Proposed revisions unveiled for compounding USP 797 standards

Changes focus on air quality, clarifications

The U.S. Pharmacopeia (USP) has published proposed revisions to chapter 797, which outlines procedures and requirements for compounding sterile preparations.

The USP seeks public comments about the revisions, which could take a year to finalize.

The revisions are based on input received by the USP, but the standards-setting group hopes to receive much more feedback, says Diane Cousins, RPh, the USP’s vice president of patient safety.

USP 797, titled *Pharmaceutical Compounding—Sterile Preparations*, was originally released in January 2004. Two-thousand comments have been received since then, says Cousins.

This is the first attempt to revise the standards. Go online to

Med management standards high on most-cited JCAHO list for 2005

Medication management (MM) standards continue to trouble hospitals, according to the JCAHO’s hospital list of “top standards compliance issues for 2005.”

A list of the most frequently cited standards during surveys for each accreditation program is released annually by the JCAHO in its *Perspectives* publication, which all accredited organizations receive. The hospital list, released in May, includes 14 standards.

Provision of care (PC) standards were also common on the list, and close behind—as well as in the top position on the list—are information management (IM) standards.

The list is rounded out by an environment of care (EC) standard, a leadership (LD) standard, a medical staff (MS) standard, and an infection control (IC) standard.

The JCAHO also recently made available noncompliance data for its National Patient Safety Goals for full surveys conducted in 2005.

Below are the standards and goals that made the lists, and the compliance issues or analysis, if available, based on information gathered during the JCAHO’s Hospital Accreditation Essentials education seminar in Chicago in May.
USP revisions

www.usp.org/USPNF/pf/generalChapter797.html to read the revisions.

Comment period through August

The public comment period runs through August 15, and Cousins says the USP will take its time sifting through everything before finalizing the revisions.

It’s possible that the changes could be unveiled in time for the next publication of the USP’s Pharmacists’ Pharmacopeia in the summer of 2007, says Cousins. The final decisions about the revisions rest with the USP’s 12-member Sterile Compounding Expert committee.

The USP has posted two versions of the revised chapter on its Web site: one with the old language crossed out and new language added, and a numbered version with only the new language included. Users who submit electronic comments through the USP Web site can refer to changes by line number.

“We’re hoping for a good number of comments,” says Cousins.

The USP would like to receive comments that provide

- alternate methods to accomplish a standard.
- “They’re free to suggest methods that might be appropriate,” Cousins notes.
- suggested implementation times.
- any data or alternate practices.

The USP’s comment process has always been through the Pharmacopeial Forum, which was only open to paid subscribers. This time around, the USP is posting the proposed revisions online for free.

The USP is also explaining the changes through the sale of a guidebook on its Web site and a series of six Webinars, which will feature speakers going through the main changes in the proposed revisions.

JCAHO backs off 797 enforcement

Shortly after the USP 797 was originally published, the JCAHO published a crosswalk in its Perspectives newsletter between USP 797 and its Medication Management standards (see “Crosswalking USP 797 with JCAHO med standards” on p. 4), and later in 2004 issued a timeline detailing dates by which hospitals should implement the various USP 797 standards.

These moves led hospitals to grow concerned about how strictly JCAHO surveyors would check for compliance with USP 797.

A look at proposed changes

The proposed U.S. Pharmacopeia (USP) chapter 797 revisions include the following:

- A glossary of terms used in the chapter.
- A fourth microbial risk category of drug preparation—Immediate Use compounded sterile preparations (CSP)—which was created to exempt CSPs from the requirements described in the previous three categories: Low-risk level, medium-risk level, and high-risk level.
- A new section highlighting hazardous drugs as CSPs. It is consistent with the language found in publications from the National Institute for Occupational Safety and Health and the American Society of Health-System Pharmacists.
- A new section addressing issues related to compounding with radiopharmaceuticals. It refers to USP chapter 823 when compounding for positron emission tomography.
- Requirements for primary and secondary engineering controls in cleanrooms, biological safety cabinets, and compounding aseptic isolators.
- Revisions to the section on environmental monitoring that refer to USP chapter 1116 on microbial monitoring of cleanrooms, anterooms, and ISO Class 5 engineering controls.
- A section on personnel cleansing and garbing that provides information about hand hygiene and personnel garbing requirements.
- Revised sterility storage times and stability beyond-use dates.
The JCAHO’s recommended deadlines called for hospitals to determine how well they conformed to USP 797, and what renovation plans would be needed by January 1, 2005. As of July 1, 2005, hospitals were to have instituted any interim measures to offset deficiencies in USP 797, according to the deadline.

In the April Perspectives, the JCAHO clarified its stance and put the onus of USP 797 compliance back on hospitals. “An accredited organization determines how it best can comply with the requirements specified in USP 797, and what time frames for compliance are reasonable,” according to the clarification. “The Joint Commission will not survey for compliance with the details of USP 797.”

How ‘exacting’ the organization complies with the USP 797 guidelines and the suggested time frames for compliance are based on organizational decisions.”

The article conceded that USP 797 is a valuable set of guidelines that describe a best practice for establishing safe processes in compounding sterile medications, which will help hospitals comply with JCAHO standard MM.8.10. The standard requires organizations to evaluate literature for new technologies and successful practices relevant to improving their medication management systems.

“Although organizations will not be surveyed against the details of USP 797 guidelines, organizations that do not, at a minimum, review their processes for preparing sterile medications in light of USP 797, will be found noncompliant with standard MM.8.10,” according to the Perspectives clarification.

Few regulatory groups enforce USP 797, and the JCAHO’s decision to back off on enforcement meant that no accreditors claim to do so, according to an article in the June 1 American Journal of Health-System Pharmacy.

Nine states in March 2005 told the National Association of Boards of Pharmacy that they require pharmacies to comply with USP 797, and six other state boards of pharmacy taking part in the survey said they were considering enforcing the standards.

Early reaction is mixed
One organization that had raised concerns about the JCAHO’s initial position on USP 797 is the American Society of Healthcare Engineers (ASHE), which called last year for the JCAHO to reconsider. The accreditor’s latest statement on the subject was more to ASHE’s liking, says Dale Woodin, ASHE’s deputy director of advocacy. “The clarification that came out in Perspectives [in April] was encouraging,” he notes. “A lot of this was confusion. We want to see what happens.”

ASHE felt that the JCAHO had “amplified” its standards to include another standard, Woodin says.

“It came off as very heavy-handed before,” he adds. “It was both prescriptive and not clear.”

As for the USP’s proposed revisions to Chapter 797, Woodin says ASHE is still reviewing them but has initial problems with some of the changes. “The quality requirements they’re calling for are substantial and concerning. Changes are good, but you have to have a reason for [them].”

ASHE has asked the USP to provide evidence backing up its proposed changes. “At first blush, it seems onerous,” Woodin says. “We need to see evidence that going to a higher level of air quality is necessary.”

Such changes would prove expensive, and in some cases, be especially difficult for hospitals that installed new cleanrooms after the first version of USP 797 came out in 2004, adds Woodin. “We’re working within our membership to determine what it would take to accomplish these things,” he says. “How much would it cost?”

Revisions make standards more clear
The proposed revisions clean up much of the language in USP 797, says Steven MacArthur, consultant with The Greeley Company in Marblehead, MA, which is owned by HCPro, Inc., the publisher of this newsletter.

“In looking at the proposed changes, my sense is that a lot of the language is what I would term clarification and, unlike the Joint Commission’s usual at-
Crosswalking USP 797 with JCAHO med standards

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Source: Adapted from the April 2004 Joint Commission Perspectives.
MM standards

National Patient Safety Goals
The percentages below relate to the number of hospitals not in compliance with the goals (identified by their numbers in 2005). Comparison data for 2004 and 2003 are noted, where applicable:

- **#1a** (two identifiers—scored at PC.5.10 EP4), 3.9% (compared to 4.1% in 2004 and 3.8% in 2003).
- **#1b** (time-out), 17.1% (8% in 2004, 8.9% in 2003). The large percentage increase can be attributed to this goal expanding beyond operating rooms.
- **#2a** (verbal orders—scored at IM.6.50 EP4), 11.6% (8.2% in 2004, 7.4% in 2003). JCAHO surveyors are finding that policies don’t always match practice. For example, some facilities require documentation of a read-back (although it’s not required by the JCAHO). If your policy requires you to document read-backs, and surveyors observe them not being documented, you can earn a requirement for improvement (RFI) for not following your own policy for documentation. However, to comply with this goal, the JCAHO says it’s enough to observe the behavior.
- **#2b** (abbreviations—scored at IM.3.10 EP2), 39.5% (24.8% in 2004, 23.5% in 2003). Using prohibited abbreviations is the biggest barrier to compliance, according to the JCAHO (see goal #2a at left).
- **#2c** (timeliness of reporting critical test results), 7.6%.
- **#3a** (concentrated electrolytes—scored at MM.2.20 EP9), 1.3% (1.9% in 2004, 3% in 2003).
- **#3b** (limit concentrations—scored at MM.2.20 EP8), 1.5% (0.9% in 2004 and 0.6% in 2003).
- **#3c** (look-alike/sound-alike drugs), 1.9%.
- **#4a** (preoperative verification), 5.5% (5.4% in 2004 and 1.5% in 2003).
- **#4b** (surgical site marking), 3.8% (4.6% in 2004 and 6.2% in 2003).
- **#5a** (free-flow protection), 0.1% (0.1% in 2004 and 1.4% in 2003).
- **#7a** (hand-hygiene—scored at IC.4.10 EP2), 3.6% (1.2% in 2004). Risks associated with animals brought into facilities tripped up some organizations here. The JCAHO recommends looking to home care organizations as a good source of information about how to meet this goal because this is a common issue for those facilities.
- **#7b** (healthcare associated infections and root-cause analysis), 0% (0.1% in 2004).
- **#8a** (medication reconciliation list), 0%.
- **#8b** (medication reconciliation), 0.3%.
- **#9a** (patient falls), 3%.

No noncompliance data are yet available for the 2006 goals, although the JCAHO has extensively updated its frequently asked questions (FAQ) for them, available at [http://hcpro.com/url/1149](http://hcpro.com/url/1149).

FAQs are the official documents of JCAHO goals interpretation and are used by surveyors.

They represent common questions that the field sends to the JCAHO’s standards interpretation group (see “JCAHO releases National Patient Safety Goals FAQs” on p. 8 for more information).

If a goal and a standard have the same requirements, and you are found out of compliance, you can only be scored in one place—so you are safe from “double jeopardy” scoring, as the JCAHO refers to it.

Standards
The percentages below relate to the number of hospitals not in compliance with the following standards in the *Comprehensive Accreditation Manual for Hospitals* (*CAMH*). Comparison data for 2004 follow, if applicable. Consult the *CAMH* for the exact wording of each standard and all of its requirements:

- **IM.3.10** (information management processes), 41% (compared to 27% in 2004). Using prohibited abbreviations is the biggest barrier to compliance, according to the JCAHO (see goal #2a at left).
- **MM.2.20** (medication storage), 37% (20% in 2004). Surveyors often find open, unattended anesthesia carts. Also, the JCAHO recommends that your facility have a strict policy for denying access to...
medication dispensing machines (i.e., Pyxis) immediately after employees are terminated.

- **PC.13.20** (sedation/anesthesia), 30% (18% in 2004, 9.1% in 2003). Surveyors expect informed consent for procedures and a preanesthesia assessment. Although the JCAHO doesn’t tell organizations how to document this, surveyors do look at records. And although this isn’t as tough an issue in units such as the operating room, it is in units such as radiology. The JCAHO says the forms used in each unit don’t necessarily have to be uniform, but they should be “equal or comparable” and the anesthesia department should be involved in their development.

- **EC.5.20** (*Life Safety Code®* [LSC]), 21%. The addition of an LSC surveyor on survey teams for hospitals greater than 200 beds lead to an increased number of findings under this standard.

- **MM.3.20** (written orders), 20% (17% in 2004). One way to help meet this standard is to eliminate range orders. If you use them, the JCAHO recommends attaching definitions or pain scales to eliminate the need for a nurse to employ judgment.

- **IM.6.50** (verbal order transcription), 15% (10% in 2004). To help meet this standard, the JCAHO recommends having a policy that doesn’t allow verbal orders except in emergency situations (see goal #2a on p. 5).

- **PC.2.120** (initial assessment time frames), 13%. Surveyors often discover missing nutritional screenings.

- **LD.3.90** (leaders develop/implement policies), 13%. Surveyors find that leaders fail to hold people accountable.

- **EC.1.10** (safety risk management), 11%. Meeting this standard requires the organization to have completed a comprehensive, proactive risk assessment, and surveyors will ask questions about it. Leaders should also be able to speak to how the organization responds to the JCAHO’s *Sentinel Event Alerts*.

- **MM.4.10** (medication order review), 11% (13% in 2004). If a pharmacy is located in the hospital, all medications must be reviewed by the pharmacy, except in emergency situations or in the event that a licensed independent practitioner can review them. Also troublesome for some organizations are the rules for oral contrast media, which the JCAHO considers a drug and must be reviewed by a pharmacist.

- **MS.4.20** (clinical privileges), 10% (9% in 2004, 6% in 2003). Surveyors are finding caregivers providing care outside of the settings in which they have privileges. Also, surveyors are finding expired privileges (those extended beyond two years).

- **IC.4.10** (goal achievement), 10% (12% in 2004). Surveyors are finding that organizations are having problems meeting the requirements for reducing risk associated with equipment and procedures, (e.g., storage, cleaning, sterilization, and disposal), appropriate reuse, and protective equipment use (see goal #7a on p. 5).
Decision rules play key role in JCAHO surveys

**Expert: Make sure that staff are well-versed in these rules**

An underpublicized set of rules can have a major effect on JCAHO accreditation decisions if hospital staff are unaware of them.

Called “decision rules,” these guidelines are printed in plain sight in the Comprehensive Accreditation Manual for Hospitals (CAMH), but they are often overlooked because of the emphasis on standards and National Patient Safety Goals, says Kurt Patton, MS, RPh, former executive director of accreditation for the JCAHO and current principal of Patton Healthcare Consulting of Glendale, AZ. “I’ve been advising people to understand the decision rules because of the impact they can have on overall decisions,” he adds.

“A lot of people rely upon the JCAHO’s small, hard-bound manual, but that doesn’t have the section on decision rules,” says Patton, a former hospital pharmacist. The rules are included in the CAMH, but “people never bother to read them,” he says.

JCAHO surveyors make accreditation decisions by applying decision rules to the scored standards. Decision rules determine an accreditation finding that appropriately represents a hospital’s overall performance as measured by evidence of compliance with the applicable standards, according to the CAMH.

In addition, since 2001, the JCAHO has put in place weighted decision rules to limit the effect that small or secondary components of a complex organization may have on the overall accreditation decision. However, the JCAHO recently revised the rules to apply equally throughout an organization if a component’s decision involved threats to patient safety, instances in which inaccurate information was provided to the JCAHO, or a violation of other accreditation participation requirements.

In these instances, when a secondary component receives a finding of conditional accreditation or preliminary denial of accreditation, that accreditation decision would apply equally to the component and the overall organization. The JCAHO also made a similar revision so that the effect of an in-house pharmacy’s performance would apply equally to a hospital’s accreditation.

**Educate staff about key rules**

Department managers such as pharmacy directors should point their staff to the CAMH and make sure that they read and understand the major decision rules, Patton recommends. “Identify the half-dozen heavy hitters and train staff on those,” he says.

The rules are featured on pp. 17–24 of the “Accreditation Policies and Procedures” section of the manual. “[The JCAHO] identifies a handful of standards that people need to really know are locked down tight,” Patton says.

The increased emphasis on decision rules can be attributed to enhanced surveyor training—focusing in part on falsification—and improved laptop technology that alerts surveyors when the decision rules are triggered, says Patton.

The decision rules for preliminary denial of accreditation include the following:

- An immediate patient safety or health threat exists within the organization.
- A practitioner who does not possess a license, registration, or certification has been providing health-care services that would require such licensure, placing the organization’s patients at risk.
- The JCAHO believes that the organization submitted falsified documents or misrepresented information to achieve or retain its accreditation. This could include discovering after surveyors arrive that certain paperwork wasn’t done, then completing it to make it appear as though the paperwork had been done before the survey began, Patton says. A better idea is to sequester that paperwork to prevent any appearance of falsification.
- The organization doesn’t possess a license, certificate, or permit required to provide the services for which it seeks accreditation.
JCAHO releases National Patient Safety Goals FAQs

The JCAHO in February published 29 new frequently asked questions (FAQ) about the medication-related 2006 National Patient Safety Goals (NPSG), with many of the clarifications being about the troublesome medication reconciliation goal.

The commission develops FAQs in response to multiple requests for clarifications of standards, elements of performance, or NPSGs and requirements. In addition to the new FAQs, the JCAHO revised and reviewed many others already posted online.

Medication safety
The JCAHO responded to questions about NPSG #3 on medication safety, specifically requirements #3b (requiring hospitals to standardize and limit drug concentrations), #3c (look-alike/sound-alike drugs), and #3d (medication labeling).

The commission elaborated on its position on the Broselow Tape, a tool used in pediatric emergencies to determine weight-based drug doses. The FAQ notes that some surveyors have mistakenly told hospitals that they were not in compliance with requirement #3b if they continued to keep Broselow Tapes in their crash carts, but this is not accurate.

The JCAHO takes issue with the Broselow Tape because it allows users to mix customized concentrations instead of standardized concentrations, which goes against the goal that all hospitals move to standardized drug concentrations by 2008. The accreditor acknowledges the utility of the Broselow Tape in the emergency care of children; it’s also used to estimate a child’s weight and select the correct size of emergency or resuscitation equipment. As a result, hospitals may continue to use the tool for functions other than drug concentrations.

With look-alike/sound-alike medications, the JCAHO provides lists of such meds for hospitals to identify 10 pairs that they use. If a hospital cannot find 10 pairs from the JCAHO’s lists, it should consult other lists of look-alike/sound-alike drugs on the Web sites of the Institute for Safe Medication Practices (www.ismp.org) and the U.S. Pharmacopeia (www.usp.org).

Another question asks whether different doses of the same medication should be treated as look-alike/sound-alike drugs. This is not covered under requirement #3c, which aims to eliminate confusion between different drugs, not different concentrations.

Labeling
Asked if requirement #3d applies only in the operating room, the JCAHO noted that it also applies to preparation areas, preop holding, and postanesthesia care units. In addition, the requirement applies to medications used by anesthesia providers, and all procedural areas that use medications or solutions including radiology and other imaging services, endoscopy units, dental services, and patient care units in which staff perform bedside procedures.

Another new FAQ details the information that must be included on the labels of medications and solutions in context of requirement #3d. Consistent with standard MM.4.30, Elements of Performance 3 and 4, labels must include the following:

- Drug name, strength, and amount (if not obvious from the container).
- Expiration date when not used within 24 hours.
- Expiration time if less than 24 hours. This applies to a select few drugs.
- Date prepared and the diluent for all compounded intravenous admixtures.

In most cases of meds and solutions in the procedural setting, only the drug name and concentration will be needed on the label.

Medication reconciliation
NPSG #8 (accurately and completely reconcile medications across the continuum of care) has continued to confound hospitals. Requirement #8a calls on hospitals to implement a process for obtaining and documenting a complete list of a patient’s current meds upon admission to the facility. The patient should be involved in the process, which should include a com-
The following is a sampling of the new JCAHO frequently asked questions regarding medication-related National Patient Safety Goals (NPSG) posted on the accreditor’s Web site:

- What is the JCAHO’s position with respect to the Broselow Tape, the Rule of Six, and the requirement under NPSG #3 for limiting and standardizing drug concentrations in healthcare organizations?
- Does NPSG #3b require that total parenteral nutrition solutions be standardized in their component concentrations, including electrolytes?
- Do we need to treat different dosages of the same medication as look-alike/sound-alike drugs?
- Does NPSG #3d apply only in the operating room?
- Are there any exceptions to the labeling requirement?
- When labeling medications and solutions in the context of NPSG #3d, what information must be on the label?
- We have discovered that presterilized, prelabeled syringes are now commercially available. Is this acceptable?
- When requirement #3d was first announced, the implementation expectations said the initials of the person preparing the medication or solution and the date of preparation needed to be on the label. Are those items still required?
- Is two-person verification of the label still required?
- Is it acceptable to label a syringe by taping the medication vial to the syringe?
- What solutions are best for labeling medication cups and basins on the sterile field?
- What does the JCAHO expect for labeling contrast media that are loaded into power injectors?
Panel releases recommendations for safe insulin use

A report released in early 2006 by the American Society of Health-System Pharmacists (ASHP) offers a series of recommendations designed to improve the safety and efficacy of hospital insulin use.

Preventable patient injuries associated with errors involving insulin use continue to be a problem in many hospitals, the report notes. The guidelines in the report are intended to meet and exceed current JCAHO standards and clinical recommendations from ASHP, the American Diabetes Association, and other professional groups.

Twelve percent of patients discharged from hospitals have been diagnosed with diabetes, and up to 25% of all hospitalized patients meet the criteria for a diabetes diagnosis, according to the report. Medications and stress can cause many nondiabetic patients to develop hyperglycemia while hospitalized. Insulin is used to treat both of these groups of patients to manage hyperglycemia.

According to the report, types of insulin-use errors include the following:

- Administration of a wrong dose
- Administration to the wrong patient
- Use of the wrong insulin type
- Administration via the wrong route
- Wrong timing of doses
- Omission of doses
- Failure to properly adjust insulin therapy
- Improper monitoring, timing, and assessment of blood glucose results

Factors that contribute to insulin-use errors include

- the use of abbreviations
- legibility problems
- calculation errors
- measurement errors
- poor timing of doses
- look-alike/sound-alike errors
- decimal point errors
- pump-setting errors
- lack of drug therapy knowledge
- inadequate access to and interpretation of patient information
- miscommunication

Recommendations

The report offers the following high-level recommendations necessary for organizations to make significant changes in the safety and efficacy of insulin therapy:

- The organization should designate a high-level project leader/sponsor with overall responsibility for program success.
- The insulin therapy multidisciplinary group should coordinate and lead development of institutional policies and procedures for insulin practices.
- Institutional policies should incorporate safe medication practices in general, as well as insulin-specific practices.
- Policies should establish evidence-based target standards for glycemic control for patients in the hospital.
- Policies should require the ordering of all components of insulin therapy in a defined format, preferably using mandatory, preprinted, guideline-based order sets for most patients who are prescribed insulin. Order-process design should incorporate medication-safety principles and evidence-based blood glucose control standards.
- Insulin orders should prompt and facilitate order transcription, pharmacist and nurse order review, pharmacy computer order entry, and nursing workflow.
- Insulin orders should include or refer to defined standards for laboratory and clinical insulin therapy monitoring practices.
- Insulin administration records, glucose monitoring results, and carbohydrate intake should be effectively displayed to allow caregivers to accurately and efficiently assess data.
- Institutional policies should promote and provide for the ongoing involvement of patients and families in care processes.

To read the report, visit www.ashp.org/emplibrary/Safe_Use_of_Insulin.pdf.
CMS initiative focuses on improved pharmacy quality

A new Centers for Medicare & Medicaid Services (CMS) effort to measure and compare the quality of pharmacy services hopes to eventually provide incentives for improved patient care.

The Pharmacy Quality Alliance (PQA) launched in April as a joint project of CMS and other key group such as America’s Health Insurance Plans, the National Community Pharmacists Association, and the National Association of Chain Drug Stores. The PQA follows similar CMS initiatives such as the Hospital Quality Initiative and the Ambulatory Care Quality Alliance.

CMS Administrator Mark McClellan said during an April 24 conference call that the PQA could lead to increased payments to pharmacies, according to the American Journal of Health-System Pharmacy.

The alliance will focus on developing strategies for defining and measuring pharmacy performance, as well as testing new pharmacy payment models, he said.

The PQA in early May announced the formation of a steering committee representing various stakeholders, including McClellan; Carolyn Glancy, MD, director of the Agency for Healthcare Research and Quality; Judith Cahill, executive director of the Academy of Managed Care Pharmacy; and other representatives from pharmacy and consumer groups.

The mission of the PQA is to “improve healthcare quality and patient safety through a collaborative process in which the key stakeholders agree on a strategy for measuring performance at the pharmacy and pharmacist levels; collecting data in the least burdensome way; and reporting meaningful information to consumers, pharmacists, employers, payers, and other healthcare decision-makers to help make informed choices, improve outcomes, and stimulate the development of new payment models,” according to a PQA release.

The PQA has established two work groups, one focused on measurement and the other on reporting. Membership in the PQA and participation in its work groups is open to all interested stakeholders.

The entire membership of the PQA will meet twice per year to discuss and reach consensus on the work groups’ activities and recommendations.

The PQA named Laura Cranston as its executive director. Cranston is president of Cranston & Associates, a Virginia-based consulting firm. Previously, she served as the executive director for the Institute for the Advancement of Community Pharmacy.

For more information about the PQA, visit www.PQAalliance.org.
Study: Pharmacists, docs struggle to ID unpackaged meds

Pharmacists and physicians were unable to identify three common medications removed from their original containers more than one-third of the time, according to a new study.

Current FDA regulations allow drug companies to develop and assign identification (ID) codes to their medications, meaning that there is no standard ID system for meds. As a result, if 10 companies made 10 acetaminophen products, each could have a different code. Removing them from their original packaging could create a safety problem, according to a release from the American Society of Health-System Pharmacists (ASHP) Foundation, which cofunded the study with the U.S. Pharmacopeia.

Healthcare professionals often must identify an unpackaged medication. For example, an elderly patient may arrive in the emergency department with meds kept in a pill organizer, but may not be able to remember the names of all of the medications that he or she takes. The pharmacist or physician must consult a clinical database containing imprint identification information to identify each pill. This could delay treatment and yield incomplete information because no imprint ID database contains every code used, according to the ASHP Foundation release.

This can also be a problem with patients who have overdosed or who refill a prescription at a community pharmacy and want to know why the new pills look different from the old ones, the foundation wrote.

Researchers randomly chose 50 pharmacists and 50 physicians from two urban teaching hospitals to test their ability to identify three medications: a brand-name tablet, generic tablet, and nonprescription generic tablet. Only 24 pharmacists (36%) and 18 physicians (48%) were able to identify all three medications. Ten physicians (20%) and five pharmacists (10%) could not correctly identify any of the tablets.

The study was published in the May 1 American Journal of Health-System Pharmacy. Visit www.ajhp.org/cgi/content/abstract/63/9/838 to read an abstract of the study.