JCAHO issues updated listing of look- alike/sound- alike drugs

The JCAHO in August released an updated list of look-alike/sound-alike medications that hospitals can use to comply with National Patient Safety Goal (NPSG) 3C.

Originally issued in 2004 with the release of the proposed 2005 goals, the list was compiled with input from the Institute for Safe Medication Practices, United States Pharmacopeia (USP), FDA, and Pennsylvania Patient Safety Reporting System.

The confusion regarding similar drug names can be increased by poor handwriting or poor communication of oral prescriptions.

New IOM report highlights medication error prevention strategies, goals

A new Institute of Medicine (IOM) report details several recommendations to help prevent medication errors, but whether hospitals actually implement those strategies remains to be seen.

Preventing Medication Errors is a 544-page report released in late July that made headlines with its findings that medication errors harm at least 1.5 million people nationwide and cost about $3.5 billion annually.

The committee that wrote the report made a series of recommendations for patients, healthcare organizations, government agencies, and pharmaceutical companies. The recommendations include ways to improve communication and interactions between healthcare professionals and patients.

The IOM panel also calls for the creation of consumer-friendly information resources that allow patients to find objective drug information. The report recommends that all prescriptions be written electronically by 2010 and suggests improvements to the naming, labeling, and packaging of drugs to prevent errors.

Another recommendation involves increased study of the effect of free drug samples on overall
Look-alike/sound-alike

NPSG 3C requires organizations to identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used in the organization and take action to prevent errors involving the interchange of these drugs. Previous versions of the goals included the expectation that the listed look-alike/sound-alike medications come from the JCAHO’s posted list, but that is not in the current version. Expect the requirement that the medications on the list come from the JCAHO Web site to be reinstated by the end of the year.

New combinations on the list

New additions to Table I (hospitals, critical access hospitals, office-based surgery) of the JCAHO’s list include the following combinations:

- **Hydroxyzine** and **hydralazine** are often stored side-by-side on pharmacy shelves and listed next to each other on computer lists because of their identical first four letters, according to the JCAHO list. They also have similar dosage strengths and tablet forms. Hydroxyzine is an antihistamine, and hydralazine is an antihypertensive agent, so care should be taken not to confuse these drugs to prevent serious adverse events.

- **Metformin** and **metronidazole** have been confused because of look-alike packaging in both bulk bottles and unit doses, as well as incorrect selection after entering “MET” as an abbreviation.

- **Oxycontin** and **oxycodone** are confused when the prescriber uses the generic name but doesn’t specify “controlled release,” according to the JCAHO. Oxycodone is an immediate release product, so the patient may receive it in a dose that is appropriate for controlled release, which could lead to an overdose. The list recommends that pharmacies not store immediate release and controlled release products together.

New additions to Table II (ambulatory, assisted living, behavioral, home care, long-term care) include the following combinations:

- **Lorazepam** and **alprazolam** are two similar drugs with different potencies. Administering the wrong drug—especially to elderly patients—would cause excessive sedation and increased risk of falls.

- **Metformin** and **metronidazole**—see the Table I list at left.

- **Topamax** and **Toprol XL** are confused because of the “x” in their names. Topamax is an anticonvulsant, and Toprol XL is a beta blocker. Patients who need Topamax may develop seizures if given Toprol XL, and those needing a beta blocker may suffer worse disease symptoms without treatment. The JCAHO recommends storing these products separately and using both brand and generic names to differentiate them when prescribing the drugs.

The document also includes a list of other drug combinations that were rated or suggested by experts, including

- **Amicar** and **Omacor**
- **Cardura** and **Coumadin**
- **Darvocet** and **Percoset**
- **Effexor XR** and **Effexor**
- **Hydrocodone** and **oxycodeone**
- **MS Contin** and **Oxycontin**
- **Tramadol** and **trazadone**
- **Zestril** and **Zyprexa**
- **Zestril** and **Zetia**
- **Zocor** and **Zyrtec**

Based on 2001 Sentinel Event Alert

The JCAHO highlighted the confusion over look-alike/sound-alike drugs in a 2001 Sentinel Event Alert that was prompted by a USP list of confusing drug name sets that identified more than 750 drug names that had been reported to its Medication Errors Reporting program.

The alert recommended that hospitals adopt the following strategies:

- Monitor error reporting information instead of relying on memory of problem drug combinations
- Store problem drugs out of alphabetical order, or store them separately to avoid confusion
- Use both the generic and brand names of drugs for medication orders to help avoid errors
- Include the purpose of the medication on the prescription to help the pharmacist as he or she screens the medication order
It’s not difficult to confuse look-alike and sound-alike drug names. There are several reasons that could lead staff to mistake one drug for another, including the following:

- Illegible handwriting on medication orders
- A lack of knowledge about drug names
- Computerized physician order entry systems that list drug names alphabetically
- Drug shortages that lead you to purchase a drug that arrives in packaging that is similar to another drug you have in stock

Following are tips to help you comply with National Patient Safety Goal 3C:

- Use colored bins on the pharmacy shelves to denote look-alike and sound-alike drugs. Staff do not have to separate the drugs and place them in separate areas of the pharmacy, which helps improve workflow in the process.
- Use current data and resources to create posters that you can hang throughout your organization to remind staff about the potential for confusion. For example, the U.S. Pharmacopeia publishes a list of more than 750 pairs of drugs with similar looking or sounding names (see www.usp.org for more information).
- Hang posters and charts with the look-alike/sound-alike drug pairs in the pharmacy and each medication room.
- Label medication bins with “tall-man lettering,” which involves capitalizing certain letters in drug names to differentiate look-alike/sound-alike drugs. For example, the Institute for Safe Medication Practices recommends the following spellings to identify these two drugs:
  - PredniSONE
  - PrednisolONE
- Use tall-man lettering in computer systems, especially if they list drug names alphabetically. This will eliminate the potential for selecting the wrong drug by confusing the names.
- Hold educational sessions as new products that could be confused with others enter the formula-ry. Make sure that the educational efforts to prevent confusion include physicians, pharmacists, and nurses.
- Carefully review trade and generic drug names on all medications at all points in the medication process.
- Use “name alert” stickers on the plastic bins to visually set a particular drug apart from other medications.
- Reeducate hospital staff using your hospital list and emphasize caution as drug names are reviewed. Also, be sure to use the hospital intranet to get the word out.

Source: Compiled from HCPro products.
IOM report

medication safety. (See p. 5 for a list of the report’s recommendations.)

Most of the recommendations in the report are already addressed in the JCAHO’s standards, but the IOM’s report is no less important, says Elizabeth DiGiacomo-Geffers, RN, MPH, CNAA, BC, a healthcare consultant based in Trabuco Canyon, CA.

“It’s a worthwhile report,” she adds. Pharmacists should “look at how [they] can integrate it into the risk assessment at [their] hospital.” (See p. 9 for an article about pharmacy risk assessment.)

National EHR should be first step

Although he agreed that the report serves a good purpose, Kasey Thompson, PharmD, director of patient safety for the American Society of Health-System Pharmacists, says it also illustrates the staggering amount of work that needs to be done to improve the American healthcare system.

“The report was a good reminder that errors are very common and very preventable, and [that] we’re not doing as much as we can societally to prevent them,” he says. “So much is left to be done in the community setting. We have a responsibility to make sure the system is safe when patients are out of the hospital.”

A major reason for medication errors is the lack of a consistent electronic health record (EHR) so that all care settings have the same information about a patient, Thompson says. “Every healthcare organization should have access to patient-specific information,” he notes.

EHRs would help with medication reconciliation, quality measurement, and performance measurement, but it’s an immense project that must overcome privacy and technology hurdles, in addition to the potentially huge implementation costs, says Thompson.

However, electronic prescribing (e-prescribing) could be wrapped into an overall EHR project, he says. “Practically, you have to look at e-prescribing and EHR as one and the same.”

Some hospitals have already instituted e-prescribing systems, which alleviates handwriting errors, “but you don’t get the full picture,” Thompson adds.

Data analysis is crucial to error prevention

The report also reminds hospitals that they need to do more than just collect data.

“A lot of people collect data for adverse drug events [ADE],” DiGiacomo-Geffers says. “It’s the analysis of the data that’s critical. We need to address methods of improvement.” Ways to identify such incidents include building ADE triggers into computerized systems, she adds.

Also, pharmacists should educate coders about how to identify ADEs when they’re going through health records. “That could enhance their data collection, especially in off-site organizations such as home health,” she adds.

Involve the patient

DiGiacomo-Geffers says the patient-focused recommendations are extremely important. “We still have the ‘captain of the ship’ syndrome. When you query patients at home, they don’t know what they’re supposed to do [with the drug].”

Caregivers must provide medication instructions to patients—both verbally and in writing—in language that patients understand, she adds.

Thompson notes that patients also need to take the medication management process seriously. “Patients don’t ask questions. The general mindset is there’s a pill for every ill.”

Thompson recommends that patients ask various health professionals for information about their medications as they move through the system.

Editor’s note: The IOM report is available for purchase at www.nap.edu/catalog/11623.html. You can read the free executive summary at www.newton.nap.edu/execsumm_pdf/11623.
IOM medication error prevention recommendations

The Institute of Medicine’s (IOM) new report Preparing Medication Errors includes the following recommendations:

- To improve the quality and safety of the medication use process, healthcare organizations should institute specific measures to strengthen patients’ capacities for sound medication self-management.

- Government agencies (e.g., the Agency for Healthcare Research and Quality [AHRQ], Centers for Medicare & Medicaid Services, FDA, and National Library of Medicine [NLM]) should develop consumer-oriented drug information and medication self-management support resources. This requires the standardization of pharmacy medication information leaflets, improvement of online medication resources, establishment of a national drug information hotline, development of personal health records, and creation of a national medication safety dissemination plan.
  - Pharmacy drug information leaflets should be standardized to a format designed for readability, comprehensibility, and usefulness to consumers. The leaflets should be available in versions that meet individual consumer needs (e.g., variations in literacy, language, age, and visual acuity).
  - A national plan should be developed to distribute and promote medication safety information. Healthcare provider, community-based, consumer, and government organizations should serve as the foundation for such efforts.

- All healthcare organizations should immediately make complete patient information and decision-support tools available to clinicians and patients. Healthcare systems should track information about medication safety and use it to improve the safety of their care delivery systems. Organizations should implement the appropriate systems to enable providers to
  - have access to comprehensive reference information about medications and related health data.
  - assess the safety medication use through active monitoring and use these data to inform the implementation of prevention strategies.

- write electronic prescriptions by 2010. Organizations should enable all pharmacies to receive prescriptions electronically by 2010. All prescribers should have plans in place by 2008 to implement electronic prescribing.

- To improve drug labeling and packaging, the pharmaceutical industry, AHRQ, FDA, and other organizations should work together to do the following:
  - The FDA should develop two guidance documents: one for drug naming and another for labeling and packaging. The FDA and industry should collaborate to develop a common drug nomenclature that standardizes abbreviations, acronyms, and terms, as well as develop methods of applying failure modes and effects analysis to labeling and packaging.
  - A study should be conducted to determine the best designs for all drug labeling and information sheets.

- Industry and government should work together in the following ways to establish standards for drug-related health information technologies:
  - The NLM should lead an effort to develop a common drug nomenclature for use in all clinical technology systems based on the standards for the national health information infrastructure
  - The AHRQ should organize safety alert mechanisms by severity, frequency, and clinical importance to improve clinical value and acceptance

- Congress should allocate funding, and the AHRQ should lead an effort to coordinate a broad research agenda on safe and appropriate medication use.

- Oversight and regulatory groups and payers should use legislation, regulation, accreditation, and payment mechanisms and the media to motivate the adoption of practices and technologies that can reduce medication errors. These efforts should also ensure that professionals have the competencies necessary to safely deliver medications.

*Source: Executive summary, Preventing Medication Errors, IOM.*
**Case study**

**Automation boosts staff image, improves safety**

Incorporating automation into a hospital pharmacy can reenergize staff and improve medication safety, according to a Kentucky-based pharmacy director.

Completing an automation project is a long and involved process, but it has many benefits to offer, said Melinda Joyce, PharmD, FAPhA, FACHE, director of pharmacy at The Medical Center (TMC) in Bowling Green, KY, during the American Society of Health-System Pharmacists’ Summer Meeting in Orlando, FL, in June.

TMC is a not-for-profit facility that is not part of a hospital chain. It includes three acute-care hospitals with more than 400 beds, one long-term care facility, and a long-term acute-care facility.

Joyce’s department provides pharmacy services to all of TMC’s facilities and is open 24 hours per day. Her staff comprises 12 full-time equivalent (FTE) pharmacists—including a dedicated clinical pharmacy coordinator, three pharmacist managers, and one operating room pharmacist—and 20 FTE technicians.

The department dispenses an average of 180,000 doses per month for all facilities, Joyce said. TMC uses profile system unit-based cabinets to dispense meds and uses Meditech for its computer system.

“One of the downfalls with Meditech is sometimes it doesn’t play well with others,” said Joyce.

The pharmacy decided to automate its processes to ultimately introduce bar coding to the facility. “We were using unit-based cabinets, but not doing bar coding,” she said. “What were we doing all day? We were entering orders and checking things. It was not the best use of our time.”

The major issues confronting the pharmacy were the time-consuming, repetitive, and labor-intensive task of dispensing, checking, and distributing medications.

- Exorbitant amount of time that pharmacists spent on medication distribution and order entry activities for multiple sites
- Limited participation of pharmacists in clinical activities on the nursing units
- Large quantity of nonpatient-specific medication inventories located in unit-based cabinets in each med station
- Difficulty in tracking medication expiration dates, which resulted in expired medication costs
- Lack of standardized bar-coded medications, which delayed further automation by the nursing staff
- Manual processes for filling and distribution of medications, which contributed to the possibility of human error

**Goals include bar coding, direct interventions**

Joyce said TMC’s goals in bringing in more automation were to move forward with bar coding and increase the number of direct pharmacist interventions on the nursing floor.

Other goals were to increase staff productivity and efficiency, reduce inventory, and be a leader in healthcare, she added.

“All time you can eliminate human activities and automate, you can increase patient safety,” Joyce said. “But it needs to be a good system.”

Other tangible benefits of the automation project included the following:

- Robot bar code-based automation of dispensing and distributing medications
- Significantly less time spent by pharmacists on medication distribution and order entry activities for multiple sites
- An increase in pharmacist time devoted to clinical patient activities in the units and remote locations
- Centralized inventory with patient-specific medications sent to floors, reducing decentralized inventories
- Continuous rotation of product within the robot,
based on expiration dates, which minimized write-offs of expired medications

- Significant cost savings from purchasing tablets and capsules in bulk, which which was enabled by the packaging service
- Reduced need for expedited shipments because remote sites were supplied with patient-specific medications
- Significant reduction of errors in filling and distributing medications through bar coding

Joyce also cited several less quantifiable benefits of the project, including

- elevating the role of the hospital pharmacist, which provides job enrichment for the pharmacist and helps TMC recruit and retain pharmacists in a competitive environment.
- reducing the risk of major medical errors, leading to a decrease in potential litigation. This takes on greater importance because TMC is self-insured.
- setting the stage for future projects. The pharmacy reengineering project enables the planned goal of going to a 100% bar code system for bedside medication. Without this project, TMC would have had to spend additional money to implement such a system.

Financially sound

The plan was financially solid, with break-even projected by 2007, Joyce said. The return on investment (ROI) is projected to be 59%, with a net project value of +$691,000.

“My feet are being held to the fire by the administrative staff,” she noted. “They want to make sure we meet the ROI.”

Before the project launched, pharmacists were only doing 10% clinical patient care and 90% distribution and order entry, said Joyce. Since April, that ratio is 30% to 70%.

“Techs were spending their whole days refilling the medication buckets,” she noted. “Now that process is fully automated.”

The techs now review patient records to switch from IV to oral therapy. In addition, “we’re looking forward to reducing the number of cabinets,” Joyce said.

Renovation work posed challenges

The pharmacy automation project faced challenges along the way, Joyce said. TMC began a renovation project in late September 2005 that coincided with the hospital having a record census.

As a result, the pharmacy was divided into thirds during the renovation, with one-third closed down at any given time.

The pharmacy area was not sufficient to house a robot, carousel, and packaging operation. In addition, there was no heat or air conditioning in the pharmacy during the renovations, said Joyce.

Other challenges included putting together a hybrid system that combined a McKesson drug robot and carousel, Pyxis, and the existing Meditech system. In addition, Joyce said she had to ease the concerns of staff who worried about potential layoffs because of the automation.

New procedures, training, and gaining buy-in for success were also major concerns, she added. “We used the train-the-trainer idea with staff,” said Joyce.

TMC met its goals so well that it plans to go ahead earlier than expected this fall with a bedside bar coding system, she noted. Other future steps include the following:

- Reworking med stations to maximize efficiency
- Continuing to measure and quantify savings
- Reviewing trends for increased patient safety
Radio-frequency identification (RFID) technology remains the best option to prevent counterfeit drugs from entering the drug supply chain, an FDA official told attendees during the American Society of Health-System Pharmacists’ (ASHP) Summer Meeting in Orlando, FL, in June.

The FDA in June pledged to fully implement the Prescription Drug Marketing Act of 1987, which includes an oft-delayed provision requiring drug distributors to document the chain of custody throughout the distribution system.

As part of this effort, the FDA is encouraging the adoption of systems such as RFID, which creates an electronic pedigree for tracking the movement of a drug throughout the supply chain.

The FDA’s Counterfeit Drug Initiative is actively working to prevent such threats, but the situation is not widespread, said Ilisa Bernstein, PharmD, JD, the FDA’s director of pharmacy affairs.

“There have been some increasing threats to our drug supply over the last several years,” she said. “There’s no way to know the prevalence of counterfeit drug problem. We believe there aren’t a whole lot of counterfeit drugs circulating.”

Fewer than 10 counterfeit drug cases were opened by the FDA until 2001, but in recent years those numbers have increased, Bernstein said.

In 2004, the agency opened 58 cases.

“Counterfeiters, unlike manufacturers, don’t make their drugs to exact specifications,” she noted.

Task force goals center on pedigree

In 2004, the FDA issued a Counterfeit Drug Task Force report outlining a framework designed to protect the public from counterfeit drugs; two subsequent updates were also issued, including this year’s decision to roll out the drug pedigree requirement in December. (See the July HPRR for details.)

The drug pedigree was originally scheduled to take effect in 1999. The goal is for the pedigree to be tracked electronically using RFID, but until such systems are in place, the records initially will be kept on paper.

For an electronic pedigree to work, each individual package has to have its own unique identifying number, Bernstein noted.

“In reality, we’re stuck with federal and state laws on pedigree,” she said. “The federal requirement says the pedigree must be passed on. States have their own pedigree laws.”

States have a responsibility to enforce the law because they license wholesalers, Bernstein added.

The reason for the six-year delay was to wait for the industry to adopt RFID or similar systems to electronically track drugs through the supply chain.

However, in addition to the expense, the pharmaceutical industry has yet to determine which frequencies should be used, agree on data elements, or implement worldwide numbering standards.

Bernstein said the FDA finally decided to go ahead with the pedigree requirement, despite the lack of technological progress. “We didn’t get there,” she said. “We can’t justify continuing to [delay] these regulations when there are dangers to the drug supply.”

In the meantime, hospital pharmacies must do their part by keeping pedigree records. “It’s the responsibility of the pharmacy to accept that pedigree and keep it,” Bernstein said. Pharmacies are expected to retain pedigree records for three years. Bernstein conceded that the FDA’s initial prediction that RFID would be widespread by 2007 will not be met, and added that the FDA will not issue a new forecast.

Still high on RFID

Despite the slow rollout of RFID, the FDA continues to tout it as the best way to ensure drug security,
Bernstein said, “We still believe it is the most promising technology.”

However, the FDA is not yet mandating RFID. “We need a feasible, yet ambitious, timetable,” she said.

The compliance policy guide for RFID tagging pilot studies remains in effect until December 31, 2007. Bernstein said the FDA encourages heightened vigilance and awareness. Hospitals should use Medwatch, the FDA’s medical products reporting program, to report counterfeit drugs. “We’re working with the ASHP to develop education” on reporting, she added.

A call for labeling improvements
The FDA is proposing increasing the length, detail, and complexity of prescription drug labeling, said Bernstein. The labeling will have a highlights section and will emphasize patient counseling information. For updated labeling information, Bernstein recommended checking out Daily Med, a site run by the National Library of Medicine (www.dailymed.nlm.nih.gov). In addition, the FDA’s bar coding requirements for drug manufacturers are currently in effect. The regulation requires all manufacturers to put simple linear bar codes on most prescription drugs and certain over-the-counter medications, and most drug-makers are already complying. However, many hospitals still have not introduced bar code systems at their facilities.

RiskMAPs are a new focus
Another focus area for the FDA is the development of risk minimization action plans (riskMAP) for new drugs. A riskMAP is an agreement between the FDA and the drug manufacturer as part of the new drug approval process, but the FDA is encouraging drug-makers to obtain input from pharmacists, physicians, and patients.

The FDA expects that most products will be handled with a riskMAP, Bernstein said.

Standard of the month
Risk assessment can help with MM.8.10 compliance

Many hospital pharmacies struggle with the risk assessment portion of JCAHO standard MM.8.10, but the process doesn’t have to be complicated, according to Elizabeth DiGiacomo-Geffers, RN, MPH, CNA, BC, a healthcare consultant based in Trabuco Canyon, CA.

“A lot of people didn’t know how to do it,” she says of hospitals she has worked with.

After the JCAHO first unveiled standard MM.8.10 as part of the 2004 medication management standards, DiGiacomo-Geffers developed a handy risk assessment chart for pharmacies to fill out annually as they assess their risk points. (See p. 10 for a sample risk assessment chart.)

The standard calls on organizations to evaluate their medication systems for risk points and identify areas to improve safety.

DiGiacomo-Geffers asks hospitals to list the potential risk points, actions taken to deal with them, process owner, and date that the task is completed. “They know where their problems are,” she notes. “[Filling out the chart] is not mandated, but it’s a way to format what your issues are.”

The chart is divided by the major processes of the medication management system:
- Selection, procurement, and storage
- Prescribing, ordering, and transcribing
- Preparation and dispensing
- Administration of medications
- Monitoring the effectiveness of the drug on the patient

The risk points listed could include anything that could create a problem with medication management, such as education and training, expired medications, medication reconciliation, and dangerous abbreviations.

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Sample risk assessment chart
Organizational evaluation of the medication management system, 2006–2007

**MM.8.10—Medication management review**

**MM.8.10**: The organization evaluates its medication system for risk points and identifies areas to improve safety.

**Scope**: Annual review and report of the risk points concerning medications and the actions taken to resolve the system defects/issues.

Major processes of the medication management system:
- Selection, procurement, and storage
- Prescribing, ordering, and transcribing
- Preparation and dispensing
- Administration of medications
- Monitoring the effectiveness of the drug on the patient

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<td><strong>Monitoring the effectiveness of the drug on the patient:</strong></td>
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Source: Elizabeth DiGiacomo-Geffers, RN, MPH, CNAA, BC. Reprinted with permission.
Groups concerned about USP 797 revisions

ASHP, ASHE cite financial burden on smaller facilities

The public comment period for the U.S. Pharmacopeia’s (USP) proposed revisions to its sterile compounding standards expired in mid-August, with two key associations voicing concerns about additional work and expense that could be incurred as a result of the changes.

USP 797, titled *Pharmaceutical Compounding—Sterile Preparations*, was originally released in January 2004. This is the first attempt to revise the standard, and it could take a year before the revisions are finalized.

“We support that there’s a need for a standard for sterile compounding,” says Lesley Maloney, PharmD, director of public health and quality for the American Society of Health-system Pharmacists (ASHP). “The concern from our members is that there have been significant changes. Although some people agree with the intent, they have problems with how to achieve them. There are significant expenses involved in complying with them.”

The ASHP solicited comments from its members via its Web site and through a series of five Webcasts on the topic of the USP 797 changes. Many of the comments wanted USP to justify its proposed changes.

“We want to see references or evidence for the recommendations,” Maloney says. “[USP] only references its own standards or other government documents.”

Smaller facilities cite a lack of space and resources to adequately build a cleanroom, as USP 797 requires, notes Maloney. The proposed revision calls for facilities to have a separate cleanroom to compound hazardous chemotherapy drugs. “That would require some significant creativity,” she says.

**Enforcement depends on state**

Although the JCAHO has backed off of its original plans to survey hospitals for USP 797 compliance, Maloney says some surveyors still check to see if the USP standards are being met.

In addition, an article in the April *Perspectives* noted that hospitals that do not meet USP 797 guidelines could be found noncompliant with the JCAHO’s MM.8.10. The JCAHO standard requires organizations to evaluate literature for new technologies and successful practices relevant to improving their medication management systems.

USP standards can be federally enforced by...
the FDA, as well as by state boards of pharmacy, says Maloney. “It varies state to state.”

The American Society of Healthcare Engineers (ASHE) asked its members to consider submitting comments about USP 797 and even provided a sample letter for members to use. The letter asks the USP to return the changes to its committee for further review and do a cost-benefit analysis for each proposed revision.

Compounding in the news
The USP 797 revision discussion comes at a time when problems with sterile compounding are making national news. In August, the FDA warned three firms—RoTech Healthcare, CCS Medical, and Reliant Pharmacy Services—to stop manufacturing and distributing thousands of doses of compounded, unapproved inhalation drugs nationwide.

The three firms warned by the FDA said they produce inhalation drugs as part of pharmacy compounding, which typically involves pharmacies preparing drugs that are not commercially available to meet a patient’s special medical needs. The FDA said it does not review compounded inhalation drugs for safety and effectiveness; such drugs are often not produced according to good manufacturing practices and typically are not sterile, posing risk to patients, the agency noted.

In addition, a USA Today article published in early August detailed incidents at Mary Washington Hospital in Fredericksburg, VA, in 2005 in which three cardiac surgery patients suffered inflammation, causing one to die. Tests found bacteria in a solution injected into patients’ hearts during surgery, and investigators later found several types of bacteria in opened and unopened bags of the cardiac surgery solution.

The hospital later found that at least 11 cardiac surgery patients fell ill during a 10-month period from late December 2004 to September 2005, three of whom eventually died. The hospital purchased the solution from Central Admixture Pharmacy Services (CAPS) of Lanham, MD. Eight families have sued the hospital and CAPS as a result of the deaths and injuries. ■