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Longer storage times now permitted if testing performed

USP Releases Newly Proposed <797> Revisions

After almost two years of anticipation, USP has issued its new proposed revisions to Chapter <797>, "Pharmaceutical Compounding—Sterile Preparations." What does this mean for sterile compounding in your pharmacy?

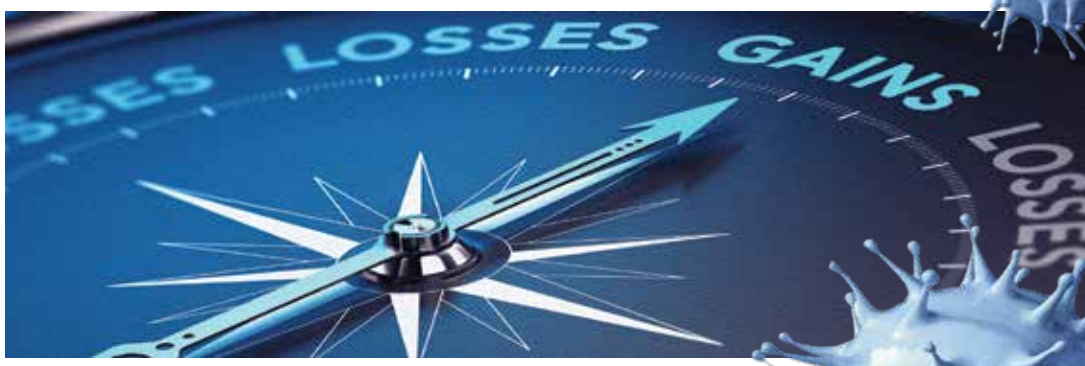
For most hospitals, which already had prepared to comply with the original <797> revisions, the temptation is to answer, probably "not much." But complacency is not advisable, experts warned. They stressed that the release still provides an important opportunity to check compliance with key provisions, and to become familiar with an important and much-awaited decision on beyond-use dating (BUD).

After the original publication

Continued on page 24

$80 million recovered at just one health system

Replacing Lost Revenue During the Pandemic



With normal revenues severely constricted by the influx of critical COVID-19 patients, health systems and hospitals across the country have had to find other ways to replace vanished income streams.

"One of the biggest challenges with COVID-19 has been the continuing downward pressure on the financials," said James Jorgenson, MS, RPh, the CEO of Visante, a pharmacy consulting firm. "Operating margins for the average hospital right now are somewhere in the 1% to 3% range."

Continued on page 34

A call for major reform

340Bs Push Back On Abuses Cited In COA Report

The Community Oncology Alliance (COA) has accused some safety net hospitals of gaming a federal drug discount program to boost profits.

The group says disproportionate share hospitals (DSH) participating in the 340B Drug Pricing Program charge nearly four times their acquisition costs for expensive oncology drugs, and pocket the margins.

Since 1992, the 340B program has required drug manufacturers to

Continued on page 26

One expert: 21% rate 'boggles my mind'

IV-WMS: Slow Adoption Remains A Threat to Compounding Safety

Although the COVID-19 pandemic continues to strain budgets and resources, U.S. hospital pharmacies have made progress in adopting IV workflow management systems (IV-WMS), which pharmacy leaders say is critical to improving the safety and efficiency of IV drug compounding.

Still, progress is slow. With a minority of hospitals using IV-WMS, advocates are questioning why the technology remains so underused despite years of guideline recommendations and robust evidence of its benefits.

"Why aren't IV workflow systems in every hospital in the country?" asked Christopher R. Fortier, PharmD, the chief pharmacy manager at Massachusetts General Hospital (MGH), in Boston, during Illuminate 2021, Omnicell's digital medication management conference. "Adoption is really low. It boggles my mind. This technology has been around for 10 or more years, so why [the delay]?"

Several factors may contribute to the low rate of adoption, but Dr. Fortier's theory is that hospitals were incentivized to focus on implementing electronic health record (EHR) systems when IV-WMS first hit the market. "I think IV workflow got put on the back burner," he said. But he and many of his colleagues hope that change is on the horizon.

Continued on page 40

IV-WMS Adoption

continued from page 1

The most recent national practice survey by ASHP found about 21% of U.S. hospitals used IV-WMS, a 1% increase from the previous year (*Am J Health Syst Pharm* 2021;78[12]:1074-1093). For comparison, the rate was 13% in 2017. "Fortunately, we've had a little bit of a push, but there's still a long way to go," Dr. Fortier said.

Many hospitals have at least adopted key components of IV-WMS, such as barcode scanning (33.8%), image verification (25.3%) and gravimetrics (5%), and small numbers reported the use of robotics (3.4%), said Amey C. Hugg, BSPharm, ASHP's director of member relations for the Section of Pharmacy Informatics and Technology. (For one hospital's experience with robotics, see page 46.)

"When all technologies are considered ... 52.7% of hospitals do not use any technologies for compounding sterile preparations, which is decreased from 2017, when 64% of hospitals did not use any technology for sterile product compounding activities."

Delay Despite Society Support

The slow rollout has occurred despite societies of pharmacy recommending the use of IV-WMS for more than a decade. That's an unfortunate delay, Dr. Hugg noted. "[IV-WMS], technology and automation are proven to improve patient safety by reducing potential for human error associated with manual processes," she said. "Use of such technologies is strongly advocated by ASHP [bit.ly/3j68Wn3] and the Institute for Safe Medication Practices [ISMP; bit.ly/3nrdkhN]."

The risks for human errors in manual preparation of IV medications are well established. A 2020 ISMP survey showed 74% of pharmacy staff were aware of at least one compounding error during the previous 12 months, most of which were incorrect doses (58%) (bit.ly/3jhGC17).

The benefits of IV-WMS in reducing these errors also are well established, said Dr. Fortier, noting a half-dozen studies published in the *American Journal of Health-System Pharmacy* over the 2010s that all demonstrated "a major amount of error detection" using IV-WMS, as well as staff satisfaction.

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—Amey C. Hugg, BSPharm

IV-WMS Versus Barcoding

A team at MGH demonstrated the benefits of implementing an IV-WMS in a recent study, according to Blake Barlow, PharmD, MBA, MS, a former resident at the hospital and now the clinical pharmacy manager for adult medicine and cardiology at WVU Medicine, in Morgantown, W.Va.

Unlike studies that compare IV-WMS with manual processes such as the syringe pull-back method, Dr. Barlow and his colleagues compared an IV-WMS (Omnicell IXV) with its existing barcode system (Epic Dispense Prep/Check) after implementation across the institution's entire nonhazardous formulary (five sterile compounding suites, two off-site infusion pharmacies, 350,000 IV doses dispensed annually, 21 technicians and nine pharmacists).

Using failure modes and effects analysis, Dr. Barlow and his colleagues found the IV-WMS significantly reduced the

10 Tips for Implementing an IV-WMS

Blake Barlow, PharmD, MBA, MS, the clinical pharmacy manager for adult medicine and cardiology at WVU Medicine, in Morgantown, W. Va., and Andrew C. Lodolo, PharmD, BCPS, BCCCP, the pharmacy manager for inpatient services at Eskenazi Health, in Indianapolis, shared key lessons they learned when implementing an IV-WMS at their institutions:

1 Involve staff early. Dr. Barlow recommended that pharmacists and technicians be integrated into the process as early as possible so they know what the device is, how it works and why it's important for patient safety. "We saw that if you're not integrating early, you might see some failures down the line due to [lack of] staff buy-in."

2 Train support staff. "Utilize training and education resources to prepare pharmacist and technician subject-matter experts for ongoing staff support in addition to the management team," Dr. Barlow said.

3 Maintain existing systems as a backup. It's important to maintain operation of your existing compounding workflow during early implementation as a safety backup. Dr. Barlow noted that a staff member "might get confused about how to proceed, or if there's a tech error up front, you need a safety system to fall back onto so a patient can get the right medicine as quickly as possible."

4 Share progress. "We utilized an implementation daily go-live project dashboard that we found very successful to really promote our progress with the group, cheer them on, show them our success ... so that everybody was kept in the loop on a daily basis as far as how well we were going with the process," Dr. Barlow said.

5 Decrease batch time intervals. Dr. Barlow said his institution plans to reduce batch times so staff can focus on a smaller volume of orders. "With a brand-new device, we found that the staff were getting a little overwhelmed when a lot of batch orders were printing out at once. Even though those orders might not be due for four to five hours, just the sheer volume that was sitting next to them maybe made them feel a little stressed and try to rush the process."

6 Identify key stakeholders up front. Dr. Lodolo emphasized the importance of aligning key stakeholders at the beginning of the product selection process. "We identified key stakeholders that would be needed to weigh in on this decision of implementing an IV workflow solution that included: 1) senior leadership that would provide the financial backing for this initiative, 2) pharmacists, both front-line and those that would maintain the system, and 3) IT [information technology] team members, as we knew we wanted an integrated system, and our EHR specialist," he said. "At go-live, we knew it would be important to identify other key stakeholders like subject-matter experts and super users."

7 Release medications in phases. Dr. Lodolo said he "was really hopeful for a big bang go-live ... for all compounded sterile products. Unfortunately, that wasn't an option. Therefore, we introduced biweekly phased releases of two to four medications into production. This allowed for staff buy-in because they were still able to use the systems that they were comfortable with."

8 Create and maintain a test environment. A test environment is something Dr. Lodolo recommended for any health system planning to implement an IV-WMS. "This allows us to develop protocols in a safe space and complete robust testing before we implement that into the production environment."

9 Use protocol selection. Dr. Lodolo recommended using gravimetric verification whenever possible, especially for products with patient-specific dosing, such as high-alert medications or partial vials. For whole vials, "we might implement volumetric workflows because we know you're going to typically use the whole vial, so there's no reason to slow down the process if you don't have to."

10 Develop a synced cadence. Dr. Lodolo's institution developed a synced cadence as "a try-out approach with our operations team, our EHR analytics team and our IV-WMS consulting team. This has allowed for robust evaluation of ordering capabilities within EHR to make sure all orders transition to IV-WMS appropriately. It also allows us the opportunity to troubleshoot protocols before they go into the production environment."

—A.L.

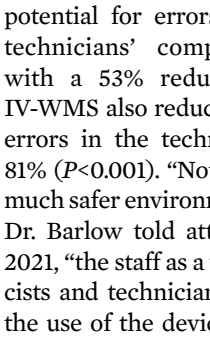
potential for errors, particularly in the technicians' compounding workflow, with a 53% reduction (P=0.02). The IV-WMS also reduced the risk for severe errors in the technicians' workflow by 81% (P<0.001). "Not only did it provide a much safer environment for our patients," Dr. Barlow told attendees at Illuminate 2021, "the staff as a whole—both pharmacists and technicians—actually preferred the use of the device, perceiving it to be both safer and more accurate."

However, total turnaround time increased by about five minutes (24.6 vs. 29.6 minutes), with a longer compounding process (15.4 vs. 22.2 minutes) and slightly shorter verification (9.2 vs. 7.4 minutes).

Slower Turnaround Times A Trade-off for Safety

Concern about longer turnaround times is understandable, but slower turnaround is a trade-off for improved safety, according to Dr. Fortier. "It primarily will slow down the technician," he said. "But that's the give-and-take of having a much safer situation. On the flip side, it will improve the efficiency of the pharmacist verification because ... it can be done remotely [and there will be] better information for that pharmacist to verify those medications."

Beyond turnaround, the cost of implementation is perhaps the most commonly cited barrier to adoption of an IV-WMS. But as previously reported, research has shown the potential cost savings of this technology can offset the up-front investment. One study of IV-WMS implementation at Cincinnati Children's Hospital showed the system significantly reduced medication waste (P<0.001) and projected more than $500,000 in annual savings (*Int J Med Inform* 2018;115:73-79).



'[IV-WMS is] not required, and unlike other technologies like [computerized provider order entry] and [barcode medication administration], it is not incentivized.'

—Christina Michalek, BSPharm, RPh

A New Standard of Practice

Christina Michalek, BSPharm, RPh, a medication safety specialist and an administrative coordinator for the Medication Safety Officers Society at ISMP, noted that the up-front investment barrier could be mitigated if an IV-WMS were to become a required standard of practice. "It's not required, and unlike other technologies like CPOE [computerized provider order entry] and BCMA [barcode medication administration], it is not incentivized," she said.

The recently released update to USP Chapter <797> guidelines for compounding sterile preparations (page 1) does not include requirements for an IV-WMS (bit.ly/3lL6949).

Navigating Vendor Selection

Another challenge can be selection of a vendor when adopting an IV-WMS. To help evaluate product features, Dr. Fortier recommended THRIV Coalition's technology checklist for five standard capabilities an IV-WMS should have (www.thrivcoalition.org/technology-checklist/). The criteria are:

- interfaced software that guides staff step-by-step through the compounding process;
- barcode scanning;
- volume verification using images, gravimetrics or volumetrics;
- auto-labeling; and
- auto-documentation.

All these and other barriers to adoption disproportionately affect smaller institutions, which explains why their adoption rates are lower, Ms. Michalek noted. "Smaller hospitals definitely have unique challenges, especially with financial and human resources," she said.

'Stay Committed'

Ms. Michalek encouraged pharmacy leaders to remain dedicated to improving safety through IV-WMS adoption despite these obstacles. "If you are struggling with gaining support, stay committed," she said. "If you've gotten support for acquisition of sterile compounding technology and are beginning implementation, leverage resources from your peers, vendors, national organizations and ISMP's forthcoming guidelines. We hope the upcoming guidelines will drive more discussions related to the need for technology in sterile compounding as well as draw attention to the best practices for their use."

—Adam Leitenberger

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ISMP, TJC push for more use of dose error reduction software in IV-WMS. See page 42.