



PATTON HEALTHCARE NEWSLETTER

JANUARY 2012

Joint Commission & CMS Requirements Update

CMS Update, Revised SOM:

We hope you had a pleasant and relaxing holiday season and return to work with a renewed enthusiasm to meet the challenges ahead. It has been somewhat of a quiet month in the accreditation and regulatory world. CMS had been very busy last fall with a revised state operations manual, proposed revisions to the COPS and new tracer tools. On December 22 CMS posted another update to the SOM with new content about telemedicine, which we will describe below. This late December revision to the early December edition eliminates the red highlighting for all the changes that were seen in the early December edition. The bad news is we suggest that you download both versions and read all the changes highlighted in red in the first update, then download the second update and just read the changes they made to telemedicine and administration of drugs. The Joint Commission's January edition of *Perspectives* does have a few issues we should highlight including their

updated standard on telemedicine which is also described below.



TO DO: Update Your Code of Conduct Policy

The Joint Commission announced a slight change to LD.03.01.01, EP 4 and 5 that will require you to refine your existing Code of Conduct policy. Previously they required your policy to define acceptable, disruptive and inappropriate behaviors. As of July 1, 2012 they have changed this

definitional requirement to require a code of conduct that defines acceptable, and behavior or behaviors that undermine a culture of safety. Since this is an A element of performance, and it has a D for mandatory documentation we recommend that you begin the change process now. Don't assume that your old policy which states something similar is acceptable. We encourage our readers to do a precise word match to the Joint Commission requirement.

TJC - Change To Medication Approval Criteria

There is also a seemingly simple change to MM.02.01.01, EP 2 that we believe may be more complex than the Joint Commission anticipated. In the criteria your hospital has for approving new medications onto your formulary there are currently 8 bulleted content expectations that should be considered. The new change announces a 9th content expectation for evaluation which is "populations served (for example pediatrics, geriatrics)." For the most part new drugs which come onto the market are FDA approved and labeled for adult populations. Often times research has not been done in pediatrics, nor is there literature that can help guide decisions about use of the new medication in pediatric populations. Our advice here is to admit new drugs to your formulary for the FDA labeled population. Then use your existing process for use of an FDA approved

medication for a non FDA approved indication. Also at a minimum as you move forward in 2012 with new drug monographs to your Pharmacy and Therapeutics Committee, be sure that your monograph addresses all 9 mandatory content issues. This is a bulleted A element of performance and as you know there is no partial credit for an A element. All 9 issues should be addressed.

Only in California - CT Safety Requirements in TJC Manual



Lastly there are new standards applicable only to California based organizations on radiation safety for CT safety. Before our readers in the other 49 states breathe a sigh of relief remember that California has a very large number of accredited hospitals. Surveyors who work there become familiar with many of the unique requirements from this state, and there is the opportunity for the surveyors to learn about CT and radiation safety from evaluating these regulations in California. While surveyors can't score these specific elements of performance outside of California, it is possible that the quality control and safety concepts they learn are score-able elsewhere in the manual. We would encourage our readers to share page 10 of the January Perspectives

with their radiology department and to discuss if these requirements could be phased in regardless of your location. It is too easy to score a more

generic leadership patient safety standard, a generic performance improvement standard or a standard like MS.03.01.01.

TELEMEDICINE UPDATE FROM CMS AND JOINT COMMISSION



The January issue of *Perspectives* has the final version of the revised Telemedicine standards. We had summarized the proposed changes the Joint Commission had posted to its website in our August edition of this newsletter. There are two important changes in the final version that you should make note of and act upon.

First, LD.04.03.09, EP 23 has revised language stating that: **“the originating site makes certain that all distant site telemedicine providers credentialing and privileging processes meet at a minimum, the Medicare Conditions of Participation at 42 CFR 482.12(a)(1) through (a)(9) and 482.22(a)(1) through (a)(4).”** The earlier draft of this standard had indicated that the distant site was required to have a credentialing and privileging process that was consistent with the requirements of

the medical staff chapter of the CAMH. This concept has been moved to a note from the element of performance. Bottom line for our readers is the quote above in bold code should be placed in any contracts for telemedicine services you might have where you are the recipient of telemedicine services and you choose to use the credentialing and privileging information from the distant site in making your decisions about privileges to issue to the distant site practitioners.

The second standard that is slightly modified is MS.13.01.01, EP 2 where a requirement has been added that states: **“The distant site practitioner has a license that is issued or recognized by the state in which the patient is receiving telemedicine services.”** You will need to check the medical board regulations in your state if you receive telemedicine services to determine if your state has a waiver of licensure requirements or recognizes other state licensure for practitioners of telemedicine services. It is more common that there is no unique recognition and you will need to verify that the telemedicine

practitioner is licensed in your state.

These two standards changes announced in the January *Perspectives* take effect immediately. For those readers who receive telemedicine services from a distant site you will want to act quickly to come into compliance with these requirements.

CMS published their final requirements in the December 22, 2011 update to the SOM. They updated new content to tags A0052, A0342 and A0363 relative to telemedicine. The good news is that it appears that the Joint Commission and CMS closely collaborated on the development of their respective updates. We did note one twist in CMS tag A-0363 that we had not noticed in

the Joint Commission standards. This tag states: "When the governing body has exercised this option (to use the credentialing and privileging decisions of their distant site partner) the medical staffs bylaws must include a provision allowing the medical staff to rely upon the credentialing and privileging decisions of the distant site hospital or telemedicine entity." The survey procedures section of this tag reinforces this requirement by advising surveyors to examine the bylaws to look for this provision. Having seen how complex it is to revise medical staff bylaws this past year for MS.01.01.01, if you utilize telemedicine services you will want to start that revision process now to be compliant with the CMS requirement.

THE ONE AND ONLY CAMPAIGN REVISITED

We have previously written about this CDC campaign to promote safe injection practices.



In addition last month when we described the tracer tools CMS had developed we mentioned their examination for multi-dose vials in

patient care areas. This month we have seen that AORN has developed one of their practice guidelines recommending against the use of multi-dose vials in the operative setting. It appears that many authoritative bodies are aligning, pointing out the potential pitfalls with multi-dose medication vials. Our readers also are very familiar with how difficult it is to be compliant with proper expiration dating of these vials. If you have not done it already it seems an appropriate time to revisit

this subject at your organizations to see if more of these medications can be entirely eliminated from use for multiple patients. Our national problem with drug shortages makes this difficult at times, and insulin injections can be difficult. However we see more and more clients dispensing insulin vials on a per patient basis rather than using one multi-dose vial for all patients. Medications that are in short supply can also be purchased from specialty compounding facilities approved by the FDA as a manufacturer, or can be drawn up in single doses using the hospitals pharmacy and USP 797 compliant compounding equipment.

Insulin pens are becoming increasingly common as a means of dispensing and administering insulin, but caution should be exercised to properly educate staff who use such devices. These cannot be shared among patients even when needles are changed. There is always the risk of backflow into the drug reservoir. Many readers will look at this and say to themselves, "of course it can only be used to one patient." Frighteningly this is not a universally understood concept, even among health professionals. The FDA has issued an advisory <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm133352.htm> about this practice based on feedback they have received

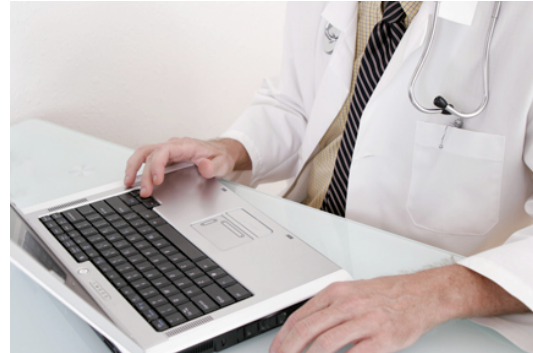
about actual patient cross contamination with these devices.

All medications labeled "single use only" must be used for just one patient. Some brands of contrast come in large vials, greater than 100 ml. Some of these are labeled for multiple patient use, and some for single patient use only by the FDA. Those labeled as single patient, must only be used on a single patient. Those labeled for multiple patients must be used with caution. The bottle of contrast can never be connected to tubing which is connected to a patient, then reused for a second patient. You can fill a power injector, then disconnect the large bottle of contrast, then connect the power injector to a patient. After the procedure the power injector and all patient tubing must be discarded. When a new power injector is used along with new tubing the injector can be filled from the large bottle of contrast, but again it must be disconnected from the power injector before the patient is connected to the IV set. Similarly be cautious in this setting when using a plain IV bag, which will usually be labeled for single patient use only.

The advice from the One and Only Campaign is well worth revisiting, studying and exploring in hospitals today. All departments should be examined to determine if there are any outliers, not fully aware of and complaint with the concept of one syringe, one patient only.

STANDING ORDERS IN HOSPITALS

Standing orders or the initiation of medication or other treatment orders by nursing staff based upon a hospital approved protocol has been a part of hospital practice for many years. In 2008 this practice was temporarily interrupted when it appeared that CMS was enforcing a requirement to obtain a physician order prior to administration of the treatment. In 2008 CMS had issued two of their Survey and Certification Memoranda stating that: "If a hospital uses other written protocols or standing orders for drugs or biological that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care." This statement caused state surveyors on behalf of CMS to believe that standing orders required an order from a physician before the standing order could be administered. At the time this caused a great deal of email chatter and professional association lobbying to undo this requirement. Emergency room providers, rapid response teams and others who use ACLS protocols were among those who complained about this interpretation. Regardless of what CMS's original intent was when issuing these memoranda, they undid that decision on October 24, 2008 by rescinding the quote above. In its



place they then said: "The use of standing orders must be documented as an order in the patient's record and authenticated by a practitioner responsible for the care of the patient, as the regulations at 42 CFR&482.23(c) and 482.24(c) require, but the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances." At that time CMS also stated its "strong support for the use of evidence based protocols which are designed to bring hospital staff with critical skills to the bedside when clinical changes that may portend the patient's deterioration are recognized by staff." CMS also expressed caution moving forward and an intention to engage the professional community in consensus building efforts to advance safe practices.

The bottom line conclusion from this revised 2008 memorandum was that hospitals could continue to use standing orders, but the physician or

other practitioner would at some time need to sign off on the standing orders that had already been utilized so that the medical record would have complete documentation.

In November 2011 CMS has published a draft revision to the COP's for hospitals and it sheds light on CMS's continued thinking about standing orders. On page 24 of the revised guideline CMS states: *"we are proposing changes to the COP's that would allow hospitals to use standing orders as long as certain provisions are met. In this rule, we propose new provisions to 482.24(c)(3) that would allow a hospital to use pre-printed and electronic standing orders, order sets and protocols for patient orders only if the hospital: 1. Establishes that such orders and protocols have been reviewed and approved by the medical staff in conjunction with the hospitals nursing and pharmacy leadership; 2. Demonstrates that such orders and protocols are consistent with nationally recognized and evidence based guidelines; 3. Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff in conjunction with the hospitals nursing and pharmacy leadership to determine continuing usefulness and safety of the orders and 4. Ensures that such orders and protocols are dated, timed and authenticated promptly in the patient's medical record by the ordering physician or other practitioner responsible for the care of the patient."*

In the draft revisions to the COP's CMS advises that hospital policies and procedures that discuss the use of

standing orders should address well defined clinical scenarios as a standard of practice for the use of such orders. They also advise against permitting clinical decision making outside the scope of practice in initiating such standing orders. My advice to hospitals here is that the medical staff cannot delegate the practice of medicine to any other health professional, however if the medical staff develops protocols that follow an "if this, then do this logic" or structure to the protocols then the hospital will be compliant with the intent. For example if the INR is X, do this, if the temperature is X, do this, if the patient is complaining about chest pain, do this. This structured approach would contrast with a less prescriptive, less clear, and non compliant process of stating if the INR is X, use your clinical judgment and order anticoagulation treatment, if the temperature is X, use your clinical judgment and order antipyretic therapy, or if the patient is complaining of chest pain, use your clinical judgment and order laboratory tests and treatments.

The draft revisions to the COP's have added in a step for the development of standing orders to make sure they are approved by nursing and pharmacy leadership in addition to the medical staff. This step has also recently been verbalized by Joint Commission presenters, assumedly based on discussion of future directions between CMS and Joint Commission. While the proposed revisions are only in a draft status, this certainly sounds like an appropriate and useful step to

take internally in developing standing orders today.

On November 18, 2011 CMS issued yet another Survey and Certification memorandum addressing the issue of standing orders. The direction and intent is consistent with their 2008 memorandum and the draft COP's. There are new concepts detailed in this memorandum which should be incorporated now in any hospitals development and use of standing orders. There must be a policy and procedure detailing how a standing order is developed, implemented, utilized, monitored and authenticated by a practitioner. Secondly there must be training for those staff who implement standing orders. In its advice to CMS surveyors CMS suggests that surveyor track back to documentation developed during the creation of standing orders and documentation of policy adherence monitoring. CMS also suggests that its surveyors interview staff who utilize standing orders to evaluate their familiarity with the policies and their

training. Based on this survey methodology it would be wise for hospitals to keep detailed approval documentation for standing orders including the literature used to support the standing order, minutes of the approval group and tickler a scheduled evaluation and re-review at a standardized interval.

The changes described in the November 18th survey and certification letter were not included in the December 2 version of the revised SOM. These changes are incorporated in red, in the December 22, 2011 version however.

It appears clear today that hospitals can utilize standing orders and be compliant with Medicare requirements as developed by CMS. The one thing CMS has not done is to allow hospitals to bypass state regulations which may be more restrictive. We caution our readers to be sure to examine any state prohibitions on standing orders that might exist.

TIMING OF MEDICATIONS ADMINISTERED

The December 22, 2011 edition of the SOM also updated Tag A-0405 relative to the timing of medications administered. The good news is: the so called 30 minute rule is somewhat

gone, but not entirely. The bad news is additional complexity has been added to identify medications eligible for scheduled dosing times, those not eligible for scheduled dosing times,

those medications where timing is critical and those where timing is not critical. CMS in describing the thought process behind loosening the 30 minute rule stated: "The application of a uniform required window of time before or after the scheduled time for administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration." CMS then asks hospitals to define 2 categories of medications, along with 2 subsets of one category:

1. Medications NOT ELIGIBLE for scheduled dosing times (e.g. stats, first doses, prn's)
2. Medications ELIGIBLE for scheduled dosing times (e.g. BID, TID, q6h)
 - a. Time critical scheduled medications
 - b. Time not critical scheduled medications

Those medications in the group identified as time critical are still going to be held to the 30 minute rule. CMS advises that at a minimum this subset should include antibiotics, anticoagulants, insulin,

anticonvulsants, pain medications, medications prescribed for administration within a specified period of time in the medication order, and medications prescribed more frequently than every 4 hours. Those medications which might appropriately be identified as not critical may include medications prescribed daily, weekly or monthly. These may be administered plus or minus 2 hours from the anticipated or routine time of administration. Medications prescribed more frequently than daily, but not more often than every 4 hours may be administered plus or minus 1 hour from the routine time of administration.



The December 22 version of the SOM also requires hospitals to establish policies and procedures to address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. These policies and procedures must identify parameters within which nursing staff are allowed to use their professional judgment regarding the rescheduling of late or missed doses and when a

practitioner responsible for the care of the patient must be notified. The last component of complexity added is the need for the QAPI program to monitor adherence to the hospitals policies.

In the end you may wish they had just retained the 30 minute rule. Hospitals will need to get busy in the first quarter of 2012 to define their timing eligible, and timing not eligible medication categories, and their timing critical and timing not critical

frequencies for the former group. These policies should be developed with nursing, pharmacy and medical staff contributors and be approved by the medical staff of the hospital. Staff in the quality improvement area will want to work with nursing, pharmacy and medical staff to develop monitoring reports to assess adherence to your policies. Those of you that have an eMAR system can quite likely work with IT to design management reports on this issue.

Regards,

Kurt A. Patton MS RPh
Kurt@PattonHC.com

Jennifer Cowel, MChSA
JenCowel@PattonHC.com

John R. Rosing, MChA
JohnRosing@PattonHC.com