CMS 30-minute rule may result in unintended consequences

The Centers for Medicare & Medicaid Services (CMS) regulation [§482.23(c)(1)] that requires medications to be administered within 30 minutes before or after their scheduled times (herein called the 30-minute rule) may be causing unintended consequences that adversely affect medication safety. While following the 30-minute rule may be necessary for hospitals to comply with CMS requirements, many nurses find it difficult to administer medications to all their assigned patients within the 30-minute timeframe. This sometimes causes nurses to drift into the following unsafe work habits in order to meet the 30-minute rule by:

- Removing medications from an automated dispensing cabinet (ADC) for multiple patients to avoid repeated trips to the cabinet that may delay drug administration.
- Removing medications from an ADC before they are due for administration to be sure they are ready to administer at the correct time.
- Documenting medication administration at the scheduled time but before actual administration is carried out (pre-charting), particularly if using an electronic medication administration record (eMAR) with bedside bar coding that flags, records, and/or reports overdue doses that are not administered within the 30-minute rule time period.
- Asking nurses from the previous shift to prepare medications that must be administered shortly after coming on duty.

Despite the safety issues with pre-pouring or pre-charting medications, or removing medications for multiple patients at the same time, the need to comply with the 30-minute rule often takes precedence—perhaps because “timely” medication administration is much more tangible to nurses than uncertain negative consequences, such as errors that may occur with the above-cited work-arounds. These errors may include possible mix-ups between patients’ medications, dose omissions, administering a drug that has been discontinued or a dose that has been changed since removal of the medication, and administering the wrong drug or dose caused by miscommunication between the nurse who may have prepared a medication and the nurse who administered it.

ISMP believes that the at-risk behaviors nurses must often engage in to comply with the 30-minute rule place patients at greater risk than if they receive non-urgent medications outside the 30-minute window but still within a reasonable timeframe to ensure efficacy. Further, the 30-minute rule is counterproductive to safety if the above-cited work-arounds are required in order to comply.

ISMP has notified CMS staff of this issue and will report the conclusions from our discussion in a future issue of our newsletter. To continue on page 2—30-minute rule
Meanwhile, we encourage you to carefully consider the risks inherent in the workarounds that may be taken to comply with the 30-minute rule, and remember that exact timeliness with scheduled medications is oftentimes much less important from a clinical perspective than making sure the correct patient receives the correct medication. Take the time to be safe.

Old habits are hard to break

A message was sent through our consumer Web site, ConsumerMedSaf ety.org, which described a concern a woman had after observing nurses who were administering medications to a hospitalized friend:

Nurses would bring a clear plastic cup with loose tablets and capsules into the room, hand the pills to the patient, and ask the patient to swallow them. None of the pills were labeled. Is this the proper procedure, since it would be difficult to assure that these unlabeled medications were right for the patient?

Many years ago, medications were supplied in bulk doses, and nurses were taught to pour the doses from the bulk supplies into medication cups. But today, hospitals have adopted a much safer unit dose system in which most medications—even injectable drugs and oral liquids—are dispensed in a single-dose package, labeled with the name of the drug, dose, and other important information. Unit dose medications can be properly identified right up to the time they are brought to the patient. In addition, unit doses have bar codes that can be scanned prior to administration. However, old habits are hard to break and some nurses still empty the packages into cups before bringing the medication to the patient.

To be safe, nurses should always keep each medication in its labeled, unit dose package until it is brought to the patient’s bedside prior to administration. This process offers an opportunity for the nurse to conduct a final verification of the selected medications by comparing the product labels to the medication administration record. It is also important when utilizing bar-code scanning at the bedside. Keeping the medications in their packages also provides teachable moments during which patients can be educated about their medications and read the labels themselves, allowing them to become familiar with the names and doses of the medications they are receiving. Communicating this information to the patient can serve as another final check to assure the right medication and dose is being administered to the right patient.

**Special Announcements**

- CE credits. One hour of free CE credit covering the January – June 2010 NurseAdvise-ERR newsletter issues is now available at www.ismp.org/nursingce.
- ISMP July webinar. Back by popular demand, on July 22 we will present our annual The Joint Commission (TJC) Medication Management Update (2010). Our speaker, Darryl Rich, PharmD, a surveyor for TJC, will discuss new and revised medication standards for hospitals and insightful tips to help you meet the intent of the standards. For details, visit www.ismp.org/educational/webinars.asp.
- ISMP Cheers Awards! Nominations for this year’s ISMP Cheers Awards will be accepted through August 27, 2010. The prestigious Cheers Awards honor individuals, organizations, companies, and agencies that have set a superlative standard of excellence in the prevention of medication errors and other adverse drug events during the previous year. For more information visit www.ismp.org/Cheers.
- ISMP Employment. Our growing medication safety consulting operation is seeking an experienced pharmacist or nurse (preferred PharmD, MSN, MS or in progress) for a fulltime position based at our Horsham, PA (near Philadelphia) office. For more information, go to: www.ismp.org/online/jobDetails.asp?id=2784. Send your CV and statement of interest to ajdicker@ismp.org, subject header: Medication Safety Specialist.
ISMP survey on the impact of the CMS 30-minute rule

Interpretive guidelines for CMS Conditions of Participation for Hospitals, Drug Preparation and Administration §482.23(c)(1) call for surveyors to observe that medications are given within 30 minutes of their scheduled times (called the 30-minute rule). ISMP plans to communicate with CMS regarding its requirement. To prepare, we encourage frontline nurses who administer scheduled medications to patients (e.g., medical-surgical nurses) to complete this 5-minute survey. Your opinion is critically important and we are very interested in your responses.

If you have Internet access, please visit www.surveymonkey.com/s/30mrt to take the survey; if you do not have Internet access, complete the survey below and fax it to ISMP at 215-914-1492. Please submit your responses to ISMP by August 31, 2010.

1. Does your organization have a policy, procedure, and/or guideline that requires administration of scheduled medications within 30 minutes before or after their scheduled times? □ No (if no, we would still like your opinion regarding the remainder of the survey questions) □ Yes, for all scheduled medications □ Yes, for some scheduled medications □ Don’t know

2. How often do you feel you are able to comply with the CMS 30-minute rule when administering scheduled medications to your patients? □ Always □ Often □ Sometimes □ Infrequently □ Never □ Don’t know

3. How often do you take these shortcuts in order to comply with the CMS 30-minute rule (and corresponding hospital policy, procedure, and/or guideline)?

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<th>Shortcut</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Infrequently</th>
<th>Never</th>
<th>Don’t Know</th>
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4. Are you aware of situations where the CMS 30-minute rule may have contributed to a medication error (either one that you made or that someone else made)? □ No □ Yes (please describe):________________________

5. During the past 5 years, has your organization encountered state or Joint Commission surveyors who require strict compliance with the CMS 30-minute rule while on site conducting a survey? □ No □ Yes □ Don’t know

6. Do you believe the CMS 30-minute rule should be retained? □ No □ Yes (skip to question #8)

7. If you answered No to #6, which of the following best describes the change you would like to see? (select all that apply)
   □ 60 minutes before or after the scheduled time for medications administered every 4 hours or less frequently
   □ Timeframes specific to the type of drug (e.g., antibiotic, insulin, antihypertensive)
   □ No timeframe should be dictated
   □ Other (please specify):________________________________________

8. Please check the features that are employed on the unit in which you work most often. (select all that apply)
   □ ADCs for some or all scheduled medications □ Electronic medication administration records (eMARS)
   □ Bedside bar-coding system to verify medications before administration

9. Please indicate your primary area of practice.
   □ Inpatient medical or surgical unit □ OR/PACU/ED/outpatient surgical unit
   □ Inpatient critical care/telemetry unit □ Long-term care facility
   □ Inpatient specialty unit □ Other (please specify):________________________________________

Send additional comments on this topic to: ashastay@ismp.org

Thank you for participating! Please submit responses at www.surveymonkey.com/s/30mrt or fax to 215-914-1492 by August 31, 2010.