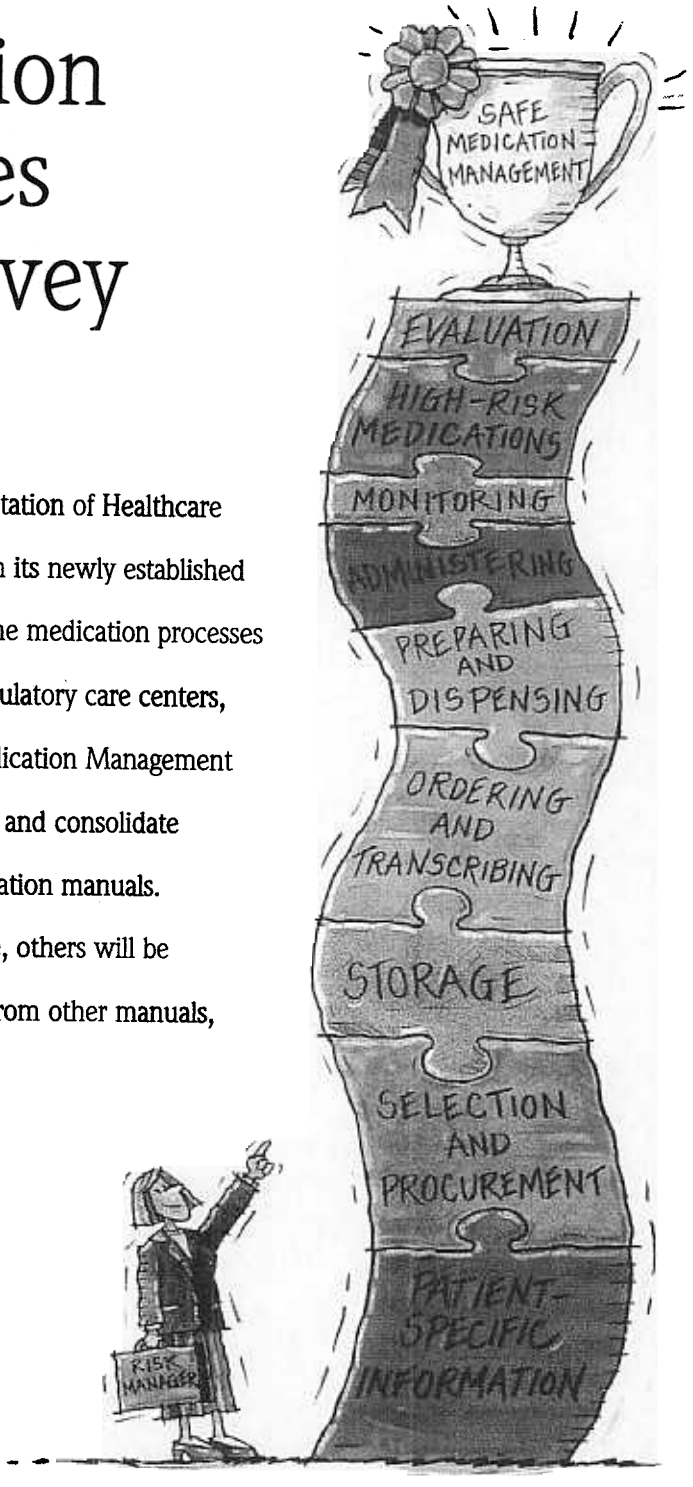
STAT
Risk Management Program℠
Chubb Health Care Newsletter
Edition 3, 2003

# Focus on Medication Safety and Changes to the JCAHO Survey Process




Beginning in January 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will assess a facility's compliance with its newly established Medication Management Standards. These standards target the medication processes that pose threats to patient safety, and apply to hospitals, ambulatory care centers, behavioral care centers, and home health agencies.[1] The Medication Management Standards are the result of JCAHO's ongoing efforts to update and consolidate standards, as well as omit redundant standards, in its accreditation manuals. Although some of the existing standards will remain the same, others will be new to some facilities, due to the incorporation of standards from other manuals, often with added detail.

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While this article reviews the JCAHO Medication Management Standards, its primary purpose is to highlight changes in the survey process and to provide practical risk management strategies to help organizations implement new, or revise their existing, medication processes to promote patient safety. As always, organizations must consult the JCAHO accreditation manual and Web site in order to comply with the JCAHO process and standards.

## JCAHO Survey Changes

Significant changes are being incorporated through JCAHO's Shared Visions-New Pathways program. The initial changes are already underway in the form of streamlining and revising standards. The program is reforming the accreditation process to respond to the public's demands to improve patient safety.[2] In 2004, organizations should expect:

Changes in the survey process.

Changes in the scoring of individual standards.

A required 18-month periodic performance review.

The elimination of overall grid scores in facility reports.

### *Format & Scoring of Standards*

JCAHO has changed both the format and scoring of its standards. A revised standards-numbering system will allow for more flexibility in adding new standards without having to renumber them. Beginning in 2004, surveyors will no longer score the rationale statements for each standard. Rather, compliance with each standard will be measured according to a list of specific criteria, called Elements of Performance. Surveyors will use a scoring system that allows for partial or qualified compliance with each of the elements. Thus, if a facility is in compliance with at least 65% of the Elements of Performance, it will be scored as compliant with that particular standard. Grid scores and performance reports will be replaced with a new quality report that provides information on a facility's efforts relative to patient safety and quality.[3]

### *Periodic Performance Review (Self-Assessment)*

Accredited organizations will be required to complete a Periodic Performance Review (PPR). At the midpoint (approximately 18 months) in the three-year accreditation cycle, organizations will be required to complete an Internet-based self-assessment tool.[4] Organizations will self-evaluate and score their own compliance with JCAHO standards. Following review of this self-evolution by JCAHO, a representative will contact the facility to assist with corrective actions. As long as the facility submits a corrective action plan, the self-assessment review will not affect its accreditation status. However, failure to correct any known deficiencies by the time of the triennial survey may result in JCAHO placing the organization on provisional status.[5]

### *Priority Focus Review*

JCAHO surveyors will perform an internal Priority Focus Review (PFR) prior to a three-year accreditation survey. This automated tool will collect and analyze information about the organization using data gathered from the ORYX initiative, the PPR, past accreditation surveys, organizational and statistical information, and Medpar/CMS.[6] The intent is to prepare and focus surveyors on validating corrective action plans from the PPR and organization-specific issues involving patient safety and quality of care identified in the PFR. Thus, the focus of the triennial survey will vary for each facility depending on the areas identified as needing review.[7]

### *Tracer Methodology*

Rather than review a massive number of records to assess compliance with organizational procedures and polices, surveyors will review the records of specific active patients and "follow" their progress through the health care continuum. Surveyors will place special emphasis on the care of patients affected by the critical focus areas identified in the PFR. For example, patients and staff may be interviewed about the medication administration process and surveyors may observe to verify that procedures are, in fact, followed. If problem areas are uncovered, a more in-depth analysis will be conducted on other similar patients to assess whether the problem is an isolated incident or a wider deficiency. JCAHO expects this approach to provide a better evaluation of how systems and processes interface across the system.

### *Surveyor Education*

In January 2002, all JCAHO surveyors were required to pass a general certification examination to ensure competency and consistency in interpreting the standards. Further training and program-specific certification will be required in the future. In addition, don't be surprised to see a JCAHO supervisor show up unannounced to observe a surveyor's skills and interaction during a survey. Also, a new JCAHO policy prohibits employed JCAHO surveyors from providing consulting services to accredited facilities.

## National Patient Safety Goals

Although not standards as such, beginning in January 2003 compliance with the JCAHO's six 2003 National Patient Safety Goals and their recommendations became mandatory for all accredited hospitals. A seventh goal has been added for 2004 (see accompanying "2004 National Patient Safety Goals and Recommendations.") Plans are in place to apply them to other accredited health care facilities. The National Patient Safety Goals were developed by the Sentinel Event Alert Advisory Group and are based on the review of more than 2,000 reported sentinel events. The recommendations are evidence-based and were developed with assistance from leading safety experts. In 2002, medication errors comprised almost 12% of sentinel events reported to the JCAHO. Consequently, five of the seven National Patient Safety Goals and their recommendations pertain to medication safety.[8] JCAHO intends to annually review the goals and change them if warranted.

Organizations may be able to achieve compliance with alternative approaches to the implementation of a specific recommendation as long as the approach has been submitted and approved by JCAHO before their next survey. Risk managers are well advised to contact JCAHO well ahead of their next survey for any guidance.

*2004 National Patient Safety Goals and Recommendations*

**Improve the accuracy of patient identification.**

a. Use at least two patient identifiers (neither to be the patient's room number) whenever taking blood samples or administering medications or blood products.

b. Prior to the start of any surgical or invasive procedure, conduct a final verification process, such as a "time out," to confirm the correct patient, procedure, and site, using active - not passive - communication techniques.

2. **Improve the effectiveness of communication among caregivers.**

   a. Implement a process for taking verbal or telephone orders that requires a "readback" of the complete order by the person receiving the order.

   b. Standardize the abbreviations, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols not to use.

3. **Improve the safety of high-alert medications.**

   a. Remove concentrated electrolytes (including but not limited to potassium chloride, potassium phosphate, and sodium chloride > 0.9%) from patient care units.

   b. Standardize and limit the number of drug concentrations available in the organization.

4. **Eliminate wrong-site, wrong-patient, and wrong-procedure surgery.**

   a. Create and use a preoperative verification process, such as a checklist, to confirm that appropriate documents (e.g., medical records, imaging studies) are available.

   b. Implement a process to mark the surgical site and involve the patient in the marking process.

5. **Improve the safety of using infusion pumps.**

   a. Ensure free-flow protection on all general use and patient-controlled analgesia (PCA) intravenous infusion pumps used in the organization.

6. **Improve the effectiveness of clinical alarm systems.**

   a. Implement regular preventive maintenance and testing of alarm systems.

   b. Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit.

7. **Reduce the risk of health care-acquired infections.**

   a. Comply with current CDC hand-hygiene guidelines.

   b. Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-acquired infection.

## JCAHO Medication Management Standards[9]

The proposed medication management standards and accompanying elements of performance illustrate JCAHO's focus on organizational processes rather than individual behavior.[10] The first step in a successfully implemented "recovery" program is to admit that there are any problems. Equally important is to abandon defensive attitudes, avoid placing blame on individuals, and move toward evaluating the operational processes that contribute to or increase the possibility of errors. JCAHO medication management standards incorporate six generally accepted critical processes in a medication management system: Selection and Procurement; Storage; Ordering and Transcribing; Preparing and Dispensing; Administration; and Monitoring. The remaining standards relate to accessing patient-specific information, high-risk medications, and evaluating the medication management system on an ongoing basis.

What follows is an outline of the proposed JCAHO Medication Management Standards and risk management strategies related to each These are sound strategies that an organization may consider in the interest of patient safety, whether or not it is seeking JCAHO accreditation. Health care organizations seeking accreditation must consult JCAHO resources directly to ascertain the specific Elements of Performance.

The JCAHO revised definition for medication as used in the standards includes prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals (food product used for therapeutic purpose, other than nutrition), over-the-counter drugs, vaccines, diagnostic and contrast agents, radioactive medications, respiratory therapy treatments, parental nutrition, blood derivatives, intravenous solutions (plain, with electrolytes and/or drugs), and any product designated by the Food and Drug Administration (FDA) as a drug. It does NOT include enteral nutrition solutions (which are considered food products and are surveyed under nutrition standards), or oxygen, and other medical gases.[11]

### *Patient-Specific Information*

*Standard MM.1.10 - Patient-specific information is readily accessible to those involved in the medication management system.*

Risk Management Strategies:

Ensure that access to all pertinent patient information is available to all professionals involved in the medication management process.[12] Licensed independent practitioners, pharmacists, nurses, respiratory therapists, etc., involved in the patient's care should be able to access information such as indications and contraindications to the patient's drug therapy.

Computerization of the medical record offers immediate access to those prescribing, dispensing, and administering medications. However, many organizations do not currently have such systems in place and may not have the means to do so. These organizations

will need to develop alternative methods for sharing patient information. For example, developing a separate form that itemizes the required patient information to be completed and faxed to the pharmacy along with medication orders.

### *Selection & Procurement*

*Standard MM.2.10 - Medications available for dispensing or administration are selected, listed, and procured based on criteria.*

Risk Management Strategies:

Form a multidisciplinary committee to develop and maintain a list of formulary and non-formulary items using clinical criterion (not just cost). The list should be readily available to all those involved in the medication management process. Develop a system for standardizing the concentration of medications and dispensing drugs in their most ready-to-use form (i.e., unit dose system).

Develop a seamless system to obtain non-formulary medications when necessary.

Ensure a system is in place to obtain emergency medications in the event of a disaster or bioterrorism.

### *Storage*

*Standard MM.2.20 - Medications are properly and safely stored throughout the organization.*

Risk Management Strategies:

Designate a pharmacy professional responsible for developing polices and procedures for standardizing storage and security of medications on patient care units.

Conduct pharmacy rounds in all clinical areas to ensure that solutions, drugs, and supplies are stored in accordance with the manufacturer's guidelines including, but not limited to expiration dates and proper temperatures.

Incorporate medication safety and storage concerns into random environment-of-care surveillance rounds. Separate look-alike/sound alike drugs, chemical reagents, and concentrated electrolytes. Accurately label diluents with contents and expiration date.

Provide clinical staff with ongoing education about the risks associated with leaving controlled substances unattended and preparing intravenous medications and admixtures on patient care units.

Include hospital-owned or -operated physician offices and clinics in the hospital's regular pharmacy rounds. Include sample medications in the medication management system.

*Standard MM.2.30 - Emergency medications and/or supplies (if any) are consistently available, controlled, and secure in the organizations patient care areas.*

Risk Management Strategies:

Create a committee, comprised of administrators as well as clinicians (physicians, nurses, pharmacists, anesthesiologists, and respiratory therapists) to standardize emergency medications and supplies that will be readily available in patient care areas.

Develop a process for securing emergency medications in a locked container or secured area, when not under the constant surveillance of staff. Include protocols for replacing emergency medication stocks and supplies as soon as possible after use.

*Standard MM.2.40 - A process is established to safely manage medications brought in the organization by patients or their families.*

Risk Management Strategies:

Develop a written policy to manage situations when patients are permitted to bring their own medications into the facility.

Ensure that there is a valid physician's order for all self-administered medications and that a pharmacist conducts an evaluation of the patient's understanding and competency to self-administer, as well as an evaluation of the integrity of the drug prior to administration in the hospital. A pharmacist should document his or her inspection in the patient's medical record.

Educate the nursing staff regarding their roles and responsibilities for educating patients about self-administered medications. Documentation of patient understanding and competence is essential.



### *Ordering & Transcribing*

*Standard MM.3.10 - Only medications needed to treat the patient's condition are ordered.*

Risk Management Strategies:

Implement a medical record review process for ensuring that all medications ordered and administered to the patient correspond to a documented diagnosis or condition.

Redesign, if necessary, pharmacy drug profiles and medication administration records to provide a listing of the medical conditions and indications for each drug.

*Standard MM.3.20 - Medication orders are written clearly and transcribed accurately.*

Risk Management Strategies:

Ensure that the Medical Executive Committee articulates the medical staff's responsibilities for writing legible and accurate medication orders. Physicians should have immediate access to the organization's formulary and nonformulary drugs.

Educate physicians and staff about avoiding the use of unapproved abbreviations and monitor compliance through the quality improvement process and chart review.[13] The Pharmacy and Therapeutics Committee should publish a list of unacceptable abbreviations, symbols, and acronyms.

Review all preprinted (standing) order sheets and eliminate the use of abbreviations.

Make it a practice to verify any incomplete or illegible order with the prescriber prior to dispensing the medication.

Evaluate and monitor clinical practices related to limiting the use of verbal orders, especially in critical areas such as the ED, OR, and ICU. The high volume of verbal orders in these areas greatly contributes to the occurrence of medication errors.

Monitor the required "readback" of all verbal or telephone orders.

### *Preparing & Dispensing*

*Standard MM.4.10 - All prescriptions or medication orders are reviewed for appropriateness.*

Risk Management Strategies:

Implement a process for a pharmacist's review of all medication orders for appropriateness and potential interactions (exception for emergency situations). Remember to include respiratory therapy medications and medication orders for patients awaiting admission in the ED "holding area." Develop a process for documenting this review in the medical record.

Educate nursing supervisors regarding their obligations to complete medication order reviews after the pharmacy is closed. The nursing supervisor should verify the correct order, route, dose, and time against the original physician's order. Provide a process for documenting this review in the medical record.

Develop a process for the pharmacist to review the safety of all "night shift" orders as soon as the pharmacy re-opens the next day.

Evaluate the pharmacist's ability to participate in drug therapy decisions by accessing critical laboratory results.

*Standard MM.4.20 - Medications are prepared safely.*

Risk Management Strategies:

Ensure that all drug compounds or intravenous admixtures are prepared in the pharmacy in accordance with the industry's professional standards. On-call pharmacists should be summoned for after-hours preparation of high-alert medications, unless an emergency exists and a licensed independent practitioner is present to review and oversee the preparation process.

Prohibit the mixing of chemotherapy agents outside of the pharmacy. Remember to be certain that outpatient areas also comply with these requirements.

*Standard MM.4.30 - Medications are appropriately labeled.*

Risk Management Strategies:

Ensure that all drug solutions are properly labeled with patient's name, strength, dose, expiration date and time, the date prepared and name of the preparing clinician, and any applicable precautionary statements.

Report any incidence of prefilled and unlabeled medication syringe as a "near miss" where the syringe is left unattended by the preparer in a clinical area.

*Standard MM.4.40 - Medications are dispensed safely.*

Risk Management Strategies:

Pharmacists should ensure that adequate quantities of medications are available to meet patients' needs yet minimize diversion.

Ensure that all medications are dispensed in the most ready-to-use forms available from the manufacturer or in unit doses.

Enforce a "back to basics" policy of reading a label three times prior to dispensing (i.e., when retrieving the drug from storage, when packaging or repackaging the drug, and when returning the drug to storage.)

Assess the layout of the pharmacy and make modifications when necessary to reduce distracting conditions, such as inadequate lighting, noise, and competing interruptions.

*Standard MM.4.50 - The organization has a system for safely providing medications to meet patient needs when the pharmacy is closed. (Applies only when an organization has an on-site pharmacy and patients present in the facility.)*

Risk Management Strategies:

Develop a process for obtaining necessary medications when the pharmacy is closed.

Limit after-hours pharmacy access to qualified and trained nursing personnel or supervisors.

Evaluate the location and content of the after-hours pharmacy to ensure that open access to it is limited to a secure area and that quality control procedures are in place to prevent medication retrieval errors.

Develop a policy for checking the medication dose and route against the original medical order.

Review the list of after-hours medications and adjust the dispensing schedule or pharmacy hours to minimize the need for nonpharmacists to enter the pharmacy after it is closed.

*Standard MM.4.60 - If the organization does not operate a pharmacy, but routinely administers medications, then the organization has a process for obtaining medications from a pharmacy. (Not applicable to hospitals because a pharmacy is an essential service.)*

Risk Management Strategies:

Review contracts with off-site pharmacies that supply the organization's medications. Mandate that the pharmacist provide appropriate pharmaceutical oversight and involvement with the medication process. This should include attending multidisciplinary meetings to develop formulary and nonformulary lists of drugs, emergency drugs, and supplies; performing regular pharmacy rounds of patient care areas to ensure that medications are stored safety and properly, and that expired and/or discontinued medications are retrieved; and participating in the data collection, investigation, and analysis of medication errors.

Establish a process for providing the pharmacist with sufficient patient health information to allow for an informed pharmacological review of all new medication orders prior to dispensing. Long-term care facilities and ambulatory care centers should develop a method for providing the pharmacist with this information. Pharmacists should develop and maintain a drug profile for each patient.

*Standard MM.4.70 - Medications dispensed by the organization are retrieved when recalled or discontinued by the manufacturer or the FDA for safety reasons.*

Risk Management Strategies:

Keep accurate logs of medication lot numbers and develop a process for retrieving medications that are recalled or discontinued by the manufacturer or FDA.

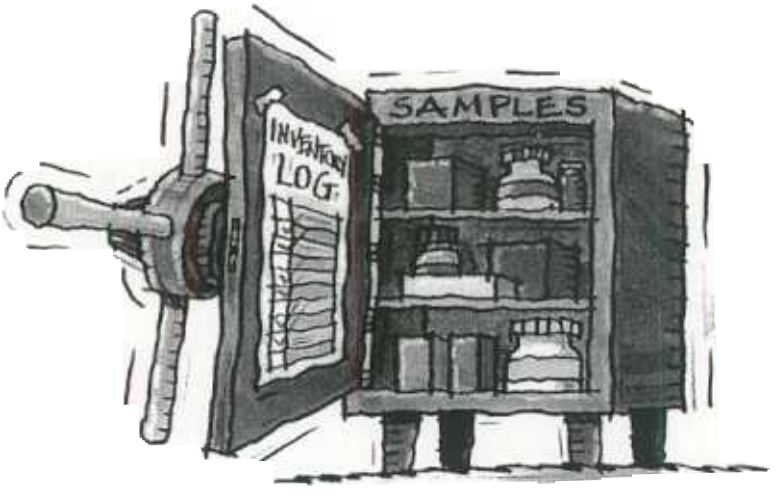
Implement a process to notify staff, physicians, and patients of any recalls, black box warnings, precautions, and adverse reactions.

*Standard MM.4.80 - Medications returned to the pharmacy are appropriately managed.*

Risk Management Strategies:

Develop an organizational policy defining how unused or expired medications will be secured prior to their return to the pharmacy. The pharmacy should have a process in place for reconciling all returned doses of medications with the medical record. Discrepancies should be routinely monitored through the medication error process.

Ensure that clinical staff understand the safety concerns associated with using the "return to pharmacy" supply of medications as replacements for other medication doses for patients in their care. Ideally, the container used to store the "return to pharmacy" medications should be equipped with a mechanism that prevents retrieval once a medication has been returned.




### *Administering*

*Standard MM.5.10 - Medications are safely and accurately administered.*

Risk Management Strategies:

Develop a written policy enumerating the mandatory qualifications and training of health care staff who are authorized to administer medication. Be sure to include the staff in radiology and respiratory therapy (refer to JCAHO's revised definition of medication).

Ensure that the policy includes the use of at least two identifiers to verify the patient's identity prior to administration.

Develop a policy for reconciling written medication orders against the medication administration record at critical points during the patient's stay, such as at admission and discharge or transfer between units or departments.

Educate staff on how to report an adverse drug reaction or medication error.

*Standard MM.5.20 - Self-administered medications are safely and accurately administered.*

Risk Management Strategies:

Develop a procedure for notifying the pharmacist when a patient is approved to self-administer medications.

Make sure medication is labeled properly, is not expired, and is the drug on the label.

Document the education and training of the patient or significant other regarding the medication's indications, side effects, frequency, and route. The individual's competency should also be documented. In addition, review written discharge instructions to ensure that there is an area to document this information.

### *Monitoring*

*Standard MM.6.10 - The effects of medication(s) on patients are monitored.*

Risk Management Strategies:

Using a multi-disciplinary team, develop and implement a list of medications requiring clinical monitoring.

Review the medication administration record to ensure that there is an area to document the appropriate vital signs and/or critical test results prior to the administration of medication, as well as actual or potential medication-related problems following administration.

Increase opportunities for direct interaction between the pharmacist and each patient to educate and discuss the various indications and side effects of medications and to clarify any misunderstandings. Document this discussion in the medical record.

Educate physicians about beginning new medications prior to discharge so that there is sufficient time to counsel the patient and monitor any response to the first dose(s) prior to discharge.

*Standard MM.6.20 - The organization responds appropriately to actual or potential adverse drug events and medication errors.*

Risk Management Strategies:

Educate staff and foster a nonpunitive environment that encourages the internal and external reporting of actual or potential medication errors or serious adverse drug events.

Collect data to monitor actual or potential medication errors, and report results and any trends to the quality improvement committee.

### *High-Risk Medications*

*Standard MM.7.10 - The organization develops processes for managing high-risk or high-alert medications.*

Risk Management Strategies:

Develop a list of high-risk or high-alert medications and standardize the process for procuring, storing, ordering, transcribing, preparing, dispensing, administering, and/or monitoring these medications.

Create preprinted forms for medications associated with a high incidence of ordering errors (e.g., insulin, heparin, chemotherapy).

Implement a two-person check (in the pharmacy) to minimize dispensing errors. Whenever possible, the second person should conduct an independent calculation of IV admixtures and rates.

Require a two-nurse verification process to check the correct name, dose, route, and strength at the time of the first dose, at the point of any transfer of patient care (shift change, unit transfer) and any time a new and continuing dose is initiated.

Ensure that the organization has replaced all infusion pumps with free-flow tubing.

*Standard MM.7.40 - Investigational medications are safely controlled and administered.*

Risk Management Strategies:

Develop a policy for the use of investigational medications that ensures staff are adequately trained in its administration and monitoring for adverse drug reactions.

Create a "flagging system" to alert pharmacists about any investigational medications. When a patient is involved in a research study outside of the hospital, the organization should review the involvement and determine if continued participation in the protocol is possible. A copy of the investigational study should be placed in the medical record.

*Standard MM.7.20 - The use of psychotropic drugs is monitored (long-term care only).*

Risk Management Strategies:

Ensure that prescribing practices are compliant with federal and state guidelines regarding the use of chemical restraints.

Perform regular reviews of resident's records to ascertain if orders for psychotropic drugs are consistent with diagnoses and plans of care.

*Standard MM.7.30 The use of psychopharmacologic drugs is monitored (long-term care and behavioral health).*

Risk Management Strategies:

Develop clinical guidelines for monitoring the effects of psychotropic drugs on patients. This may include performing routine laboratory tests to verify that a patients' drug levels are within the therapeutic range.

Perform regular record reviews for patients on psychotropic drugs to ensure that the appropriate laboratory tests are being performed and acted upon.

### *Evaluation*

*Standard MM.8.10 The organization evaluates its medication management system.*

Risk Management Strategies:

Evaluate the entire medication management system for failure modes and identify areas for improving patient safety.

Perform literature reviews to keep abreast of new technologies and successful practices that have been demonstrated to enhance safety in other organizations.

Review internally generated reports to identify adverse trends in internal systems.

## *Conclusion*

Similar to the focus of patient safety being directed to systems rather than individual error, JCAHO's focus is shifting from compliance with individual standards to evaluating whole processes and systems to better promote patient safety. Every health care organization should evaluate its medication management processes in the interest of patient safety and for compliance with the new standards. As always, risk managers should contact JCAHO directly for assistance with any questions about the interpretation of any new standards or elements of performance.

The new hospital standards for 2004 will be published in September 2003. However, the prepublication standards (absent scoring information but without substantive changes) are available at: www.jcaho.org/accredited+organizations/2004+standards.htm. The medicati standards for assisted living, health care networks, office-based surgery, and critical access hospitals are scheduled for revision in 2005.

oint Commission, *Perspectives*. Vol. 22. No. 10. October 200?

*Risk Managers React to JCAHO Accreditation* Management Reporter, E April 2003.

Accredited facilities can access the PPR at www :aho.org. (A login nd password a required.) Organizations scheduled for survey p or to July 2005 wi be required to the self-assessment tool. However, JCAHO will prior to the midcycle survey to assist organizati The PPR process presents significant legal and risk management ( tection. Risk Managers should read the Quality Advisory: Le \HO Pe Review which was developed by the AHA and Availal http://www.hospitalconnect.com/ashrm/news/ad :acy.h

Organizations surveyed between January 1, 2004, a June 30, 2005, will have 90 submit an Evidence of Standards Compliance re JCAHO recogr e opportun ormance Revie Begi rganization ip re

Orientation/training deficiencies and faulty communication were identified as root causes of errors in 60% of the events. JCAHO Sentinel Event Statistics (1995-2002). Available at www.jcaho.org.

The proposed standards are available on the JCAHO Web site. Organizations should consult i the final standards.

*JCAHO Executive Briefings on the New Medication Management Standards*, April 2003. Se also JCAHO Medication Management Prepublication Standards available on the JCAHO Web The standards and the elements of performance were approved in April 2003. The final versi the standards will be available to accredited organizations in September 2003.

*Medication Management Prepublication*, Hospital Version, JCAHO 2003.

Remember, however, that an organization's policies should also comply with the Health Insura Portability and Accountability Act (HIPAA).

The Institute for Safe Medication Practices (www.ismp.org) and The National Coordinating Council for Medication Error Reporting have published sample lists of unapproved/dangerous abbreviations. *See also* JCAHO Sentinel Event Alert 23, September 2001.


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**Managing Editor:**

Susan Chmieleski, BSN, APRN, CPHRM,
*Director of Health Care Risk Managemen*

**Contributing Writers:**
*Health Care Risk Managers*

Mary Danner, RN, MS, CPHRM
Charlene Glock, RN, BSN, MHS
Laura Martinez, BSN, MS, CPHRM
Sharon McNamara, RN, CPHRM, ( HC

*STAT* is published quarterly for Chubb agents and policyholders. Archives are available on-line at http://csi.chubb.com/publications/stat/news-stat.asp.

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