies that support patient safety and the workflows of anesthesiologists and other qualified anesthesia professionals. Those facility leaders may consider appointing task forces or advisory committees to advance the development of these policies. Anesthesiologists and their groups should also engage with hospital administrators, pharmacy, infection control, and other stakeholders to review and update their protocols. According to TJC, those relevant protocols should be based on specific manufacturer instructions, evidence-based guidelines, and applicable state laws and regulations.

With the issues of USP <797> now settled, our members have an opportunity to implement a renewed focus on continuing education on sterile pharmaceutical development, as well as on the proper handling, preparation, and administration of medications with an emphasis on patient safety and care quality. On the advocacy front, we can turn our attention to supporting increased state and federal funding to better educate health care professionals on the best practices and federal, state, and local policies for preparing and administering medications. We can partner with our pharmacist colleagues in this advocacy as we look to build on the momentum of our policy victory in the new USP guidelines. ASA will continue to serve as a collaborative voice to support anesthesiologists and other health care professionals in providing the safest and highest quality of care for their patients. ■

Disclosure: *Dr. Gupta is an advisory committee member of the ASHP Research and Education Foundation, a special government advisor for the FDA, and a board director of the California Society of Anesthesiologists.*