tional components of REMS programs, which have lacked such incentives for prescribers to participate.

A perhaps unusual aspect of the upcoming classwide REMS for long-acting and extended-release opioids is that the proposed education requirements will not be mandatory, at least initially.

According to FDA, the agency is concerned that a REMS program mandating prescribers’ education about these drugs would overly burden the health care system and could impede patients’ access to necessary pain medications.

If the agency adopts this policy, “there is nothing that prohibits a prescriber from actually prescribing long-acting opioids in the absence of doing anything specific” related to the REMS, Fetterman said.

Another shift in FDA’s processes is evident in the recently approved classwide REMS program for transmucosal immediate-release fentanyl products. In this program, the Dear Healthcare Provider letter portion of the REMS is part of the elements to assure safe use (ETASU).

Older REMS programs had included such educational letters as part of the communication plan. And the ETASU portion of REMS programs has mostly consisted of restricted-distribution systems, compulsory certification programs, and other mechanisms to control who can prescribe, dispense, or receive medications.

The Food and Drug Administration Amendments Act of 2007 states that when an innovator drug’s REMS program includes a risk communication plan, FDA is responsible for implementing that plan for any corresponding generic drugs. ETASU obligations, however, remain the responsibility of manufacturers.

Fetterman speculated that FDA’s lack of resources to implement risk communication plans may be helping to motivate the agency to bring educational letters into the ETASU portion of REMS programs.

Overall, he said, FDA appears to be shifting its focus from purely paperwork-related REMS tasks to more practical ones, like standardizing REMS programs and making the REMS-development process more transparent.

“Now all entities can begin to focus on the real goal here, which is to truly improve patient safety. And that’s what we anticipate the advances of the next few years will be focused on,” Fetterman predicted. “We fully expect more proactive evaluation of the care delivery process to proactively mitigate consequences of potential risks.”

—Kate Traynor
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Remote technician supervision up and running in Kansas

How many onsite pharmacists does it take to oversee the dispensing of medications and refilling of automated dispensing cabinets in a Kansas hospital?

None—now that the state’s pharmacy board has adopted regulations allowing pharmacists to remotely supervise pharmacy technicians in health care facilities.

Debra Billingsley, executive secretary of the Kansas State Board of Pharmacy, hopes the newly sanctioned technology will improve patient care and reduce adverse drug events, particularly at rural hospitals.

Billingsley said most towns in the state are served by rural hospitals that lack full-time pharmacy services.

And a substantial portion of the state suffers from a dearth of pharmacists in all care settings. According to data cited by the nonprofit Kansas Health Institute, at least 30 of the state’s 105 counties have just one pharmacist, and 6 have none.

“That’s been a real concern, mainly in the rural areas. And so we’ve just been trying to see if we can come up with some kind of care model that would be safe for the patient and provide pharmaceutical care,” Billingsley said.

Mark Gagnon, director of ePharmacy at Wichita-headquartered Via Christi Health, knows remote supervision of pharmacy technicians works, because his team recently used the technology in a demonstration-type project for the pharmacy board.

The first official run occurred during the 2011 Thanksgiving holiday, when Gagnon used a live video link to remotely supervise a pharmacy technician at 25-bed Hiawatha Community Hospital in Hiawatha, Kansas.

Hiawatha isn’t part of Via Christi, the state’s largest provider of health care services. But Gagnon’s group has, for the past few years, provided remote order-entry services to the community hospital and a handful of others in the state.

“We always had the vision of providing remote order entry for our own facilities as well as providing outreach for hospitals that didn’t have a pharmacist available to them,” Gagnon said. “It’s one of our missions.”

Gagnon said Via Christi’s rehabilitation and behavioral health hospitals in Wichita lack round-the-clock pharmacy services. Among other things, this affects the facilities’ use of medication dispensing cabinets.

“When an Omnicell needs to be refilled, a pharmacist and a technician get in a car and drive out there minutes and refill the devices,” Gagnon said. He said establishing remote supervision of pharmacy technicians at these facilities will eliminate the pharmacist’s downtime from the drive and from being unavailable at the normal worksite.

Gagnon said he looks forward to establishing remote supervision of tech-
nicians at all Via Christi facilities that would benefit from the service.

How it works. The new regulations allow a Kansas-licensed pharmacist to electronically supervise one pharmacy technician or pharmacy student located in a licensed pharmacy at a medical facility in the state. The supervising pharmacist may be employed by the medical facility or work for it under contract.

Electronic supervision requires the use of a secure, real-time video link between the supervising pharmacist and the site of the technician’s work. Gagnon said Via Christi’s system uses webcams for the video link.

Billingsley said the pharmacy board needs to be satisfied that the remote system captures images of sufficient quality to allow the pharmacist to clearly view medications and any necessary paperwork.

Remotely supervised technicians perform their normal duties, such as reviewing cart fills and filling automated dispensing cabinets, with the offsite pharmacist observing the procedures through the video link.

The same pharmacist can supervise a technician at another facility but may not communicate with or review the work of more than one technician at a time.

Under existing Kansas law, when no pharmacist is onsite, a nurse may enter the pharmacy to obtain a single dose of medication from a stock container for immediate use by a patient. Billingsley said these patients may miss out on important pharmaceutical care because the medication dose is dispensed and administered by a nurse without a pharmacist’s review.

Kansas allows a pharmacy technician to work in the pharmacy as long as a supervising pharmacist is somewhere at the facility but not necessarily in the pharmacy.

Billingsley said the board concluded that if technicians are permitted to work in the pharmacy when the pharmacist is out of the room, allowing them to work under remote supervision makes sense, too.

“It will let technicians work alone, but they’ll still be under the supervision of the pharmacist for everything they’d do if the pharmacist were there,” she said.

Gagnon, who helped shape the remote supervision regulations, said there was some discussion of whether a pharmacy technician could be trusted to work alone without an onsite supervisor. But he said it’s always essential for hospitals to hire trustworthy pharmacy technicians, no matter how they are supervised.

“You really have to have a good, reliable technician that you can count on,” he said. “If you don’t trust your technicians when you’re there, then you’re not going to trust them when I’m watching them.”

He also said the image-capturing provisions of the regulations, which call for images to be saved for five years, introduce a layer of accountability that goes beyond what is required for onsite work at a hospital.

He said if he checks an i.v. bag when he’s physically present at a hospital, the bag is sent to the floor and then disposed of after use.

“If, tomorrow, they what to know who checked that i.v. bag for Mr. Smith, nobody knows,” he said. “Or even if it’s oral tablets. Well, this way, they save all the files and the images, so they can go back and check.”

Looking ahead. Billingsley said the pharmacy board has been contacted by two hospitals that want to submit applications to establish remote supervision of pharmacy technicians. The regulations went into effect last September. As of early January, Via Christi was the only hospital system in the state to use the technology.

Billingsley said the pharmacy board is nearly finished writing regulations that, if implemented, would allow the remote supervision of pharmacy technicians in community pharmacies.

She said the board recognized that the work done by pharmacy technicians in institutional settings differs substantially from that done in community pharmacies and necessitates separate regulations.

“We couldn’t really draft something that fit both,” she said.

Gagnon is looking even farther ahead. He said the technology exists today to wire hospital rooms for pharmacists and other health care providers to provide remote counseling services to inpatients. He envisions the future use of videoconferencing technology to bring practitioners to the patient’s bedside as needed to clarify issues that arise during counseling.

“That would be fabulous for a lot of places,” he said.

—Kate Traynor

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News Briefs

• For the remainder of the current fiscal year, Border Patrol agents are not supposed to prevent a person from bringing a 90-day personal supply of a prescription drug into the United States when crossing from Canada. Congress included this directive in the Consolidated Appropriations Act, 2012, which funds most government operations through the end of September. The directive applies to instances in which the person is not in the business of importing drugs, is transporting the drug “on their person,” and is bringing a prescription drug that is not a controlled substance and not a biological product.

• Rosemary Botchway was selected for the Innovation Advisors Program, an initiative of the Centers for Medicare and Medicaid Services Innovation Center. Botchway is the director of the Center for Medicine Access at the Primary Care...