As 2005 continues, many hospitals are still developing plans to comply with the JCAHO’s National Patient Safety Goal on reconciling medications.

Part of that planning process includes deciding who should head a medication-reconciliation project and who should be on a reconciliation team. At SSM St. Mary’s Health Center in St. Louis, the pharmacy department took the lead and created a position solely devoted to reconciling medications.

The 325-bed hospital hired Ruth Seabaugh, PharmD, BCPS, a clinical pharmacy specialist, in January to head the hospital’s reconciliation program. Seabaugh is not only developing the program, but she is also the pharmacist responsible for checking any discrepancies on patients’ medication records.

“We’re the department that...”

Full-time pharmacist helps hospital comply with reconciliation goal

A new bill in Congress would require hospitals to report pricing data for some prescriptions. Find out how this will affect hospitals on p. 7.

Is price reporting on the horizon?

A new bill in Congress would require hospitals to report pricing data for some prescriptions. Find out how this will affect hospitals on p. 7.

Book excerpt

Check out this case study on one hospital’s experience with implementing computerized physician order entry on p. 8.

Survey medication safety

Find out how to use a medication-safety survey from the Institute for Safe Medication Practices on p. 6.

Survey monitor

The JCAHO questioned staff about USP 797 and medication reconciliation during this Kentucky hospital’s March survey. Read more and get some insider survey tips on p. 10.

JCAHO standard of the month—MM.3.20

Teach staff about the importance of proper documentation

Make sure that all staff are on the same page when it comes to range orders and that they know how to properly document how and when they administered the order. This will help staff consistently answer a surveyor’s question about the hospital’s policy.

JCAHO standard MM.3.20 requires hospitals to specify in a policy the necessary elements of range orders, where the dose or dosing interval varies over a prescribed range depending on the patient’s condition.

But having a policy may not solve a hospital’s woes completely. “The problem with a policy is you have 600–1,000 nurses, and [the policies] stay in a book,” says Michael Hoying, RPh, MS, pharmacy director at Fairview and Lutheran hospitals in Cleveland. “It’s difficult for all nurses to memorize all policies.”

MM.3.20 was one of the most-cited standards during the JCAHO’s 2004 surveys, according to data from the commission.

Set a range

The American Pain Society outlines several guidelines for writing range orders, including using a dosage range with a fixed time interval and a dose where the maximum is no more than...
Reconciliation

Neil Schmidt, MA, RPh, FASHP. “This has always been one of the pieces that pharmacy has never been able to put into the puzzle.”

The JCAHO goal requires hospitals to accurately and completely reconcile a patient’s medication list, and communicate that list to the patient’s next care provider. The JCAHO began surveying for compliance with the goal January 1.

Surveyors will make sure hospitals have a plan in place to be fully compliant by January 1, 2006.

The right choice

In the past, patients at St. Mary’s would have been discharged with minimal instructions about their medications, Schmidt says, something that led to more complications down the road. “They became ‘frequent fliers,’” he says. “They came back in here.”

Schmidt proposed to hospital administration in 2004 that a pharmacist position be dedicated to medication reconciliation. Administrators had some misgivings at first, he says, because pharmacists are high-cost positions.

Administrators wondered whether the task of overseeing reconciliation should fall to the nursing or quality improvement departments, Schmidt says. But because of their knowledge of medications and their interactions, the choice seemed obvious that pharmacists should have that responsibility, he says.

Review for errors first

Seabaugh currently assesses what the hospital needs to do to comply with the JCAHO goal. She conducts chart reviews to determine which errors are associated with medication reconciliation, she says. She also checks the admission, transfer, and discharge phases of a patient’s record—areas where errors could occur because of a mix-up in medications.

The results of those chart audits will help Seabaugh establish a formalized program at the hospital.

“At this point, we are really working to get the bugs out of the system,” Seabaugh says. “If you look at what we looked like in January when we started to where we will be in, say, August, I think there really will be a difference.”

Get their home medications

The hospital currently uses a home medication order sheet that nurses complete when a patient arrives at the hospital. The sheet allows nurses to record any allergies patients have and what medications they take at home.

The sheet then becomes an order sheet, and prescribers can decide whether to continue a patient on a listed medication, Seabaugh says. Staff can also use the form to reconcile medications upon discharge, she says. For example, a patient taking the blood thinner warfarin could have that drug changed to Coumadin, another blood thinner, while in the hospital, Schmidt says. If staff fail to reconcile medications, the patient could be sent home on both Coumadin and warfarin, which could prove dangerous.

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“It’s a major, major problem, sending a patient out with no information on how to take medications,” Schmidt says.

Check out a sample home medication order sheet on p. 4.

**Involve people at every step**

The pharmacy department helped draft the home medication order sheet, Seabaugh says. If a discrepancy exists on it, Seabaugh will investigate.

Nurses can verify medications with a patient’s physician upon admission, Seabaugh says.

At discharge, hospital staff also give patients a card, which they can keep in their wallet, that helps them keep track of the medications they take, Schmidt says.

**Watch high-risk patients**

Regardless of which staff hospital leaders may place in charge of reconciling medications, nursing and pharmacy need to work together to get the program off the ground, Seabaugh says.

“The process is so all-encompassing,” Seabaugh says. “It touches every department, and it really impacts the patient so much you’d think by now we’d have come up with a better process.”

Part of Seabaugh’s job is to use these early experiences with reconciliation to determine how the hospital can effectively comply with the JCAHO goal.

Seabaugh is looking to improve the accuracy of the home medication list and make sure patients get the attention they need. “One person cannot interview every patient—that one person being me,” she says.

To solve that problem, Seabaugh may identify high-risk patients on numerous medications to interview in person about their drugs and conditions, she says.

**Take the lead in education**

Seabaugh also has the task of making sure all staff involved know what medication reconciliation is and what they need to do. She worked with the staff development office to set up nursing education. Staff educators had to attend meetings to learn about reconciliation, and then they went out and spoke with nurses to teach them, Seabaugh says.

As Seabaugh and other staff identify problems in the reconciliation process, they will work with the staff development office to resolve the issues, she says.

**Get administration hooked**

Other hospitals can replicate St. Mary’s reconciliation program regardless of their size, Schmidt says. The key is to have support from administration, he says, as hiring a full-time pharmacist to handle reconciliation could be a tough sell at first.

“The selling point is that pharmacy [owns] the approach and then would bring in nursing in the future,” Schmidt says. “[The pharmacist] is the person who has the background to pull all of this together.”
The Sample home medication list order sheet

<table>
<thead>
<tr>
<th>Height (ft)</th>
<th>Weight (Kg)</th>
<th>Is patient pregnant?</th>
<th>N/A</th>
<th>Yes</th>
<th>No</th>
<th>Is patient lactating?</th>
<th>N/A</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu vaccine</td>
<td>No</td>
<td>Yes</td>
<td>Date:</td>
<td>Pneumonia vaccine</td>
<td>No</td>
<td>Yes</td>
<td>Date:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Allergies and drug reactions (check reaction)

- [ ] Allergies
- [ ] Nausea / Vomiting
- [ ] Rash
- [ ] Hives
- [ ] Difficulty Breathing
- [ ] Other

- [ ] No Known Allergies

- [ ] Do you have allergy/reaction to latex? No / Yes / Unsure (Please note: History of asthma may increase risk.)
- [ ] Yes - describe reaction

- [ ] Check the box below if you have ever experienced runny nose, tearing, sneezing, or itching after:
  - [ ] Dental/Internal exams
  - [ ] Contact with rubber gloves/products
  - [ ] Blowing up balloons
  - [ ] Use of condom or diaphragm
  - [ ] Eating bananas, avocados, water chestnuts, kiwi

### List of Home Medications

- [ ] No Home Meds

Include blood thinning products, over-the-counter medication, herbal supplements (list only those currently being taken)

Sources of information: [ ] Patient
- [ ] Medication Bottles
- [ ] Patient's Family
- [ ] Med List
- [ ] Doctor's Office

Pharmacy Name: _________________________
Pharmacy Number: _________________________
Old Chart: [ ]
Other: _________________________

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<tr>
<th>Continue?</th>
<th>Drug Name</th>
<th>Dose</th>
<th>Route or topical site</th>
<th>Frequency</th>
<th>Last Dose</th>
<th>Comments</th>
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### INSTRUCTIONS FOR PHYSICIANS:

These checked orders will become active when authorized by Physician.

Medications/herbal/vitamins will be dispensed in accordance with the hospital formulary.
Non-formulary herbs/vitamins will be held during hospital stay. Resume after discharge unless directed by the physician.

Date: ___________ Time: ___________ Physician: _________________________
Date: ___________ Time: ___________ Nurse: _________________________
Date: ___________ Time: ___________ Transcribed by: _________________________

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Range orders

four times larger than the minimum.

For example, 10 mg–40 mg would be acceptable, but 50 mg would not, says Doug Wong, PharmD, a consultant with Pharmacy Healthcare Solutions in Fort Washington, PA.

Staff at Fairview Hospital consider the route, dose, and frequency when carrying out range orders, Hoying says. They prefer to use an oral administration route for pain medication if possible, and they generally start patients on the lower dose.

Staff also generally give the higher frequency, such as every six hours instead of four, if there is a frequency range.

Tip: Document a reason in the medical record for varying from policy or standard practice, Hoying says, such as giving a larger dose in the range.

Make sure physicians get all pertinent information about a patient and the administration of range orders, Hoying says. This helps them determine whether the order is correct for the patient’s condition.

Drive the point home

Both staff and patients need to know the importance of effective pain management and the proper use of range orders. “Emphasize that it’s a safety issue,” Wong says.

Tip: Use internal newsletters to educate staff about the hospital’s range-order policy.

New nurses at Fairview and Lutheran receive training on range orders during their orientation, and all staff receive annual competency training on the topic, Hoying says.

Pharmacists can also help answer nurses’ questions about medications and how to properly administer a range order. “They’re the ones [who] are really the gatekeepers,” Wong says. “Nurses have to be able to base decisions about the implementation of range orders through a pain assessment and a knowledge of drugs.”

Staff clearly and accurately document medication orders.

Requirements for MM.3.20

The hospital has written policies that address the following:

1. What is required in a complete medication order
2. When staff may use generic or brand names in an order
3. Whether or when staff must write an indication for use
4. Necessary precautions for ordering look-alike or sound-alike drugs
5. What to do when orders are incomplete or unclear
6. The hospital outlines what should accompany any order it uses, including “as needed” (PRN) orders; standing, hold, or resume orders; titrating and taper orders; range orders; compounded drug orders; medication-related device orders; investigational medication orders; and discharge orders
7. Minimizes verbal and telephone orders
8. Reviews and updates preprinted order sheets
9. Notes that blanket reinstatements of previous medication orders are unacceptable
10. Documents requirements for weight-based dosing for pediatric patients

Standard MM.3.20 at a glance
Survey helps hospitals assess medication-use safety

Even though the submission deadline has passed, using the Institute for Safe Medication Practice’s 2004 Medication Safety Self Assessment for Hospitals could be a useful way to evaluate where your hospital stands regarding medication-use safety.

The 10-part survey, published by the ISMP, the American Hospital Association, and the Health Research and Educational Trust, allows a team of hospital leaders and other staff to sit down and see what they do well and where they can improve medication safety, says ISMP Executive Director Allen Vaida, PharmD, FASHP.

“Part of it is the learning experience—to go through it and see if some light bulbs do go off,” Vaida says. “You might say, ‘Gee, we don’t do that. I don’t know why we don’t do that.’ ”

Where do you stand?
The survey allows staff five choices to respond to statements about the medication-use process. For example, for the statement, “A pharmacist or prescriber routinely adjusts doses of medications that may be toxic in patients with renal or liver impairment,” staff could choose one of the following:

- No activity to implement
- Considered, but not implemented
- Partially implemented in some or all areas
- Fully implemented in some areas
- Fully implemented throughout

Tip: Organize a team to take the survey. At minimum, the team should include someone from administration, a physician, nurses, pharmacists, risk management, and information technology staff, Vaida says.

Working in a group can help staff identify areas of improvement, Vaida says. “You may get caught up on what you’re doing every day, and you need team members to say, ‘Why weren’t we doing this?’ ” he says.

Improvements in safety
The ISMP published the first version of this survey in 2000. More than 1,400 hospitals submitted their results anonymously online in 2000, and more than 1,600 did so in the 2004 survey, which included 37 new items for hospitals to answer, Vaida says.

The increased interest is due to safety issues moving to the forefront in the past five years, Vaida says.

The last survey came out a few months after the Institute of Medicine report To Err Is Human: Building a Safer Health System, and since that time, the JCAHO and national, state, and local collaboratives have aligned themselves with patient-safety causes.

An early comparison of 2004 data to 2000 survey results show a 43% increase in nonpunitive error-reduction systems, including incentive-based error reporting. There has also been a 30% increase in the use of automated communication, including linking computer systems with pharmacies, and a 23% increase in patient education about medications.

The ISMP will publish the full results in the coming months, Vaida says, but despite the increases in patient-safety efforts since 2000, the healthcare system still has a long way to go to reach complete medication-use safety.

A crowded scene
The ISMP may have received more results from hospitals had there not been a number of patient-safety collaboratives and surveys already in existence, Vaida says.

The ISMP hopes to secure enough funding to conduct another survey in the future, Vaida says. In the meantime, hospitals can use the 2004 survey to evaluate their current practices.

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**Happenings on the Hill**

**Bill would require pharmacies to report drug-price data**

Pharmacies could have to file quarterly reports about the 50 most-prescribed medications to a government-run Web site if a bill introduced March 17 on Capitol Hill becomes law.

The Hospital Price Disclosure Act would require hospitals to report quarterly pricing data for the 25 most-performed inpatient procedures, the 25 most-performed outpatient procedures, and the 50 most-frequently administered medications. The U.S. Department of Health and Human Services would collect the data and post it on a public Web site.

Representatives Dan Lipinski (D-IL) and Bob Inglis (R-SC) cosponsored the legislation. Lipinski drafted the bill after seeing a hospital invoice for care after a bicycling accident last summer, according to his office.

“I looked closely at the bill, and I was amazed at the costs,” Lipinski said in a statement. “The hospital was charging nearly $5 for a single-use packet of antibiotic ointment. Walgreens charges little more than $6 for an entire tube of the same stuff that is 32 times larger than the hospital’s packet.”

The bill’s goal is to allow consumers to shop for the lowest-priced care, which will in turn drive down costs and increase quality, Lipinski’s office said.

A spokesperson for the American Society of Health-System Pharmacists said her association is aware of the bill but declined further comment.

**AHA: Bill could improve care**

Pricing transparency could help hospitals improve care, says American Hospital Association (AHA) spokesperson Alicia Mitchell.

“From a hospital perspective, having an informed consumer is good for the patient, good for families, and good for the hospital,” Mitchell says. “We’re supportive of making billing information available. The test of that is doing so in a meaningful way.”

The AHA is reviewing the bill and has not taken an official position, Mitchell says.

The AHA in December 2003 issued a set of billing and collection guidelines for hospitals. One of the guidelines is that hospitals should make specific information about charges available for public review.

Several states have similar laws. South Dakota enacted a price-reporting law in March that requires hospitals to report up to 25 of their most commonly performed procedures each year.

California currently has a law that allows patients to request prices of the 25 most-performed procedures. A bill currently in the state legislature would extend that disclosure to outpatient procedures as well.

But having one federal law may place a burden on hospitals, Mitchell says. “Hospitals are as unique as the patients they serve,” Mitchell says. “What makes sense in Des Moines may not make sense in Detroit.”

For example, one hospital maintains a pricing hotline for patients to call with questions about bills or charges, Mitchell says. Hospitals must be able to present the information to their communities in user-friendly means, she says.

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CPOE in progress: One hospital’s experience

From the moment Memorial Health University Medical Center hired Steve Stanic as its chief information officer in 1999, a vision of an automated clinical information system emerged.

The vision started with an update of existing digital programs for ordering and results retrieval. Extensive planning, careful vendor selection, and intensive effort by the information services (IS) department, medical staff, nurses, and all Memorial Health team members have since led to the beginning stages of actual digital implementation.

Memorial Health, a 530-bed tertiary care medical center and physician network and an exclusive McKesson customer, went live with a systemwide electronic medical record (EMR) in April 2003 and began a limited pilot of computerized physician order entry (CPOE) in March 2004.

Moving from vision to reality
Memorial Health put EMR in place specifically to prepare for CPOE. Once it accomplished EMR rollout, it established a more sophisticated order-entry process and a separate nurse documentation application.

The enhanced system provided interactive clinical decision support with real-time clinical data alerts for providers during order entry. It also streamlined and improved many other processes tied to the order-entry process.

Several clinical considerations led to agreement on two primary characteristics of the ultimate goal. One was that the new EMR/CPOE technical design would parallel an established clinical commitment to evidence-based, best-practice medicine.

The second was that it would standardize processes and minimize variation. These two early concepts—analysis of the reasons for innovation and the need to reinforce the best practice model—dictated that profound cultural changes would directly influence the day-to-day behavior of the entire institution.

Pilot testing with nursing
Another challenge was to determine who will pilot test the program. Although no other hospital is on record as initiating CPOE with nursing, Stanic decided to pilot test CPOE with selected clinical nursing stations.

There were many advantages to starting the CPOE pilot test with nurses, Stanic noted:

- Nursing staff had one system instead of two
- Nurses had the ability to create order sets
- Physicians and nurses were put on a single system
- It created instant cheerleaders/teachers for physicians when the time came to expand online ordering to them
- It facilitated communication and team building between physicians and nurses
- Nurses were already well-versed in technology and used computer systems for routine ordering and report retrieval, so they could pick up the new system quickly

The hospital knew there were long-term opportunities, as well. The CPOE system would decrease the amount of time it took to put in an order, and it would decrease medication errors through decision support at the time of order entry.

About the book
You’ll find these tips on building an effective scorecard and more in the HCPro book Lessons Learned: A guide to evaluating and implementing CPOE, by Frank Carlton, MD, Linda Hotchkiss, MD, and Richard Sheff, MD. To learn more or to order a copy, call our customer service department at 800/650-6787.
Build working principles
Once leaders decided on implementation phases, they created the following three working principles:

1. Maintain the efficiency and safety of patient care workflow
2. Focus on known CPOE issues, workflows, user wishes, and “showstoppers” (i.e., issues that would actually stop the implementation project)
3. Thoroughly assess, plan, and implement the process in order to produce a mature product—especially in terms of safety—but make sure the complete transitional process is as quick as possible

Immediate adoption of these guidelines allowed the hospital more time for strategizing, building, testing, executing, and monitoring than leaders would have had if they relied on a traditional assessment of the current situation.

For example, one surprising lesson they learned was that building orders and order sets made workflow analysis much easier.

It also made clear that the most obvious and pressing need was a new pharmacy system that would provide the necessary checks and balances for medication orders.

Teaching and training
There is an old IS axiom that states, “Testing never ends, but training must begin.” In Memorial Health’s case, the hospital had to consider training equipment, rooms, material, and trainers, competency evaluation, when training would begin, the time required for each class, and the registration process.

IS personnel and certified trainers from the Memorial Health department of education worked together to develop a training manual and curriculum. In the end, the training involved 985 nurses and unit secretaries in 64 three-hour classes over an eight-week period.

The hospital used an e-learning system for registration to document participation.

Key factors to implement CPOE

The key factors essential to Memorial Health’s project include:

- thousands of cheat cards for users (revised daily)
- hard work
- long hours to build the system and train users
- dedication
- patience
- a sense of humor

Answer the ‘how-to’
This constant level of intense and focused effort kept the implementation schedule on track. Memorial Health was able to install CPOE in an additional 24 nursing units and in its rehabilitation hospital over the following three weeks.

Memorial Health had application, interface, technical, and management support from the IS team and from the vendor. During the weeks of rolling out to larger units, the vendor provided on-site 12-hour support each day and roaming educators at night.

As expected, most of the support effort was devoted to answering “how-to” questions and working one-on-one with the unit secretaries and nursing. Other issues include new conflicts and system performance issues that continue to evolve.

Physician “beta testers” are currently testing the new model, following orders through the system and checking for loop closure.

Once they are satisfied that the model is mature, the hospital will pilot CPOE to small physician groups on the same sites that served as the nursing test sites.

Once that proves successful or when all new problems are resolved, the hospital intends to roll out CPOE to all clinical areas, with the probable exception of critical care, neonatal, pediatric, and emergency areas.
Survey monitor
JCAHO touches on USP 797, reconciliation during survey

Prepare your staff for a wide range of questions

Be prepared for surveyors to watch staff prepare IVs to check your hospital’s compliance with U.S. Pharmacopeia (USP) Chapter 797 on compounding sterile preparations.

Surveyors asked staff at The Medical Center in Bowling Green, KY, about the risk level of the IVs they compounded and even watched staff make IVs during the hospital’s March survey, says Melinda Joyce, PharmD, FAPhA, CHE, the hospital’s pharmacy director.

“I could tell they didn’t miss anything,” Joyce says. “They were looking at everything that was going on.”

Teach staff about 797
The JCAHO is currently surveying hospitals for compliance with USP Chapter 797. Hospitals should be able to show an action plan outlining how they will move toward compliance in the future.

Surveyors asked Joyce whether the hospital conducted a gap analysis, but they did not ask to see it after she answered yes, she says. They also asked who was trained to make IVs and who did the training.

Surveyors also checked the risk level of the hospital’s IV compounding practices, Joyce says. The hospital can make high-risk solutions—which include using a non-sterile drug to compound a preparation that staff will eventually sterilize or medications made but not used for several days or more—but staff generally mix less-volatile, medium-risk compounds, she says.

Staff in the pharmacy and on the nursing units also received questions about total parenteral nutrition, including who looked at calorie content and who looked at additives, Joyce says.

Tip: Remind staff to tell surveyors simply what they do as part of their daily routine, Joyce says.

Not much education from JCAHO
Surveyors will help educate facilities on USP 797 compliance, according to the JCAHO, but inspectors at The Medical Center didn’t do much to teach staff, Joyce says. The Medical Center’s IV room met all requirements, Joyce says.

Pay attention to reconciliation
Another hot topic that surveyors touched upon was reconciling medications, a 2005 National Patient Safety Goal, although again it was a relatively brief glance, Joyce says.

Pharmacy staff received questions about handling and documenting medications that a patient may bring from home, Joyce says. They told surveyors they work with nursing and medical staff to gather a complete and accurate list.

Staff showed surveyors a “discharge grid,” which resembles a calendar. Nurses write all medications a patient is on when leaving the hospital, including the time of day they should be taken and whether the patient should take them with or without food.

The surveyors were happy with this approach and thought the grid was helpful for patients, Joyce says.

Tip: Teach staff about the National Patient Safety

About the facility: The Medical Center in Bowling Green, KY, is one of the largest healthcare facilities in south central Kentucky. The 484-bed medical center also has a long-term care facility in Scottsville, KY, a home-care company, and a home-care respiratory company.

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Goals and what the hospital does to comply. “Do not underestimate the Patient Safety Goals,” Joyce says. “All staff, both clinical and nonclinical, need to be very aware of them and understand them.”

A lot covered, little time
Surveyors only spent about 10–15 minutes in the pharmacy, Joyce says, but in that time they managed to touch upon several issues.

One of those issues was unapproved abbreviations. Surveyors asked what staff would do if they received an order with an unapproved abbreviation. Holding true to the JCAHO’s new “three-strikes” stance on abbreviation compliance, surveyors found three instances of unapproved abbreviations in charts, meaning The Medical Center did not meet the intent of the National Patient Safety Goal.

Joyce asked surveyors what they have seen in the field that has reduced unapproved-abbreviation use, but they said thus far they had not seen much that would help for hospitals.

Surveyors also checked the hospital’s safety features to prevent look-alike and sound-alike drug mistakes and high-alert medication errors, Joyce says. Joyce had made shelf tags that highlight look-alike/sound-alike medications with stop signs and reminders to verify that the correct medication had been chosen.

Highlight your successes
To educate pharmacy staff about the survey, Joyce went through each standard and National Patient Safety Goal and highlighted what the pharmacy had done to comply with them. She then put that into a PowerPoint presentation and gave staff a quick overview.

Joyce reminded her employees that they knew everything surveyors would probably ask, as the questions would focus on their daily tasks. She also told them to ask for clarification or additional information if they did not understand the surveyor’s question.

Tip: Remind staff of key words or phrases that may be helpful when talking with a surveyor, such as “urgent use” or “multidisciplinary approach.”

Survey at a glance
Hot spots: U.S. Pharmacopeia Chapter 797, reconciling medications, unapproved abbreviations, look-alike/sound-alike medications, high-alert medications

Critical advice: Have documents and policies ready to go in case a surveyor asks for them. Even though the survey process focuses on patient-care procedures, knowing where policies are in case surveyors need them is crucial

Survey tip: Put staff at ease and tell them to explain to surveyors simply what they do during their daily routine when answering a surveyor’s questions.

Quote of note: “I could tell they didn’t miss anything. They were looking at everything that was going on.”
Withdrawal leaves patients scrambling for alternatives

Seven months after Merck & Co., Inc., halted sales of the anti-inflammatory drug Vioxx because of cardiovascular risks, another drug in the COX-2 class will come off the market, the FDA announced April 7.

Pfizer, Inc., suspended U.S. and European sales of Bextra pending further discussions with the FDA, said Steven Galson, MD, acting director of the agency’s Center for Drug Evaluation and Research.

In addition, Pfizer will add a black-box warning to its other COX-2 drug Celebrex outlining increased risk of cardiovascular problems and gastrointestinal bleeding.

All other manufacturers of prescription nonsteroidal anti-inflammatory drugs (NSAID) will place the same warning on their labels, Galson said. Nonprescription NSAIDs will carry similar labels.

Public hearings held in February about NSAIDs led to the announcement, Galson said. Although the advisory panel determined that there was a cardiovascular risk involved with all NSAIDs, research also showed an increased risk of skin reactions in patients who used Bextra.

The new black-box warning will go on the package insert in prescription medications, Galson said. Manufacturers must also put the warning on medication guides that pharmacists will give to patients when they fill the prescription, he said.

Consumers should continue to take NSAIDs as directed, Galson said. Patients should receive the painkiller that best suits their needs and take the lowest dose needed for the drug to be effective, he recommended.

Physicians and other healthcare providers should talk to patients currently taking Bextra to determine alternative treatments, Pfizer said in a statement.

Editor’s note: This story was adapted from a breaking-news fax sent on April 7. If you did not receive it, contact customer service at 800/650-6787 to update your contact information.