MM.4.5: JCAHO standard of the month

Monthly reviews, leaving sample drugs help safeguard facilities without a 24-hour pharmacy

It's 6 p.m. on an average work day. If your hospital is one of the many without a 24-hour pharmacy, it's probably time for staff to head home for the night.

As your facility's pharmacy director, you must make sure that the policies and procedures you have in place during your absence—as well as your staff's departure—will protect patients from potential medication errors after hours.

Crafting a creative and competent policy will also help your hospital comply with the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) medication standards.

The draft medication standard MM.4.5 requires organizations to develop specific processes and procedures to safely provide medications to patients when the pharmacy is closed (see the box on p. 2 for a synopsis of the standard).

Note: The overhaul of the JCAHO’s hospital manual involves revising the medication standards and placing all TX medication standards in the new Medication Management chapter, thus changing the standards’ names from TX to MM.

Facilities report employee resistance to CPOE systems

Experts say hospitals should wait for improved technology, work on standardization

Health care consultants and advisors, including the Leapfrog Group, suggest that hospitals install computerized physician order entry (CPOE) systems, touting the systems as excellent ways to improve patient safety and enforce hospital policies.

However, other experts urge facilities to wait, citing a still developing technology, high costs, and a host of system flaws.

"[Hospitals] should wait two to three years," a source close to the Joint Commission on Accreditation of Health Care Organizations (JCAHO) tells HPRR. "The technology isn’t there yet. That doesn’t mean they shouldn’t be planning, though.”

Convenience is key
One of the most serious
The accreditor approved the MM standards and is set to post them at www.jcaho.com in July, a source close to the JCAHO tells *HPRR*. The standards will go into effect January 1, 2004.

**After-hours access**

Administrators at St. John’s Medical Center in Jackson, WY, created several measures to protect patients from potential medication errors after hours, says Linda Donohue, RN, the facility’s JCAHO coordinator and performance improvement director/quality resource member.

Her facility uses Pyxis machines, which contain about 90% of the medications the facility dispenses. If a patient needs a medication from the 10% of drugs not available via Pyxis, the night shift supervisor has keys to the pharmacy and can enter after hours to obtain the medication.

To cover the gap between when pharmacy staff leave for the day and the night shift supervisor comes on duty, several charge nurses also hold keys to the pharmacy, adds Donohue.

All nurses with access to the pharmacy after-hours must pass an annual competency exam and undergo orientation to the pharmacy. The hospital maintains a list of all approved nurses.

Nurses leave a sample drug at night

When a nurse enters the pharmacy at St. John’s, he

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**Preparing and dispensing medications**

**Standard MM.4.5**

The hospital has a system for safely providing medications on an emergency basis when the pharmacy is closed.

**Rationale**

The hospital must be able to safely obtain medication for an urgent or new patient when the facility’s pharmacy is closed. Staff must maintain the same level of quality in procuring drugs for patients when the pharmacy is closed as they do when it is open.

**Elements of performance**

When hospitals permit health care professionals who are not members of the pharmacy staff to enter the pharmacy to obtain medication after hours, the following must apply:

- The facility limits staff members’ access to medications only approved by the hospital. The hospital places these medications in a specific section of the pharmacy, stores them in a night cabinet, or keeps them in an automated dispensing device.
- Only trained and designated employees can access these medications.
- The hospital creates quality control procedures to prevent medication retrieval errors. Such procedures might require two individuals instead of one to check medications.
- The facility arranges for a qualified pharmacist to be on call or accessible (such as at another hospital with a 24-hour pharmacy) to answer any medication-related questions or to provide those medications that non-pharmacy staff are unqualified to dispense.

Hospitals must periodically evaluate their related procedures, identifying both the medications routinely obtained after-hours and the reasons why staff enter the pharmacy after-hours.

Facilities must also aim to decrease the number of times non-pharmacy employees obtain medications after the pharmacy is closed.
or she must now follow a new policy that administrators created earlier this year.

“They have to leave a copy of the doctor’s orders, and they have to leave a sample of the drug that they took [in the pharmacy],” says Donohue. “It’s worked out very well.”

The nurse takes two portions of the medication from the shelf—one to give to the patient and the other to leave on the counter with the orders. That way, when the pharmacist comes in the following day, he or she can verify that the nurse took the correct medication for that patient.

Monthly reviews decrease pharmacy entries
St. John’s nurses who enter the pharmacy after hours must also sign a log each time they enter and write down the medication they take. The facility’s pharmacists review the log on a monthly basis, says Donohue.

If pharmacy notes a frequency in a certain medication, they then add it to the Pyxis machine to reduce entries into pharmacy.

“That has really improved over the past year. We’ve really cut back on the need to go to pharmacy for medication,” says Donohue.

On-call pharmacists available for questions
Once in a while nurses will need to speak with a pharmacist after hours about a medication issue, such as a compatibility problem. Therefore, the facility places a pharmacist on-call for such situations.

Though staff take care of 99% of problems over the phone, occasionally a pharmacy staff member will need to come into the facility, Donohue says.

Night supervisors and charge nurses also do not have access to narcotics, potassium chloride, and several other high-risk medications—hospitals double-lock these drugs.

Pharmacists will occasionally come in after hours to obtain one of these medications for patients.

Quick tips
Advice from your peers on what to do without a 24-hour pharmacy

Approximately two-thirds of hospitals in the United States have pharmacies that are not open 24 hours a day.

Some facilities use the following policies and procedures to safely give patients medications after hours:

• Maintain a night cart on the nursing units and a dispenser in the emergency department

• Administer only those medications considered an immediate need; employees base this decision on a hospital policy that specifically defines an immediate need medication

• Monitor monthly, the reasons staff enter the pharmacy, and make appropriate modifications to limit this practice
Sample policy for accessing medications after hours

Policy
1. St. John’s Hospital Pharmacy is not staffed 24 hours a day. During the hours the pharmacy is not staffed, the night supervisor or primary care unit (PCU) supervisor has a key to enter the pharmacy and obtain medications needed by the hospital.

2. When necessary, the night supervisor or PCU supervisor shall sign out enough medications required by patients until scheduled pharmacy staff are available to get the patient through until 8 a.m. the following day. Pharmacy staff are available on-call for emergency situations.

3. When a designated registered nurse (RN) removes a medication from the pharmacy after hours, he or she will leave a copy of the physician’s order and a sample of the medication removed for patient administration. This sample may be an additional unit dose, or the identifying container. The nurse is not required to leave a sample of a refrigerated item. The following morning the pharmacist will verify that the RN obtained the appropriate medication.

Procedure
1. The night supervisor or the PCU supervisor may obtain patient medication orders for medications not loaded in the Pyxis medstations after-hours. The supervisors will undergo training annually on the proper procedure for this by the director of pharmacy.

2. The night/PCU supervisor has the key to the pharmacy department and will write down all medications removed from the pharmacy on the night log sign-out sheet. He or she will document the date, time, room, patient name, drug, medication quantity, and sample of the medication taken, or the empty container; and sign his or her name.

3. The pharmacist will review and reconcile the night log every morning. The pharmacy will charge for all removed medications, which must have an order for removal. The pharmacist will sign the night log daily as proof of reconciliation.

4. If medications removed do not have an order, or are not documented correctly, an incident report will be written.

5. For security purposes, only the night supervisor and PCU designated supervisor who have undergone inservices on the correct procedure for obtaining medications, are permitted to use the pharmacy key.

Source: St. John’s Medical Center, Jackson, WY. Reprinted with permission.
problems with CPOE systems is that they aren’t always convenient for physicians, experts say. At some facilities, a lack of open computer terminals forces physicians to compete with coworkers, especially members of the nursing staff, for a free computer.

“If they have to fight for computer terminals, they probably won’t use it. Doctors have to be able to use it on the fly,” says the unnamed source.

His facility tried to install a CPOE system several years ago and even offered incentives to physicians to use it. Administrators arranged for the doctors’ malpractice carrier to give discounts to physicians who used the system—but staff did not take to it.

The hospital was lucky if they had 5% of the medical staff using the system, he adds. “It was faster for a doctor to write an order out than it was to use a computer;” says the source. “The selling point is, you’ve got to make their lives better, and right now I don’t think computers make their lives better.”

Other experts agree that the technology still has room to grow, but say many hospitals have decided to install a CPOE system.

“We agree that the products available are not yet at their ideal state,” says Suzanne Delbanco, PhD, executive director of the Leapfrog Group. “So, it’s challenging for hospitals to implement them. But that certainly hasn’t stopped a huge number from doing so.”

Delbanco equates the decision to purchase a CPOE system to a consumer’s decision to buy a laptop computer. “If I wait six months from now, I can get a cheaper and faster [computer], but I will have gone for six months without getting the benefit of it.”

Only 5% of hospitals fully use systems, and another 22% plan to install them by next year. “We’re really at the beginning of a sea change,” she says.

Handheld devices ideal for doctors
Some say CPOE systems can be useful when dealing with standing orders. It’s easier to click on the computer screen to send standing orders than it is to write them out. Though even with standing orders, difficulties do pop up.

“The problem is, a lot of hospitals already have [standing orders] preprinted, so all the doctor needs...
CPOE

< p. 5

to do is pick up the printed form, cross out the ones he [or she] doesn’t want, and sign it. That’s faster than finding a computer,” says the unnamed source.

An ideal technology for doctors is not the current system, but a handheld device or tablet that physicians use at the bedside and then take back to their office to download information onto their computer. However, this technology may take a few years to develop.

“They’ve already got handheld products for the outpatient world so doctors can do their prescriptions on their handheld and beam them to a center in their office that will fax [or e-mail] them into the pharmacy,” says the source. “But they don’t have it set up quite yet for the hospital milieu.”

Standardization should come before CPOE
In the meantime, experts recommend that hospitals work to standardize the protocols physicians use when prescribing medications to patients—a crucial step before installing a system such as CPOE.

Roger Resar, MD, a Mayo Health System physician and senior fellow at the Institute for Healthcare Improvement (IHI) also feels that hospitals should wait to purchase CPOE, adding that the Leapfrog Group has changed it’s criteria for system implementation, giving facilities more time to incorporate the system into their current operations.

Hospitals can receive partial credit towards a perfect rating for CPOE installation if they plan to install the system by 2005 instead of 2004.

“Part of the problem is that a lot of CPOE systems are being purchased for the wrong reasons,” he says. “One of the wrong reasons is that it’s going to solve your problems. The CPOE systems are complex, and they have the need for a lot of standardization before they work. Most organizations have been unable to standardize anything.”

Some facilities have many different protocols for the same scenario. This is because each physician has his or her own idea about the best way to proceed and wants the flexibility to define treatment on a case-by-case basis. However, this lack of standardization can become confusing and result in medication errors, says the unnamed source.

Resar agrees. “When you start dealing with the complexities of everybody doing it [his or her] way, the CPOE becomes extremely difficult to work with.”

TIP: Experts recommend that facilities set up specific protocols for as many situations as possible. For example, “if the blood sugar is A, then all physicians must do B; if it’s C, then they must do D.”

Hospital executives should lead the charge
Another problem with CPOE is that doctors may start
closing system pop-up windows, such as confirmations of checks for allergies or drug interactions, adds Resar. After a while, physicians don’t want to bother with them and simply click through “no, no, no.”

He has also seen situations in which a doctor will write an order in a chart and then pass the chart to the ward clerk to enter into the CPOE system.

“That’s not a computerized physician order entry system,” he says. “All it is is an electronic system, and I’m afraid that’s what a lot of these are being degraded into because people have not set up the standardization and the acceptance of the rules so that it can be a truly safer way of administering drugs to our patients.”

A first step in the right direction is for hospital leaders to stress standardization, says Resar. “I think the chief executive officer and the medical director have to lead the charge to standardization and rules as part of their safety responsibilities.”

Delbanco agrees that hospitals must examine themselves before installing CPOE. Facilities should have good clinical information systems in place and make sure that all data is electronic and is able to interact. A strong foundation is crucial to a successful CPOE system, she says.

Experts say that before purchasing a computerized physician order entry (CPOE) system, hospitals must standardize their protocols for the medications physicians prescribe to patients with the same diagnoses.

Standardization will make CPOE safer and more effective.

Consider using the following possible protocol:

**Diagnosis:** Acute myocardial infarction

**Protocol:** Any patient suffering from an acute myocardial infarction will receive at discharge aspirin, beta blockers, and (if the patient had congestive heart failure) an angiotensin converting enzyme

“A good CPOE system will make sure that [protocol is] done on every patient who has an acute myocardial infarction,” says Roger Resar, MD, a Mayo Health System physician and senior fellow at the Institute for Healthcare Improvement (IHI).

“Everyone has to agree that’s what they want done. Once you start making decisions on your own, then the rules start breaking down.”

**TIP:** Useful systems should remind physicians about the above medications if they elect not to prescribe the complete set.

A good system would then prompt doctors to enter a reason for their decision, adds Resar.

Facilities must then consider whether physicians will pay attention to the reminder and what their reasons might be for abandoning certain medications.
Final OIG guidance focuses on marketing practices, regulating drug samples

Editor’s note: In the May HPRR we looked at the Office of the Inspector General’s (OIG) proposed voluntary guidance for pharmaceutical manufacturers. The guidance is now final. See what our experts say about how the final guidance differs from the proposed version and what this will mean for your facility.

The guidance focuses on three major areas of potential risk for pharmaceutical manufacturers:

1. **Compliance with laws that regulate drug samples**
   As a result of recent billing violations involving drug samples, the OIG urges both providers and pharmaceutical companies to educate employees on the proper use of drug samples. When health care providers bill federal health care programs for samples, they not only violate the Prescription Drug Marketing Act of 1987, but also the anti-kickback statue and the False Claims Act in the OIG’s guidance, experts say.

   "That’s now a discussion about the potential for patients or others to be misled. That’s not really an anti-kickback issue. It reflects some very broad policy perspectives that the OIG is trying to push through this document that, I think, frankly exceeds their authority.”

   - Extending inappropriate entertainment, travel, meals, gifts, recreation, or gratuities to physicians or other health care staff
   - Paying doctors to listen to a drug rep’s sales presentation
   - The guidance also includes information on safe harbors—legal protection extended to manufacturers if they agree to follow set guidelines related to interactions with business associates. The guidance especially addresses the personal services harbor, which allows pharmaceutical companies to hire physicians and others on an independent contractor basis to provide services, such as clinical research or making speeches, to the pharmaceutical companies. Sarraille adds that this is an important component of the guidance, as “most, if not all, of the relationships with pharmaceutical companies are not within the safe harbor.”

   He worries, however, that the guidance on safe harbors may go too far. When hospitals evaluate the identity of the sales agent marketing or promoting company products—e.g., is the agent a “white coat marketer” or in a position of exceptional influence—they are not addressing an anti-kickback issue.

2. **Kickbacks and other illegal remunerations**
   Both drug companies and providers should pay close attention to marketing activities that involve physicians and hospital pharmacy staff. The final guidance lists the following potential drug manufacturer practices as problematic:

   - Extending inappropriate entertainment, travel, meals, gifts, recreation, or gratuities to physicians or other health care staff

3. **The integrity of data provided by manufacturers**
   The final guidance also stresses the importance of pharmaceutical manufacturers’ providing accurate and detailed data to the government. The government...
many times uses this information to set reimbursement under Medicare and Medicaid, experts say.

Like many other hospital leaders, Terry Buchanan, MS, RPH, director of pharmacy at St. Francis Hospital in Columbus, GA, says his hospital implemented the proposed guidance when it was first released as a show of good will.

“If audited and found guilty of an unintentional violation, having a corporate compliance program would help demonstrate that it was unintentional,” he says. “Thus, the OIG would treat us more leniently than if we did not have a program—the fines would be less.”

Industry experts and hospitals have recently expressed concern as to whether the guidance also applies to device manufacturers and durable medical equipment suppliers. Sarraille thinks it does apply.

“There might be some suggestion by the OIG here that this guidance should not only be considered with respect to pharmaceutical relationships, but potentially with respect to relationships with other types of suppliers.”

TIP: Hospitals should ask themselves whether they should use this guidance in more than one context, says Sarraille.


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PhRMA code quick tip: How to set limits on the drug rep-physician relationship

Does the Pharmaceutical Researchers and Manufacturers of America’s (PhRMA) Code on Interactions with Healthcare Professionals go far enough in defining appropriate physician-drug representative interactions?

One federal agency seems to think so. The code offers good advice for reviewing and structuring such relationships, the Office of the Inspector General (OIG) says in its final voluntary guidance for pharmaceutical manufacturers.

But some experts disagree, saying portions of the code are too general, such as its recommendation for reps to pay for only a “modest meal when meeting physicians.” A modest meal in Topeka, KS, is very different from one in New York, experts say.

To help pharmaceutical representatives, experts from the recent HCPPro audioconference, “The OIG guidance for pharma: How it affects providers,” suggest the following:

• Hospitals should set their own standards.

Work with physicians to establish appropriate guidelines for interactions with drug reps.

• Set up specific rules. For example, if administrators at your facility decide not to allow preceptorships—the shadowing of physicians by drug representatives—they should instruct representatives not to ask physicians permission to engage in them. If administrators prohibit doctors from working as paid consultants, they should tell representatives not to ask physicians to work in these roles.

“I think communication is the way this thing is going to work,” says Valli F. Baldassano, director of global compliance at Pharmacia. “Everyone has to be transparent about it. We can all work together to resolve whatever issues are out there because it’s in both sides’ best interests.”

TIP: If you or a colleague has problems with the way a representative behaves, call the compliance officer at his or her pharmaceutical company.

Editor’s note: The PhRMA code is available on PhRMA’s Web site at www.phrma.org.
HIPAA help: What your staff need to remember when interacting with patients

Editor’s note: In the May Hospital Pharmacy Regulation Report our experts offered advice on complying with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) when sharing patient information. This month, we present the third in our five-part HIPAA series: HIPAA and patient interactions.

HIPAA’s privacy rule went into effect on April 14, 2003, so you must make sure that all pharmacy staff members are compliant. Confirm that all employees understand when and with whom it’s acceptable to share patient information.

“I don’t think people have to go to tremendous extremes,” says Phil Klein, a senior consultant with the San Diego-based Pharmacy Healthcare Solutions. “But on the other hand, there are many situations I’ve encountered that aren’t that private at all, and there’s not much of an effort to improve that.”

Protecting privacy during counseling
Several states require patient counseling for outpatient prescriptions. Administrators should think about how their pharmacy is set up and how much privacy is afforded to their patients in such situations, Klein says.

Hospitals can make minor modifications to offer more privacy, says Klein. Identify an intake point and a dispensing point at the pharmacy counter and put up a panel to divide the two areas.

TIP: Think about what type of approval you may need for this minor construction. Will you need state approval? To whom must you submit your plans?

As a HIPAA consultant, Klein says he has seen several clinics do an excellent job in protecting patient privacy during counseling.

One area clinic that offers disease counseling created a separate room for sessions, complete with a VCR and educational tapes.

Safeguarding patient logs
Outpatient pharmacies should also review their patient logs to make sure they comply with HIPAA.

“They shouldn’t be signing a list that has everybody else’s name on it too,” says Klein. “If they sign something, remove the sticker and then place it on the list afterwards.”

Most facilities use paper logs for patients to sign following a consultation. But experts say there’s no reason why pharmacists can’t gather signatures electronically. Such a system might look like the technology stores use to get your signature after a credit card purchase.

Be discreet when filling coworkers prescriptions
Many hospital pharmacies also serve their own employees. When filling prescriptions for colleagues, you must be careful in your interactions.

HPRR summer drawing
Hospital Pharmacy Regulation Report is looking for your ideas.

Have you heard of any creative new programs to help pharmacy comply with state or federal regulations?

Perhaps you’ve been hoping to learn more about a certain regulatory issue, and would like to see an article on the topic in HPRR.

Send us your ideas for future stories. If we use your idea, we’ll enter you into a drawing this summer for a $50 prize.

E-mail Associate Editor Debbie Blumberg at dblumberg@hcpro.com or call 781/639-1872, ext. 3425. Mention the summer drawing when you submit your tip.
Health care employees should make special efforts to keep their passwords private, stresses Phil Klein, a senior consultant with the San Diego–based Pharmacy Healthcare Solutions. When complying with the Health Insurance Portability and Accountability Act of 1996, password control is very important, he says.

“[Staff] don’t think anything of it. They don’t realize that the consequences [of sharing their passwords] can be rather severe,” says Klein.

When a celebrity was admitted as a patient to one hospital, an employee leaked the celebrity’s presence to the media. Following the incident, administrators checked all unauthorized staff who had viewed that patient’s record. A number of employees allegedly accessed the system who were not even working that day. They had shared their passwords, and a coworker used this information to log into the system. The hospital suspended several staff members for three days without pay. In some organizations, such behavior would have resulted in termination, says Klein.

Make sure employees understand the importance of never sharing their passwords with coworkers, and always logging off a computer when they’ve finished their work. Enforce these practices in your department to ensure HIPAA compliance.

To interfere with care delivery, and should never delay or disrupt a patient’s care, adds Klein.

Editor’s note: We’ll continue our HIPAA series in the July HPRR with a look at how to make sure business associates comply with HIPAA.

HIPAA quick tip
Educate employees on the consequences of password sharing

Health care employees should make special efforts to keep their passwords private, stresses Phil Klein, a senior consultant with the San Diego–based Pharmacy Healthcare Solutions. When complying with the Health Insurance Portability and Accountability Act of 1996, password control is very important, he says.

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Make sure employees understand the importance of never sharing their passwords with coworkers, and always logging off a computer when they’ve finished their work. Enforce these practices in your department to ensure HIPAA compliance.

“For example, it’s not acceptable to announce to a colleague that her prescription is ready when surrounded by other staff members in the hall or in the hospital cafeteria.

Most of this is common sense, say experts, though it’s good to be clear on exactly what is and is not appropriate to say in such situations.

Craft policies for placing patient calls
Another key area to review for compliance is how you and your staff contact patients by phone about their prescriptions. If the patient is not home, most employees will leave a message on the answering machine.

But what is the best message to leave that both protects privacy and conveys all the necessary information to the patient?

“You have to be careful,” says Klein. “There have been instances where the husband or the wife or somebody who was living in the house had no idea that the person had even seen a doctor. You have to come up with a policy for your employees.”

TIP: When patients turn in their prescriptions, ask them whether it’s all right for you to call them or leave a message. Ask whether there’s a special number that you could call. Add a note about their preferences to their file.

When leaving messages, be general—but not too general. If you leave a message saying “This is Bill, please call me back,” the patient may not remember a Bill and not return the call. Work with your staff to craft an appropriate message.

You can also create a policy that says the pharmacy does not call patients; patients must call the pharmacy for information, says Klein.

Most important is to make sure that employees understand the basics of HIPAA and the reasons why they must comply, says Klein.

“HIPAA has an overriding concern for the safety and delivery of care,” he says. HIPAA was not designed to interfere with care delivery, and should never delay or disrupt a patient’s care, adds Klein.

Editor’s note: We’ll continue our HIPAA series in the July HPRR with a look at how to make sure business associates comply with HIPAA.
**Government News**

Prescription drug plan update

Legislators predict more movement in July

Here's the latest update on President Bush’s proposed Medicare prescription drug plan benefit, with commentary from Bill Sarraille, a partner at the Washington, DC-based law firm Sidley, Austin, Brown & Wood LLP:

• Both the House and Senate agreed to set aside $400 billion over 10 years for Medicare reform with prescription drug coverage. Democrats, such as Senator Edward Kennedy (D-MA), would prefer $700 billion over 10 years, but would consider a plan closer to $400 million.

  “There is political interest in a broad benefit, but real doubt [about] where the funds will come [from],” says Sarraille. “Four-hundred-billion dollars creates a modest benefit.”

• A bill that would reform Medicare and include a prescription drug benefit will most probably reach the Senate floor by July, said Senate Majority Leader Bill Frist (R-TN) in a CongressDaily report. Republicans on the Senate Finance Committee are working on bill plans, he added. This plan will most likely pass the committee by the July 4 recess. Frist expects the House to pass similar legislation either before or in conjunction with the Senate.

  “The idea that both chambers would pass a bill and then fail to resolve differences in conference would hurt the Republicans,” says Sarraille. Instead, he expects the Senate Republicans to push a plan that the Democrats can’t tolerate, forcing the Democrats to prevent cloture.