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SOFTWARE STRATEGIES

Hospital pharmacies — large and small — find ways to make new software work

Software helps meet USP 797 rules

Hospital pharmacies have had to scramble to meet the tough revised requirements of the U.S. Pharmacopeia (USP) chapter 797 standards for pharmaceutical compounding and sterile preparations, which were made official on June 1, 2008.

For mid-sized and large hospital systems, adherence to the new standards would be very difficult without help from an electronic system that provides an efficient way to track real-time compliance and eliminates paper documentation.

Drug Formulary Review has interviewed several hospital pharmacy supervisors from hospitals around the country about how they've implemented an electronic documentation and process that simplifies USP 797 compliance.

"USP 797 came up with new standards for monitoring and quality assurance for IV preparations," says **Jim Roe**, RPh, a pharmacy supervisor at the Greenville Hospital System University Medical Center in Greenville, SC. The hospital system has more than 100 pharmacy rotations, 60 pharmacists, and 60 technicians serving a facility that has 900 beds and seven sterile compounding areas.

The original changes for the USP 797 were done a couple of years ago, and then the final version came out this summer.

"USP 797 was looking at all sterile products given in the health care system," Roe explains. "You might not see a problem immediately, so how do you know someone didn't receive a contaminated IV product?"

The answer is to put in place processes that make certain the facility is preparing the best sterile product it can, Roe says.

"USP chapter 797 outlines a series of quality improvement processes, process control steps that you're required to do to make sure your compounding technique and facilities and staff adhere to these rules," says **David Musa**, MBA, RPh, assistant director in the department of pharmacy at the University of Wisconsin Hospitals and Clinics in Madison, WI.

Summary points

- USP 797 software program assists pharmacies with meeting new rules.
- Electronic documentation saves staff time, eliminates huge paper trail.
- Managers easily can adapt program to suit their pharmacies' needs.

OCTOBER 2008

VOL. 24, NO. 10 • (pages 73-84)

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The biggest outcome since the pharmacy switched to the electronic system has been a better organization of compliance documentation, Musa says.

"We all have limited amounts of time, so if you spend time following up to make sure documentation is complete, then you can't spend that time doing other tasks," Musa adds.

Also, the software enables Musa to have a global view of the hospital system's multiple compounding sites throughout the city.

For others, the elimination of paperwork is a big plus.

"In the past we used paper logs and individual notebooks for each compounding area," Roe explains.

The hospital system eliminated the time-consuming paper documentation process by implementing an electronic system that tracks compliance and streamlines quality assurance measures, Roe says.

Called Simplifi 797, the software is sold by Pharmacy OneSource Inc. of Bellevue, WA.

"Simplifi 797 also e-mails a monthly report to pharmacy managers that gives us a grade on how well we're performing," Roe says. "This provides documentation for the board of pharmacy."

Saving paper is a big plus, he adds.

"We had seven notebooks with probably six pages of entries per day, 365 days a year, because of what USP 797 says," Roe says. "And the board of pharmacy says that if you're not documenting it, you're not doing it."

The electronic system eliminates the need for those notebooks.

Since switching to the electronic system, Advocate Lutheran General Hospital of Park Ridge, IL, has saved staff time and improved compliance, says **Geri Anderson**, CPhT, BSBM, pharmacy technical services manager.

"I guess it's saving me a good day's work in a week," Anderson says. "It lets me get out on the floor into the pharmacy to make sure everything is running well, and it allows me to help them in the pharmacy if they're getting behind and need help."

Martha Jefferson Hospital in Charlottesville, VA, which is using the software for its third year, used to have four to six papers hanging on every isolator for documenting controls, and now all paper logs, including paper refrigeration logs, are gone, says **Peggy L. Toms**, CPhT, RPhT, pharmacy regulatory and quality analyst.

"It's made a huge, huge difference," Toms says.

"It didn't change staffing needs within the IV

room, but it expedited and saved time for the staff," Toms says. "And for me personally as the one who oversees the IV area as far as environmental monitoring, I can't even begin to explain how much difference it made in that part of my job."

Toms uses her extra time now to perform more audits and oversee or even staff the IV room, as needed.

"They were very busy this morning, and I was in there helping them," she says. "It absolutely improves job quality."

The software also provides standard templates for various procedures, including clean room procedures, and there's a web page with links to necessary references and documents, Musa says.

"We have the whole policy and procedure module on-line and USP 797 continuing education programs to access," Musa says.

An electronic USP 797 program gives the pharmacy flexibility in monitoring compliance, Toms notes.

"I can go to 'tasks' in the software, and I can change the tasks," Toms says.

For example, Toms recently changed the tasks to include sterile gloves, which are required in the latest USP 797 revision.

"I can change, delete, and change the schedule on tasks," she explains. "And anytime the schedule prompts us to do something different, we can go into the program and adjust it at that time."

Also, new stations can be added to the program as regulations change.

Implementing the new software involved working with the software company to tailor it to the pharmacy's specific needs, Anderson says.

"It didn't take an extraordinary amount of time," Anderson says. "A woman from the software company had a couple of sessions with us on the phone, and then we downloaded the competencies, templates, tasks, and anything else our pharmacy manager wanted."

There also was a web-based training program for management and supervisors, Roe says.

"They helped us set up all competencies and processes that have to be monitored," Roe explains. "Then they helped assign pharmacy personnel to the program with log-on information."

Roe trained each employee handling sterile products individually on how to log-on and how the system works.

Basically, they need to get to know the dashboard, which shows at log-on the various daily tasks, including daily cleaning, temperature logs, pressure differential, Roe explains.

"The technician only has to click the task, complete the task that needs to be done, and then hit a check box that says it's done, and it will go into the column for tasks completed," Roe says.

"I can teach someone how to log-on and how to complete scheduled tasks in about 30 minutes," Roe says.

It wasn't difficult achieving staff buy-in, Musa says.

"Our organization is very efficient, and the staff are coming to expect electronic documentation," he says.

Employees enjoy the electronic system because they no longer have to keep the paper logs, which were more time-consuming than the electronic check boxes, Roe says.

Finally, the electronic system provides internal benchmarking reports.

"The monthly report we receive from Simplifi gives us a number grade and shows us how we're performing as an institution compared to our previous months or years," Roe says.

"Basically, it started out kind of low, about 60% compliance in tasks performed, when we first implemented the software, and now we're running almost 100% compliance." ■

Software Strategies

How an electronic system can make USP 797 easier

Variety of tasks are easier

Hospital pharmacists who have been using an electronic system to meet USP 797 standards

say it makes it easier to be consistent and timely with a variety of tasks.

Here are some of the jobs where the new system has helped:

- **Expiration dating:** "Before we had the software, most of our

Summary points

- Pharmacy technicians check box on computer when task completed.
- Managers can check compliance with a few key strokes.
- Modules offer easy quality assurance checks, staff training, and education.

tracking devices for expiration dating, tasks technicians have to do on a daily basis, like cleaning the machine or hood and temperature logs, were all done manually," says **Geri Anderson**, CPhT, BSBM, pharmacy technical services manager at Advocate Lutheran General Hospital in Park Ridge, IL.

The manual process involved looking at each individual item, writing it on paper, and keeping monthly records, Anderson explains.

"It was very time-consuming," she adds. "I'd have to transfer the information on a spreadsheet on my computer."

Now the USP 797 software, distributed as Simplifi 797 by Pharmacy OneSource Inc. of Bellevue, WA, does all of these tasks for Anderson.

"Each individual item they have to do during the day, the food-cleaning of refrigerators, cleaning of hoods and machines is all separate," Anderson says. "You check a box that the task is done, and the documentation is complete."

If the tasks aren't done by a specific time frame, then the electronic program sends the staff e-mail reminders that the task must be done before the end of the day, she adds.

Anderson can click on a report of these tasks and pull up the temperature log for an entire month for each of the pharmacy's eight refrigerators.

Under a paper system, a pharmacy manager would have to review lengthy paper logs to find out the temperature on a particular day, notes **Peggy L. Toms**, CPHT, RPHT, a pharmacy regulatory and quality analyst at Martha Jefferson Hospital in Charlottesville, VA.

"Now with four key strokes I can find it," Toms says. "It really validates what we do, and it's a quick, painless way to do it."

The other benefit is that it's easy to see who recorded the temperature and when trends occur.

"On any given day people switch schedules around," Toms explains. "So if questions come up because one refrigerator is out of range, we can go into the software to see what the temperature was that morning and how long it's been out of range."

- **Task compliance:** "When someone does not complete a scheduled task, the system will automatically e-mail supervisors and technicians working in that area that something has been missed in documentation," says **Jim Roe**, RPh, pharmacy supervisor with the Greenville Hospital System University Medical Center in Greenville, SC.

"This ensures we're always in compliance," Roe adds. "The software automatically knows

Software Strategies

Drug Formulary Review launches a new, occasional feature in this month's issue with the cover story about software strategies. As many hospital system pharmacies across the nation begin to improve and implement new electronic systems to assist with their pharmacy practices, compliance with regulations, safety initiatives, and quality assurance, this feature will highlight electronic strategies that some hospitals have used successfully. Where there are competitive software strategies, *DFR* will feature the more successful ones in different issues. If you have any software strategies that you've used and would like to share with other readers, please contact *DFR's* writer and editor Melinda Young at MelindaGYoung@charter.net or by calling (864) 241-4449.

when the time is missed, and it automatically sends out an e-mail to technicians in that area, saying, 'You have not completed all of your tasks.'"

The automatic e-mail reminders save time and ensure complete documentation, says **David Musa**, MBA, RPh, assistant director in the department of pharmacy at the University of Wisconsin Hospitals and Clinics in Madison, WI.

"If workers haven't complied with a task then there are e-mails that go out to the area manager," Musa says. "Pharmacists follow-up and make sure the tasks are completed, so it forces your documentation to be complete."

• **Batch processing:** There is a batch processing module for pharmacies that need it.

"We have about 20 different products we batch for convenience," Anderson says. "So we enter the information in, pull up a product that needs to be compounded, enter information, check the information and product, and then sign off on it

on the computer."

This process was done entirely on paper before the pharmacy switched to the electronic system, she adds.

The electronic documenting of batch processing ensures that there is complete documentation in the event of a problem, Roe says.

• **Quality assurance:** "We run a quality assurance program to make sure all our staff are adequately trained," Roe says. "We can identify staff that need additional training."

There are competencies required by USP 797, and these can be linked to the electronic system.

"The staff can see which competencies have to be accomplished that month," Roe explains.

"Some of these are personal aseptic technique tests, personal hand-washing and garbing, automated compounding devices, etc."

• **Staff education:** "We have put all of our competencies on this software," Anderson says. "We have 11 different competencies that each technician has to do in a year, and we've loaded all of these in the system."

The technicians take one competency test per month, and their compliance is monitored through the software program, she adds.

"They log in, complete it, and it's sent back to me," Anderson says. "I check it on-line for a passing score."

The non-electronic version of this process was time-consuming, she notes.

"I'd have to remember when these were due and make sure each employee had a copy of the competency," Anderson says. "Now it's a much cleaner process."

The electronic program also has on-line manuals and references, which spell-out how to conduct specific tasks, Roe says.

"It tells staff how to clean and disinfect, how to glove and gown, how to store medications, how to do surface sampling, and how to record temperatures and humidity," Roe explains. "It saves tons of paperwork." ■

For more information on Simplifi 797 visit www.simplifi797.com or call 800-654-8395.