very often one she found at least one discrepancy—Continued from page 296

“...roll it out on the main campus,” Knoer said. “But it’s so much bigger [than the other hospitals], and there are so many more patients. This is a little bit more complex.”

Validation of medication reconciliations. At Tufts Medical Center in Boston, a pharmacy technician who previously worked at a community pharmacy validates the medication reconciliations performed by physician residents for patients admitted to the general medicine service, said pharmacy director Ross Thompson.

Although this pilot program entered only its fourth month in January, Thompson said Tufts expects its rate of unintended readmissions of patients with pneumonia to decrease. These patients typically are under the care of the general medicine service.

So far the pharmacy technician, whom Thompson called “a really good communicator,” has spoken with about 400 patients.

He said an early analysis revealed that she found at least one discrepancy—very often one of clinical consequence—in about 46% of the medication reconciliations.

“The technician is spending maybe 20 [or] 25 minutes on average with the patients, including contacting retail pharmacies, getting everything done such that the pharmacist comes in and spends about 8 minutes,” Thompson said.

Hiring someone who already knew how to get information from community pharmacies and ensure patients could access their medications in the community proved beneficial, he said. That was the piece that the staff would have had difficulty teaching. Patient flow and the workings of the general medicine service were not difficult subjects for the staff to teach.

Thompson said the grant funding the pilot program comes from a performance-based payment from Blue Cross Blue Shield of Massachusetts to the Tufts-affiliated physicians network.

Beyond reconciliations. Pharmacy director Edward G. Szandzik at Henry Ford Hospital in Detroit said his pharmacists are in the second year of an “extended pilot” targeting patients with heart failure or chronic pulmonary obstructive disease, both of which increase the risk of pneumonia.

“We’re not only addressing discrepancies” in the medication history on admission, Szandzik said, “we’re looking at assessing adherence and ability for the patients to pay for those meds postdischarge.”

The pharmacists document what they find and solve in the progress notes of the electronic health record that employees, including those in the health system’s 1200-physician group practice, can access, he said. Likewise, the pharmacists can access that electronic health record to determine what transpired before patients’ admission to the hospital.

“Communication is the big thing, especially in these transitions of care,” Szandzik said.

In that spirit, he said, the hospital’s pharmacists will start indicating in the electronic health record the need for a pharmacist on the ambulatory care medication management team to check on a patient three to five days after discharge.

Clinic for at-risk patients. Szandzik said a pharmacist from nearby Wayne State University just started working at the hospital’s internal medicine clinic for patients at high risk for readmission.

This clinic, he said, attempts to see at-risk patients three to five days after hospital discharge, before the routine follow-up appointment with their physician.

Details on which of these patients will see the pharmacist have not been finalized, Szandzik said.

—Cheryl A. Thompson
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Shared REMS programs expanded in 2012

The number of drug products subject to a shared risk evaluation and mitigation strategy (REMS) program has grown substantially since FDA introduced the first one in late 2010, and more shared REMS programs may be coming, says a consulting firm.

The first FDA-mandated single shared system REMS program, for isotretinoin products, was implemented in October 2010 and now affects five medications, said Karen Lenoir, client services director for ParagonRx International LLC of Newark, Delaware. A single shared system REMS for transmucosal immediate-release fentanyl that was established at the end of 2011 now affects seven products.

During the second half of 2012, FDA approved two additional single shared system REMS programs. The one for mycophenolate applies to 9 products, and the program for long-acting and extended-release opioids applies to 35 currently marketed products.

In all, 58 products are covered by the four shared REMS programs, while 70 other drugs each have their own REMS program.

Lenoir predicted that during 2013, “there will be more single shared system REMS” programs.

The reason?

Compared with having a separate REMS program for each product, a shared system REMS reduces the burden on the health care system, she explained during a January 9 webinar.

Each shared REMS program provides a single Web portal to access medication

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guides, prescribing information, and other documentation and information about the program.

Single shared system REMS programs are collaborative efforts managed by the drug companies whose products are subject to the programs. According to FDA, benefits of these REMS programs include simplification of patient registries and prescriber and pharmacist education platforms for programs that require these elements.

“It certainly makes it easier for health care professionals to administer or prescribe the products, and it allows patients to have the necessary access,” Lenoir said.

**Evolution.** FDA approved more than 200 REMS programs from 2008 through 2012. The vast majority consisted of a medication guide only. Some REMS programs also included or consisted solely of a risk communication plan involving “Dear Healthcare Provider” letters to prescribers and pharmacists or educational information in printed academic journals.

A smaller number of REMS programs have contained elements to assure safe use (ETASU), which may include restricted-distribution systems, certification programs, and other mechanisms to control who can prescribe, dispense, or receive medications. A total of 28 active individual REMS programs with ETASU were listed on FDA’s website in mid-January.

All REMS programs also include a timetable for assessment of the program.

FDA in 2011 began releasing from REMS program obligations many medications whose program consisted of a medication guide, a communication plan, or both. In all, 132 drugs had been released from their REMS program obligation as of mid-January, according to information on the agency’s website.

In many instances, the medication guides are still required, but they are part of a product’s labeling instead of forming part of a REMS program. But 13 drugs still have a REMS program that consists solely of a medication guide.

**REMS in 2012.** FDA approved 10 new individual REMS programs last year, including 4 for new molecular entities that were approved during 2012. Lenoir said this is a decrease from 2011, when 33 individual new molecular entities or new biologics were approved with a REMS program.

The REMS program for the erythropoiesis-stimulating agent peginesatide, which was approved last March, consists of a communication plan requiring the manufacturer to send letters to prescribers and professional societies.

The letters describe the appropriate patient population for treatment and outline cardiovascular risks associated with the drug.

REMS programs for the new molecular entities apixaban, lomitapide, and teduglutide were approved in December. The apixaban REMS program consists of a communication plan.

The REMS programs for lomitapide and teduglutide include ETASU. Although the ETASU provisions in the teduglutide REMS mostly affect prescribers, the REMS program for lomitapide requires certification of pharmacies before they can dispense the drug.

Lomitapide is an orphan drug indicated for the treatment of homozygous familial hypercholesterolemia. The goal of the lomitapide REMS program is to ensure that prescribers are aware of the drug’s hepatotoxic effects and will appropriately monitor patients for liver toxicity.

Among the five individual REMS programs with ETASU that were approved last year, “there is definitely a common theme,” Lenoir said.

“Almost all . . . have some form of prescriber training or education,” she said.

“Several have Dear Healthcare Provider or medical society letters. I’m almost positive that all of them have a dedicated website.”

She said only two of the five programs, those for lomitapide and loxapine, “require the certification or the enrollment in their program in order for the drug to either be dispensed or prescribed.”

—Kate Traynor

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**California pharmacy board takes next steps toward electronic pedigree**

The California State Board of Pharmacy in December addressed comments from the public about the implementation of state-mandated requirements for electronic pedigrees for prescription drugs.

The public comments were a response to the board’s release, last summer, of proposed regulations to implement parts of the law. These proposed regulations address the use of identification numbers for medication packages and requirements for informing the board about the phased-in serialization of drug stocks.

The meeting was held December 13, and a webcast of the event is available at the pharmacy board’s website.

**Package size.** One of the basic questions for the board was what packaging

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**Appointment**

Paul W. Abramowitz, Pharm.D., FASHP, chief executive officer of ASHP, has been appointed to a four-year term on Pharmacy Quality Alliance Inc’s Board of Directors.

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