Patient Safety Brief
Emergency Medicine Patient Safety Foundation

CMS Requirements on Order Sets, Protocols, Preprinted Orders, and Standing Orders

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There are three separate tag numbers that hospitals must review in order to understand the Center for Medicare and Medicaid Services (CMS) requirements for standing orders, protocols, and order sets. Additionally, CMS included information on this topic in the changes to the hospital CoPs which was published in the Federal Register and which became effective July 16, 2012. Any hospital that accepts Medicare or Medicaid reimbursement must follow the conditions of participation (CoPs) and they must be followed for all patients seen in the hospital.

The development of protocols and standings orders is better described as a journey. Initially CMS said that a physician order was needed first and that standing orders had to be signed before one could implement them. Then on October 17, 2008, CMS updated the hospital condition of partipation (CoP) manual. Seven days later, on October 24, 2008, CMS issued a survey and certification memo to explain the section, S&C-09-10, which was titled “Standing Orders in Hospitals”-Revisions to S&C Memoranda. This amended tag number 406 and 450.

This certification memo, S&C-12-5-Hospital, which was published November 18, 2011, is available off the CMS website at www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage. It was finalized in a transmittal issued December 22, 2011. All transmittals are available off the CMS

website at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html?redirect=/Transmittals/01_overview.asp.

This final interpretive guideline was added to the CoP manual on this date and all manuals are available at http://cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf.

Tag 450 was later amended again on June 5, 2009. Tag 405 was amended again on November 18, 2011. As discussed above, Hospitals must read all three of these sections to fully understand all the interpretive guidelines for order sets, protocols, and preprinted orders. In addition to reading tag 405, 406, and 450, hospitals must review the changes that were published in the Federal Register that became effective July 16, 2012.

Standing orders must be approved by the medical staff even if they are department specific. When a standing order is implemented, it is important that the order be entered into the medical record and signed off later by the physician along with a date and time. For example, the Medical Executive Committee (MEC), the Emergency Department (ED) Physicians and the hospital approve a standing order that a nurse may start an IV on a patient in the emergency department who comes in with a history of chest pain. The nurse writes the order in the order section after the IV is started and the ED physician later signs off the order and dates and times the order. Emergency departments use many standing orders to give tetanus when indicated or to for respiratory to see the patient having a severe asthmatic attack. CMS was concerned because things were being done per protocol and there was no corresponding order in the chart. CMS says the order should be entered as soon as possible.

CMS and the Joint Commission have always had an exception for flu and pneumovax. The MEC approves a policy and the nurse can then give it and write the order. Otherwise, all other appropriate orders can be administered per the physician approved hospital policy. Drugs and biologicals must then be entered into the order sheets and the order signed off by one who is responsible for the patient’s care. This is usually the physician but could be licensed independent practitioners (LIPs) acting within their scope of practice. For example, the state sets forth the scope of practice and not CMS and determines if the person is a LIP such as nurse practitioners and physician assistants. Orders may also be provide by others who are authorized such as podiatrists, dentists, optometrist, chiropractor, or clinical psychologists.

CMS supports the use of evidenced based protocols to improve patient safety and the quality of care, when appropriate. Protocols are often drafted to optimize compliance with current clinical guidelines and standards of practice. CMS notes that many hospitals have created protocols, preprinted orders, or order sets for patient's diagnosis of a MI, heart failure, pneumonia, or having surgery. Hospitals have developed protocols for a number of specific other areas such as codes or rapid response teams.

These should be appropriate for the situation such as life threatening or urgent situations. CMS says there needs to have significant merit to using them because there is a potential for harm if nurses and clinical staff are expected to make clinical decisions for things outside their scope of practice. CMS mentions this is a work in progress and CMS continues to formulate specific steps to accomplish these goals.

CMS discusses preprinted orders. A preprinted order set is a tool generally designed to assist qualified practitioners as they write orders. An orthopedic surgery is admitting a patient for a total hip and has preprinted order sheet. Preprinted order sheets are permitted by CMS but must still be reviewed and approved by the medical staff. It is important that all orders be signed, dated, and timed.

CMS states that if the physician is using a three page preprinted order set that the last page must identify the total number of pages in addition to the signature, date, and time. CMS also implemented a process to prevent alterations of the order sheet in a paper record. If the physician strikes through an order or adds additional orders at the end then all must be initiated. This is done to prevent alterations to the medical record. By initialing changes and additions it makes it easier to show that the order was written by the practitioner signing the order.

Order sets may include computerized menu that are a functional equivalent of the preprinted order set. In the case of electronic orders, the physician or LIP selects the orders and then affixes an electronic signature which includes a date and time.

Tag number 406 requires that all orders for drugs and biologicals must include things like the name of the patient, date and time of the order, weight if applicable (be sure to only get weights on children in kilograms and not pounds), drug name, dosage, frequency, etc.

This brings us next to tag 450 which was amended June 5, 2009. This standard discusses that all entries in the medical record must be legible, complete, dated, timed, and signed off by the person responsible for providing or evaluation the care. CMS reiterates that if the practitioner is using a preprinted order set then the practitioner

must sign with the total number of pages, date, time, and initial all additions or strike-outs.

The third section changes in tag 405, was finalized in the December 22, 2011 transmittal that amended the timing of medication changes. It used to be where all medications had to be given within 30 minutes of the scheduled time. Now there are three windows of time to administer scheduled medications. This memo also has a section on standing orders.

Hospitals must adopt policies and procedures that permit the use of standing orders to address well defined clinical situations. An example would be starting an IV in patients in the ED with chest pain or albuterol/atrovent breathing treatment in the asthmatic patients. It might be standing orders for a level one trauma patient. Remember that all protocols must be approved by the Medical Executive Committee (MEC).

The policies and procedures must address the process by which standing orders are developed, approved, monitored, initiated, and authenticated. The hospital might have a special committee and the committee would ensure they are based on standards of care and standards of practice. The policy might say that there are reviewed every year to make sure they are current.

The specific criteria for a nurse or other authorized staff to start a standing order must be clearly identified in the protocol. There are many requirements for the policy. This includes making sure that nurses and others are educated on the protocol. It must address that education for medical staff so if a new ED physician is hired there is education on the existing approved protocols such as nurse administration of tetanus in patients who meet the American College of Surgeon standard contained in the policy.

This tag number also reiterated that the order must be contained in the medical record. The physician responsible for the care of the patient must come along later and sign off the order, date, and time the entry.

CMS has issued changes to the federal regulations for the CoPs on May 18,, 2012. These were finalized on July 16, 2012. These are federal regulations so CMS will issue interpretive guidelines on these later. It was clarified that CMS is allowing for the administration of medications and biologicals on the orders contained within preprinted and electronic standing orders, order sets, and protocols for patient orders that meet their standards.

CMS notes there are many situations, besides rapid response teams, where standing orders would be helpful. This includes the emergency department for things such as

asthma, heart attacks, and stoke. Again the ED would need to sign off the orders as discussed above. It could be used to improve immunization rates and to help in the PACU.

A summary of each of the four CMS sections is at the end. In addition, they are many organizations that proffer evidence based guidelines and order sets.

ACEP on Order Sets

Many professional Organizations have policies or statements on order sets. For example, The American College of Emergency Physicians (ACEP) has a policy on the use of nurse implemented order sets. They recognize the importance of this practice. These are predetermined orders initiated based on nursing assessment of the patient. This clinical policy was approved by the ACEP Board of Directors on June 10, 2010 and is available at http://www.acep.org/Clinical---Practice-Management/Use-of-Nurse-Implemented-Order-Sets/

Cardiovascular Order Sets

There are many organizations that put out order sets based on the current evidenced based literature. For example, The Institute for Clinical Systems Improvement (ICSI) has a website which houses many clinical order sets. It was developed to improve patient safety and improve outcomes by ensuring patients received appropriate orders on admission. These are based on current guidelines and standards. It has order sheets related to heart disease, hypertension, and other causes of cardiovascular disease. It has admission order sets for patients admitted with heart failure. Heart failure is one of the three things that hospitals are working on to prevent unnecessary readmissions. Any hospital that has a higher rate of readmissions after October 1, 2012 is at risk for seeing a reduction in monies from the Center for Medicare and Medicaid Services (CMS).

There is also an order set for admission to the CCU from the emergency department for acute coronary syndrome (ACS). It included orders such as daily weights, to notify the physician for any fever over 101 degrees (38.3 C), notify the physician for new ST elevation, beta-blockers, VTE mechanical prophylaxis, diet, IV, medications, platelet counts every other day, and hemoglobin every other day if on low molecular weight heparin or the other choices, etc. This can helpful to the emergency department staff

since the issue of boarding and overcrowding can often result in admitted patients staying longer periods of time awaiting an inpatient bed.

There is also an order set on admission orders for stroke patient not receiving tPA and one for medical patients with venous thromboembolism. There are also many other order sets on patient safety and reliability order sets, respiratory disease, musculo-skeletal disorder sets, and more.

Their website includes many other things that may be of interest such as new and recently revised scientific document and on the development and revision processes for guidelines, order sets, and protocols. This document is available at http://www.icsi.org/guidelines_and_more/document_development_process/ and this document can be of assistance is helping hospitals to meet the interpretive guidelines in the CMS hospital conditions of participation manual.

This document defines a guidance, order sheet, and protocol as the following:

- **A health care guideline** is an evidence-based statement of best practice in the prevention, diagnosis, or management of a given symptom, disease, or condition for individual patients under normal circumstances.

- **A health care order set** is a set of standardized instructions for the management of a particular disease, condition, or procedural intervention, presented as a group of orders to be individually selected and signed by an authorized prescriber.

- **A health care protocol** is a step-by-step statement of a procedure routinely used in the care of individual patients to assure that the intended effect is reliably achieved.

CHA Provides Order Set Guidelines

The California Hospital Association (CHA) has a resource guide that hospitals may find helpful, especially hospitals in California. The full name of this document is “CHA Guidelines for Standing Orders, Standardized Procedures and Other Delegation Tools.” It also provides several definitions that may be helpful although some of these definitions are found in California statutes or laws. The CHA Order Set Tool is available at http://www.calhospital.org/sites/main/files/file-attachments/final-_cha_final_phys_order_chart_6-1-12.pdf

Standing orders are defined written orders used in the absence of a specific order for a specific patient provided by a licensed health care practitioner acting within the scope of his or her professional licensure. Standing orders can be used by physicians to authorize a nurse practitioner to provide certain services. Many states use a collaborative agreement between the nurse practitioner and the physician.

The CHA document has a section on protocols. There is also a section on preprinted orders and written instructions. The document is seven pages long.

In Summary

In summary, the CMS hospital CoPs require the following:

Tag 405, changes effective December 22, 2011

- Need an order for all drugs and biologicals and this includes one that are done under a protocol
- Hospitals may adopt P&P that permit the use of standing orders as long as they address well-defined clinical scenarios regarding medication administration
- P&P must address the process by which a standing order is developed, approved, monitored, initiated by authorized staff, and subsequently authenticated by physicians or practitioners responsible for the patient's care,
- Specific criteria by which a nurse or other person is allow to initiate a standing order must be clearly identified in the protocol for the order
- This would include the specific clinical situation, patient condition, or diagnosis in which initiating the order would be appropriate
- P&P must address the education of the medical, nursing, and other applicable professional staff on the conditions for using the standing order
- P&P must include the criteria for using standing orders and the individual staff responsibilities associated with their initiation and execution
- An order must be placed in the order section of the medical record when a standing order is used
- The standing order P&P must specify the process to make sure the standing order gets singed off, dated, and timed by the physician or practitioner with the exception of flu and pneumovax
- P&P must also establish a process for monitoring and evaluating the use of standing orders, including proper adherence to the order's protocol
- There must be a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions
- Surveyors are instructed to ask to see an example of one or more standing orders involving medication administration, including the documentation on the development of the order, evidence of training of personnel on the order's protocol, and periodic evaluation of the use of the standing order, including adherence to P&P

- Surveyors are instructed to interview nursing staff to make sure they are familiar with the hospital P&P on standing orders and to determine whether they initiate medications in accordance with standing orders.

Tag 406 and 407 Effective Date October 17, 2008 and

CMS Memo October 28, 2008

- Vaccines may be administered per physician-approved hospital policy after an assessment of the contraindications (MEC must approve the protocol)
- Order for vaccine must later be signed by the physician
- An exception to having the order signed off (dated and timed) is flu and pneumovax
- Need to have an order for all drugs and biologicals

CMS Memo on Standing Orders in Hospitals

- Standing orders must be documented as an order in the patient's chart
- Standing orders must later be signed off by the physician, or other qualified practitioner, along with being dated and timed
- When a physician has a written set of orders, or is using a preprinted order set contained on one page, or on several pages, the physician must sign, date, and time each page of orders
- Physician or practitioner must identify the total number of pages in the order set such as page 3 of 3
- Any additions to preprinted orders, strike outs or deletions must be initialed
- In the case of an electronic order set the practitioner would affix an electronic signature, date, and time
- All qualified practitioners responsible for the care of the patient and authorized by the hospital in accordance with State law and scope of practice are permitted to issue patient care orders
- Standing orders should be evidenced based
- Many hospitals used protocols to standardize and optimize patient care in accordance with clinical guidelines or standards of practice
- Many hospitals have implemented evidenced based protocols or order sets to be used with patients diagnosed with MI, CHF, pneumonia, or who are undergoing certain surgical procedures
- Formal protocols may also be used with code team or rapid response teams
- Pre-printed orders are a tool designed to assist qualified practitioners as they write orders. Preprinted orders are allowed but must be approved by the medical staff

- All orders must be signed off, dated, and timed

Tag 450, Last Updated June 5, 2009

- All entries in the medical record must be legible and complete
- Every entry must be signed, dated, and TIMED
- Reiterated that the last page of the order sheet must identify the total number of pages, be dated, timed, and signed off or authenticated
- Reiterated that the practitioner must initial every deletion, addition, strike out to preprinted orders
- Same principles apply to electronic order sets as far as signed, dated, and time

Federal Register July 16, 2012

- Remember to stayed tuned as CMS generally adds interpretive guidelines to new federal regulations
- Hospitals may use pre-printed and electronic standing orders, order sets and protocols for patient orders only if certain criteria is met
- Orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership
- The order or protocol must be consistent with nationally recognized and evidenced based guidelines
- There must be periodic and regular review of orders and protocols by the Medical Staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols
- All orders and protocols must be dated, times, authenticated promptly in the medical record by the ordering physician or another physician who is responsible for the care of the patient
- The person signing off the order must be acting according to their scope of practice and in accordance with state law

Resources

Institute for Clinical Systems Improvement (ICSI) website at http://www.icsi.org/guidelines_and_more/order_sets/

See tag number 405, 407, and 450 in the CMS Hospital CoP, Appendix A, which is located at www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

July 16, 2012 section, in the Federal Register, Vol. 77, No. 95, Page 29034,on standing orders, order sets, and protocols is published at www.federalregister.gov/articles/2012/05/16

CMS Survey Memo, October 24, 2008, “Standing Orders in Hospitals” Revisions to S&C Memoranda, at www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage.

CMS Survey Memo, February 8, 2008, Hospital Revised Interpretive Guidelines for Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Post-anesthesia Evaluations Final Rule at www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage. (Contained changes which were added to the CMS CoP Manual June 5, 2012).

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