

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

Friday, December 5th, 2014



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Speaker

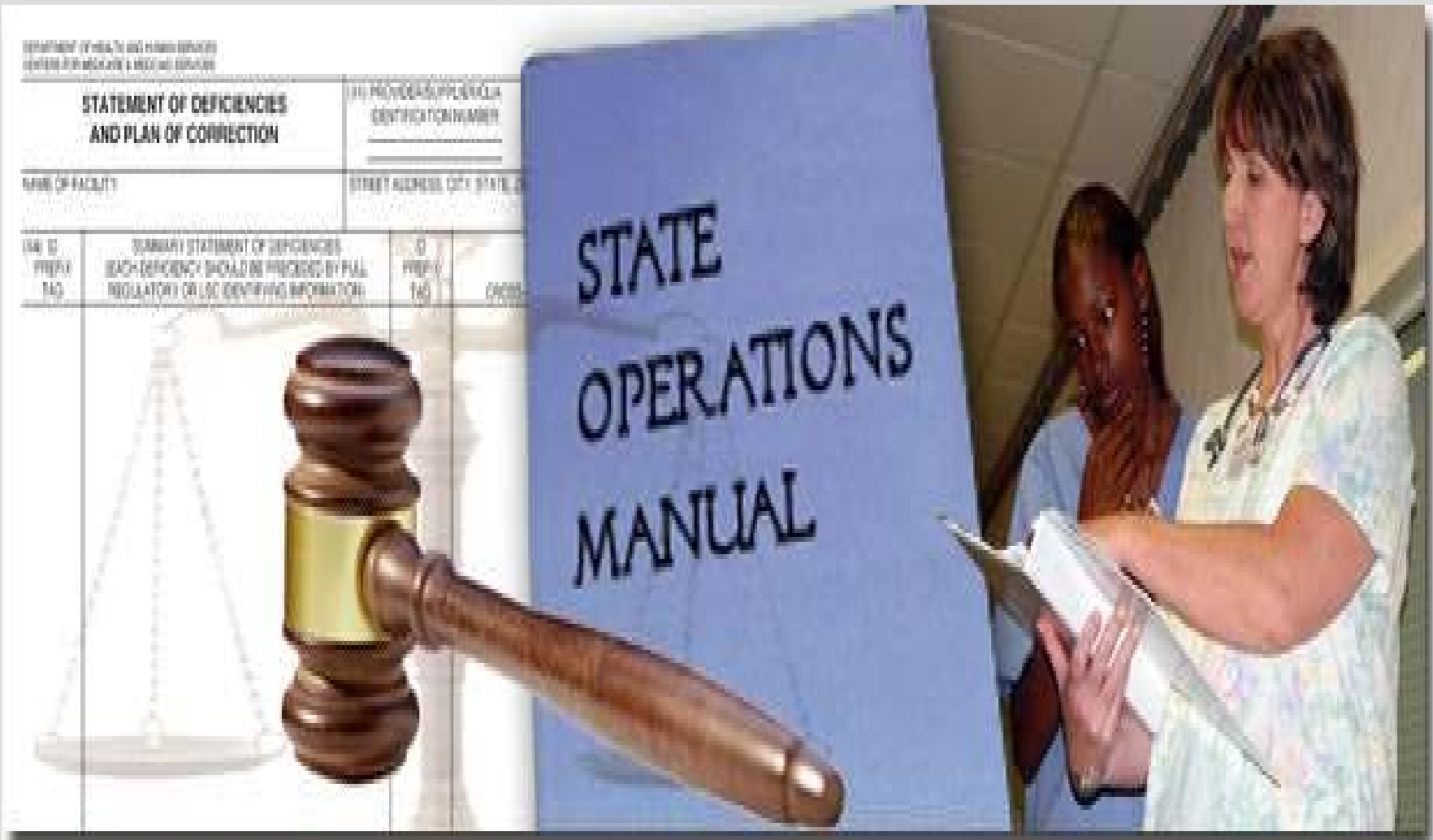


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Learning Objectives

1. Recall hospital compliance requirements with the CMS CoP.
2. Explain the CMS requirements for standing orders and protocols.
3. Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
4. Evaluate compliance requirements and penalties.

You Don't Want One of These



The Conditions of Participation (CoPs)

- Many revisions since 1986
- Hospital CoP Manual updated June 6, 2014
- First regulations are published in the **Federal Register** then CMS publishes the **Interpretive Guidelines** and some have **survey procedures** ²
 - Hospitals should check this website once a month for changes

¹ <http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>

² www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

CMS Issues Final Regulation

- CMS publishes 165 page final regulations changing the CMS CoP and has section on **standing orders**
- Moved standing orders to **457 in Medical Records** which is the primary section
- So now in sections **405, 406, 450, and 457**
- Changes effective June 7, 2013
 - CMS publishes to reduce the regulatory burden on hospitals-more than two dozen changes
 - Available at www.ofr.gov/inspection.aspx

Final IGs on Standing Orders

A-0457

(Rev.)

§482.24(c) (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.24(c)(3)

What is covered by this regulation?

There is no standard definition of a "standing order" in the hospital community at large (77 FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. For purposes of brevity, in our guidance we generally use the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, we note that the lack of a standard definition for

Location of CMS Hospital CoP Manual

Medicare State Operations Manual Appendix

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers

New website

www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

App. No.	Description	PDF File
A	Hospitals	 2,185 KB
AA	Psychiatric Hospitals	 606 KB

CMS Survey and Certification Website

CMS.gov

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Policy & Memos to States and Regions



CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Select From The Following Options:

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There are 455 items in this list.

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Click on Policy & Memos

Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data
- Includes acute care and CAH hospitals
 - Does not include the plan of correction but can request
 - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
- Updates quarterly
 - Available under downloads on the hospital website at www.cms.gov

Access to Hospital Complaint Data

- There is a list that includes the hospital's name and the different tag numbers that were found to be out of compliance
 - Many on restraints and seclusion, EMTALA, infection control, patient rights including consent, advance directives and grievances and **standing orders**
- Two websites by private entities also publish the CMS nursing home survey data and hospitals
- The ProPublica website for LTC
- The Association for Health Care Journalist (AHCJ) websites for hospitals

Access to Hospital Complaint Data

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
2000 Secretary Boulevard, Mail Stop C3-21-16
Baltimore, Maryland 21244-1800



Center for Clinical Standards and Quality/Survey & Certification Group

Re: SAC: 13-21- ALL

DATE: March 21, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Access to Statements of Deficiencies (CMS-2567) on the Web for Skilled Nursing Facilities, Nursing Facilities, Hospitals, & Critical Access Hospitals

Memorandum Summary

- **Survey Findings Posted on www.cms.gov:** In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on *Nursing Home Compare*. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memorandum describes the contents and location of these files.
- **Other Web-based Tools Based on These Data:** At least two additional websites, provided by private parties (*ProPublica* and the Association for Health Care Journalists), publish information based on the CMS-2567 data. These websites are independent of CMS. CMS does not endorse or sponsor any particular private party application.
- **Plans of Correction (POC):** The posted CMS data do not contain any POC information. State Survey Agencies (SAs) and CMS Regional Offices (RO) may see an increase in requests for both the CMS-2567 and any associated POCs.
- **Questions & Answers:** We plan to issue an update to this memorandum that will include an attachment of frequently asked questions in order to provide answers to other queries that may arise.

Background – Nursing Home Survey Findings

In July 2012, CMS began posting nursing home statements of deficiencies, derived from the Form

Updated Deficiency Data Reports

CMS.gov

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Hospitals

This page provides basic information about being certified as a Medicare and/or Medicaid hospital provider and includes links to applicable laws, regulations, and compliance information.

A hospital is an institution primarily engaged in providing, by or under the supervision of physicians, inpatient diagnostic and therapeutic services or rehabilitation services. Critical access hospitals are certified under separate standards. Psychiatric hospitals are subject to additional regulations beyond basic hospital conditions of participation. The State Survey Agency evaluates and certifies each participating hospital as a whole for compliance with the Medicare requirements and certifies it as a single provider institution.

Under the Medicare provider-based rules it is possible for 'one' hospital to have multiple inpatient campuses and outpatient locations. It is not permissible to certify only part of a participating hospital. Psychiatric hospitals that participate in Medicare as a Distinct Part Psychiatric hospital are not required to participate in their entirety.

However, the following are not considered parts of the hospital and are not to be included in the evaluation of the hospital's compliance:

- Components appropriately certified as other kinds of providers or suppliers. i.e., a distinct part Skilled Nursing Facility and/or distinct part Nursing Facility, Home Health Agency, Rural Health Clinic, or Hospice; Excluded residential, custodial, and non-service units not meeting certain definitions in the Social Security Act; and,
- Physician offices located in space owned by the hospital but not functioning as hospital outpatient services departments

Accredited Hospitals - A hospital accredited by a CMS-approved accreditation program may substitute accreditation under that program for survey by the State Survey Agency. Surveyors assess the hospital's compliance with the Medicare Conditions of Participation (CoP) for all services, areas and locations covered by the hospital's provider agreement under its CMS Certification Number (CCN).

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospitals.html

Deficiency Data CMS Hospitals

Section	Tag	July 2014	April 21, 2014
Administration of Drugs/Standing Orders	405	291	273
Standing Orders	457	37	37
Standing Orders or Drugs	406	29	27
MR Services/Standing Orders/Date and Time of Order	450	152	148

CMS Order Sets, Protocols, Standing Orders

- CMS has chosen **not to define** the differences between order sets, standing orders, pre-printed orders, and protocols
- However, in the March 15, 2013 memo CMS says nurses and other staff may administer drugs in accordance with pre-printed and electronic standing orders, orders and protocols which are collectively referred to as “**standing orders**” and effective June 2013
 - These must address **well defined clinical scenarios** involving medication administration
 - Refers to MR chapter and creates new tag 457
 - Moved most of standing order information in tag **405 to 457**
 - So now look at tag numbers **405, 406, 450, and 457**

CMS Order Sets, Protocols, Standing Orders

- However, CMS establishes criteria and directions on the process and policy requirements and there are several key points
- Orders and protocols are approved by the Medical Staff in conjunction with pharmacy and nursing
- The orders and protocols must be consistent with nationally recognized and evidenced based guidelines

What is the Difference?

- **What is the difference between an order set, standing order and protocol.?**
- An **order set** is a list of individually selectable interventions that the ordering practitioner may choose from
 - Tool designed to help practitioners as they write orders
- An order set 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

What is the Difference?

- Examples might include evidenced based order sets (printed or electronic) for:
 - Acute MI, CHF, or Pneumonia,
 - CABG, stroke, asthma, ventilation weaning,
 - Total knee replacement, total hip replacement, hip fracture,
 - Sepsis, flu immunization
- It is important to know what the different organizations standards are such as ENA, ACEP, AORN, ASPAN, etc.

What is the Difference?

- A **standing order** is an order (orders) that may be initiated without an initial order by the nurse if the patient meets certain criteria
- Standing orders are written documents that contain orders for the patient based on various stipulated clinical situations
- They usually name the condition and prescribe the action to be taken in caring for the patient
- They are commonly used in ICU's, CCUs, and the emergency department
 - Note some hospitals use standing order and protocol interchangeable

Standing Orders

- Those criteria and the resulting orders require prior approval in policy by the medical staff
- Example; start an IV in the ED on a patient having chest pain
- Give tetanus to patient in the ED who has not had one in the specified period
- Give ACLS drugs to a patient in cardiac arrest
- Example: The surgery center has a preop standing order to start an IV on all patients of 1000 cc 0.9 NaCl at 25 cc an hour

What is the Difference?

- A **protocol** also requires the patient to meet certain clinical criteria, but there must be an order to initiate the protocol
- It 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
- Example would be a heparin protocol for a patient having a MI in the emergency department and the physician has ordered the same
- Important thing is to understand the CMS standards for what the hospital is doing

What is the Difference?

- **Pre-printed order set** is a set of orders which is printed physician orders
- This prevents the physicians from having to write all the orders from memory
- Can be specific to a physician such as his or her orders for total knee surgery
- Can be pre-printed orders to reflect order sets approved by the Medical Staff to promote best practices and the current evidenced based literature
- Has the potential to improve patient safety and outcomes

Preprinted Orders Vs Order Sets

- In some hospitals, preprinted orders were traditionally individual physician specific
- Order sets replaced these traditional ones in some hospitals
- Order sets in some hospitals are diagnosis specific and based on published guidelines and research
- Order sets are implemented only by the physician or licensed independent practitioner (LIP) or their delegate
 - Insulin order set, cellulitis order set, ACS thrombolytic therapy order set, newborn circumcision order set

Appendix

Creating Preprinted Physician Orders for Clinical “best practice” Review www.ahrq.gov/downloads/pub/advances2/vol2/Advances-

Criteria for consideration when creating or revising preprinted physician orders [Ehringer, 1](#)

Content and Format		Yes
1	Orders reflect current “best practice”	
2	Orders are created in Arial 10- or 12-point font	
3	Orders do not contain unapproved abbreviations	
4	Orders do not contain confusing symbols (e.g., < and >)	
5	Blanket orders are not used. (i.e., Resume home meds).	
7	Order contains space for physician signature, physician ID #, and date	
8	Admission orders include “Admit as inpatient,” “Outpatient,” or “Observation Status,” as appropriate	
9	Orders are single-sided (Reverse side of sheet should contain additional information or references only)	
Medication Safety		Yes
10	Abbreviations, when used, are kept to a minimum	
11	Medication orders are not numbered	
12	Medication orders contain drug name, dose, route, and frequency	
13	If multiple routes are listed, order contains criteria to determine which route to use	
14	When possible, order contains dose written as mg, and not as tablets or mL	
15	Order does not contain multiple ranges	
16	Order contains indication for PRN medications	
17	Time frame is written for IV bolus / IV push orders	
18	Generic and trade names (if applicable) of medication are used	
Actions by the Clinical “Best Practice” Committee (CBP) may include:		
	Arranging presentation of orders according to standardized format	
	Adding indications of regulatory / Performance measures, etc.	
	Adding DVT prophylaxis, vaccination status, smoking counseling, patient education, etc	

So What's In Your Policy?

PRE-PRINTED PROVIDER ORDER SETS

- All pre-printed orders shall be created and approved by the appropriate FHS IDT or Leadership Team and provided on FHS forms. The FHS pre-printed orders have been reviewed, approved and aligned with medical staff rules and regulations, hospital policy, Joint Commission, CMS, Department of Health, FHS formulary and other relevant regulatory agencies.
- All relevant order sets involving medication are additionally reviewed by Pharmacy and the PT&T Committee and as needed the Medication Safety Leadership Team to ensure appropriate medication prescribing and ordering practices are followed.
- The Pre-Printed Provider Order Set process is supported centrally by the Clinical Effectiveness Division and its oversight Provider Orderset Standardization and Implementation Workgroup (POSSI).
- The use of pre-printed orders must be individualized, documented as an order in the patient's medical record and authenticated by a practitioner responsible for the care of the patient and authorized by the Medical Staff and state law scope of practices.
- The registered nurse verifies that the orders have been processed and indicates the time, date and signature next to the order.
- A Registered nurse may complete the order sets through use of verbal or telephone orders from an authorized practitioner provided that the orders are read back to the practitioner per policy.
- Items on the order set that do not have a box to check or are pre-checked are intended to be used for all patients. These items may be denoted by a bullet point or dash.
- Items that have a checkbox in front of them are only carried out if the box is checked. This provides customization to fit the individual patient needs and/or practitioner preference.
- Items without a checkbox or pre-checked that the physician does not want ordered must be lined out and initialed.
- Note: Some of the pre-printed orders have multiple choices within the individual medication sections as denoted by a line preceding the medication. Examples include oral/IV analgesics or anti-emetics. If there is no guidance provided as to the preferential order for medication administration.

What is the Difference?

- **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
- CMS requires that standards of practice and standards of care be entered into P&P and guidelines
- Examples: The CDC intravascular guidelines, CDC guidelines to prevent catheter associated UTI, CDC hand hygiene guidelines, etc.

ISMP Guidelines for Order Sets

ISMP DEVELOPS GUIDELINES FOR STANDARD ORDER SETS

From the March 11, 2010 issue

www.ismp.org/Tools/guidelines/default.asp

ISMP has long been an advocate for the use of standard order sets to minimize incorrect or incomplete prescribing, standardize patient care, and ensure clarity when communicating medical orders.(1-3) Whether in electronic or paper format, well-designed standard order sets have the potential to:

- Integrate and coordinate care by communicating best practices through multiple disciplines, levels of care, and services(4)
- Modify practice through evidence-based care(4)
- Reduce variation and un-intentional oversight through standardized formatting and clear presentation of orders(1-4)
- Enhance workflow with pertinent instructions that are easily understood, intuitively organized, and suitable for direct application to current information-management systems and drug administration devices(1-4)
- Reduce the potential for medication errors through integrated safety alerts and reminders(1-4)
- Reduce unnecessary calls to prescribers for clarifications and questions about orders. (1-4)

However, if standard orders are not carefully designed, reviewed, and maintained to reflect best practices and ensure clear communication, they may actually contribute to errors—many of which have been described in our newsletters and still occur today. In fact, the ISMP consulting team often identifies dozens of serious problems related to the content, format, and approval/maintenance of standard order sets when visiting healthcare organizations of all sizes and types. Below we describe the importance of paying careful attention to the design and maintenance of standard order sets as well as provide examples of commonly observed problems that can lead to serious errors. ***Guidelines for Standard Order Sets*** to help avoid these problems can be found on our Web site at: www.ismp.org/Tools/guidelines/default.asp.

Content

Careful attention to the content of standard order sets helps ensure they: 1) are complete, 2) include important orders beyond what the prescriber may initially consider (e.g., specific monitoring requirements), 3) reflect current best practices,

FORMAT

LAYOUT AND DIRECTIONS FOR USE

- Follows an official standard format that has been approved by an appropriate interdisciplinary committee (e.g., pharmacy and therapeutics committee, safety committee, forms committee)
- Identifies the order set name at the top of the form/screen and, as appropriate, specifies the targeted patient population (e.g., adult, pediatric, neonatal, adult oncology)
- Differentiates similar order sets employed for similar conditions (e.g., different heparin order sets based on various clinical conditions)
- Includes directions for completing the order set at the top of the form/screen
- Uses a standard method (e.g., check boxes, circling) for prescribers to activate/select desired orders that minimizes confusion regarding how inactivated/unselected orders are to be interpreted (e.g., yes/no check boxes may be problematic regarding correct interpretation if the physician checks neither the yes nor no option; with paper order sets, a single box to check—activate—an order may be less error-prone)
- Separates orders into logical groupings of treatment, procedure, and medication orders
- Uses separate lines/entries for each medication order; multiple orders do not appear on one line or within a single entry
- Includes the name of the drug and dose/strength on the same line/entry
- Avoids listing products with look-alike names near each other
- Lists the most common or preferred drug, strength, and dose first, if multiple drugs, strengths, and doses are available from which to choose
- Uses "OR" to indicate when choices between products must be made and includes specific guidance regarding that choice
- Provides adequate space between the medication name and dose (e.g., "propranolol 20 mg, not propranolol20 mg, which may look like 120 mg), and between the numerical dose and unit of measure (e.g., 3 units, not 3Units, which can look like 30 units)
- Provides adequate space between numbers used to sequence orders and the actual orders themselves (to prevent misinterpretation of the

CMS Requirements

- So what are the CMS requirements for order sets, protocols, pre-printed orders and standing orders?
 - Any hospital that accepts Medicare or Medicaid must follow these for all hospital patients
- CMS included a section in the June 7, 2013 changes to the Federal Register and added to tag 457
- CMS has now a total four sections on standing orders; tag 405, 406, 450, and 457
 - Remember most of the information in tag 405 was moved to 457 which was effective June 7, 2013
- The development of protocols and standing orders is best described as a journey

Standing Orders, Protocols, Order Sets

- First, CMS said that a physician order was needed first and that standing orders had to be initiated before one could implement them
 - Hospitals argued this is not what the federal register said.
- CMS agrees and issues changes to the CoP manual October 17, 2008
- CMS issues “Standing Orders in Hospitals” memo October 24, 2008, S&C 12-5
 - It amended Tag 406 and 450 (which gets amended again June 5, 2009, March 15, 2013 IG, and June 7, 2013)

Standing Order Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-10

DATE: October 24, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#ToPage

SUBJECT: “Standing Orders” in Hospitals – Revisions to S&C Memoranda

Memorandum Summary

- A. Standing Order Clarification:** We are clarifying a portion of S&C-08-12 and S&C-08-18, issued on February 8 and April 11, 2008 respectively, regarding use of standing orders in hospitals. The use of standing orders must be documented as an order in the patient’s medical record and signed by the practitioner responsible for the care of the patient, but the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances.
- B. Future Directions:** We express our interest in working with the professional

Revised Tag 405 and 406

Old Tag	New Tag
<p>A -0404 – combine with A-0405 §482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).</p> <p>A -0405 (1) - All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p>	<p>A-0405</p> <p>§482.23(c) Standard: Preparation and administration of drugs.</p> <p><i>(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under §482.12(c), and accepted standards of practice.</i></p> <p><i>(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p> <p>§482.23(c)(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p>
<p>A-0406</p>	<p>A-0406</p> <p><i>§482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).</i></p> <p>§482.23(c)(3)- With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy and who is responsible for the care of the patient as specified under §482.12(c).</p> <p><i>§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p>

Tag 405 Standing Orders 2014

- Most of the sections on standing orders was moved to tag 457
- CMS says drugs must be administered in response to an order from a practitioner or on the basis of a **standing order**
- The standing order must subsequently be signed off or authenticated by the practitioner
 - This includes a date and time along with the signature
- The surveyor is to determine if there is a standing order and the right medications was given to the patient

Tag 405 Amended in 2014

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: March 14, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

Memorandum Summary

- **Medication Administration:** We are updating our guidance for the hospital medication administration requirements to:
 - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements under the pharmaceutical services and quality assessment/performance improvement CoPs, to take a comprehensive approach to the medication process.
 - Update our guidance for IV medications and blood transfusions in general; and
 - Reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.
- **Immediate Post-operative Care:** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate

Final Transmittal Issued June 6, 2014

CMS Manual System

Pub. 100-07 State Operations
Provider Certification

Transmittal 116

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Date: June 6, 2014

SUBJECT: Revised State Operations Manual (SOM), Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.23(c), concerning medication administration, and 42 CFR 482.51(b)(4), concerning post-operative patient care.

NEW/REVISED MATERIAL - EFFECTIVE DATE: June 6, 2014
IMPLEMENTATION DATE: June 6, 2014

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0405/§482.23(c)Standard: Preparation and Administration of Drugs
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0409/§482.23(c)(4)/Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0412/§482.23(c)(6)/The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0957/§482.51(b)(4)/There must be adequate provisions for immediate post-operative care.

www.cms.gov/Regulations-and-Guidance/Transmittals/Downloads/R116SOMA.pdf

Tag 406, 407, and CMS 2008 Memo

- **Standard:** Drugs and biologicals must be prepared on the orders contained within pre-printed and electronic standing orders, order sets, and protocols only if meets the requirements of tag 457 (June 7, 2013 change)
 - Again, order can be signed by physician or practitioner (like a PharmD, NP or PA) who is allowed by state law, hospital P&P, and the Medical Staff
- Tag 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.

Tag 406 Flu and Pneumovac

- Order must be documented in the chart
 - Reiterated that flu and pneumonia vaccines can be administered per physician approved hospital policy after an assessment of the contraindications
 - There is no requirement for the physician or other practitioner to sign or authenticate the order
 - The Joint Commission recognizes the same exception

Tag 406 Order Required

- Your state law sets forth the scope of practice and not CMS and determines if the person is a LIP such as nurse practitioners
- Orders may also be provide by others who are authorized such as podiatrists, nurse practitioner, pharmacists, dentists, optometrist, chiropractor, or clinical psychologists
- In July 16, 2012 FR: CMS does not want to be an obstacle to what state law permits so for example if state allow PharmD to manage anticoagulant clinic will allow to sign off order if done by MS approved protocol

CMS Changes July 11, 2014

- CMS published some final changes to hospital CoP on May 7, 2014 and in FR May 11, 2014
- Says will save healthcare providers \$660 million annually and 3.2 billion over five years
- Several are important to the CMS dietary CoPs
- Reiterated about not restricting scope of practice and deferring to the state law and state scope of practice
- Practitioner such as dietician and pharmacist can be C&P and either a member or not a member of the MS

Final Federal Register Changes

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 440, 442, 482, 483, 485, 486, 488, 491, and 493

[CMS-3267-F] [www.ofr.gov/\(S\(5jsvwwmsi4nfjrynav20ebeq\)\)/OFRUpload/OFRData/2014-10687_PI.pdf](http://www.ofr.gov/(S(5jsvwwmsi4nfjrynav20ebeq))/OFRUpload/OFRData/2014-10687_PI.pdf)

RIN 0938-AR49

Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule reforms Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This final rule also increases the ability of health care professionals to devote resources to improving patient care, by eliminating or reducing requirements that impede quality patient care or that divert resources away from providing high quality patient care. We are issuing this rule to achieve regulatory reforms under Executive Order 13563 on improving regulation and

CMS Memo on Standing Orders Oct 28, 2008

- 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
- Went over standards for pre-printed orders discussed under tag 450
- 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

CMS Memo on Standing Orders Oct 28, 2008

- 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
- 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

Pre-printed Orders Tag 450

- This section was amended October 17, 2008 and again on June 5, 2009
- Note in final IG, **new** section adds tag 457
- If a physician or LIP is using pre-printed order set, then must comply with the below sections
- A preprinted order set is a tool generally designed to assist qualified practitioners as they write orders
 - For example, an orthopedic surgeon goes to the cabinet and gets out his three page order sheets for total knee surgery

Pre-printed Orders Tag 450

- CMS states the physician must identify the total number of pages in the order set
 - Doctor documents 3 of 3 pages
 - Remember must sign, date and time the order
- If electronic medical record still need to date and time the order and affix electronic signature
- The physician or practitioner must sign, date, and time the last page of the orders also
- This includes initiating or signing either the top or the bottom of the pertinent pages

Pre-printed Orders Tag 450

- This was done to prevent alterations in the medical record
- If any additions, deletions, or strike outs are done in the order sheet then the physician or LIP needs to initiate to show that they made the change and not someone else
- 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

Standing Orders and Protocols

- CMS issued more than two dozen changes that went into effect June 7, 2013 and added new tag number 457
- This was first in March 15, 2013 interpretive guideline in a CMS memo
 - And effective on June 7, 2013 and now in current CMS manual
- 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

Order Sets, Protocols, Standing Orders

- 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 stroke
- Again the ED staff would need to enter the order in the chart and sign off the orders as discussed

Tag 457 Added CMS C&S March 15, 2013

Old Tag	New Tag
<p>New content for this Tag number. Previous citations under old Tag A 0457 will be attributed to Tag A-0454</p>	<p>A-0457</p> <p><i>§482.24(c)(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:</i></p> <ul style="list-style-type: none"> <i>(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;</i> <i>(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;</i> <i>(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and</i> <i>(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i>
<p>A-0458</p>	<p>A-0458 §482.24(c)(4) - All records must document the following, as appropriate:</p>

Tag 457 Standing Orders 2013

- **Standard:** hospitals can use preprinted and electronic standing orders, order sets, and protocols for patient orders only if the hospital has the following 4 things:
- Make sure the orders and protocols have been reviewed and approved by the MS (such as the MEC) and the hospital's nursing and pharmacy leadership
- Demonstrate that the orders and protocols are consistent with nationally recognized and evidenced based guidelines

A-0457

(Rev.)

§482.24(c) (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.24(c)(3)

What is covered by this regulation?

There is no standard definition of a "standing order" in the hospital community at large (77 FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. For purposes of brevity, in our guidance we generally use the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, we note that the lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care

Tag 457 Standing Orders 2013

- Ensure that there is periodic review the standing orders conducted by MS, nursing and pharmacy leadership to determine the usefulness and safety
- Ensure that the standing orders are dated, timed, and authenticated by the ordering physician or other practitioner responsible for the care of the patient
 1. As long as practitioner is acting in accordance with state law
 2. Scope of practice
 3. Hospital P&P and
 4. MS bylaws and R/R

Tag 457 Standing Orders 2013

- No standard definition of standing orders
- For brevity CMS uses standing orders to include pre-printed orders, electronic standing orders, order sets and protocols
 - Said these are forms of standing orders
- States lack of standard definition may result in confusion
- Not all preprinted and electronic order sets are considered a standing order covered by this regulation

Tag 457 Standing Orders 2013

- Example; doctor or qualified practitioner picks from an order set menu and treatment choices can not be initiated by nurses or other non-practitioner staff then menus are not standing orders covered by this regulation
- Menu options does not create an order set subject to these regulations
- The physician has the choice not to use this menu and could create orders from scratch or modify it

Tag 457 Standing Orders 2013

- In cases, where a nurse can initiate without a prior specific order,
 - Then policy and practice must meet these regulations
 - Doesn't matter what it is called
 - Must meet certain pre-defined clinical situations
 - Emergency response or part of an evidenced-based treatment where it is NOT practical for a nurse to obtain a written order or verbal order
- Hybrids still require compliance with this section
 - Order set has a protocol for nurse initiated such as KCL

Standing Order Requirements 457

- Must be well-defined clinical situations with evidence to support standardized treatments
- Appropriate use can contribute to patient safety and quality care
- Can be initiated as emergency response
- Can be initiated as part of an evidenced based treatment regime where not practicable to get a written or verbal order
- Must be medically appropriate such as RRT

Standing Order Requirements 457

- Triage and initialing screening to stabilize ED patients presenting with symptoms of MI, stroke, asthma
- Post-operative recovery areas like PACU
- Timely provisions of immunizations
- Can't be used when prohibited by state or federal law so no standing orders on R&S
- CMS has set forth a number of minimum requirements for standing orders that must be present for a well-defined clinical scenario

Minimum Requirements for Standing Orders

- Must be approved by MS, nursing and pharmacy leadership
- P&P address how it is developed, approved, monitored, initiated by staff and signed off or authenticated
- Must have specific criteria identified in the protocol for the order for a nurse or other staff to initiate
 - Such as a specific clinical situation, patient condition or diagnosis
- Must include process to have them signed off

Minimum Requirements for Standing Orders

- Hospital must document standing order is consistent with nationally recognized and evidenced based guidelines
- Burden is on the hospital to show there is sound basis for the standing order
- Must have regular review to ensure its still useful and a safe order
- P&P address how to correct it, revise or modify
- Must be placed in the order section of the chart
- Must be dated, timed, and signed

Tag 457 Standing Orders

- Make sure there is periodic and regular review of the orders and protocols conducted by the MS, nursing and pharmacy leadership to determine the continued usefulness and safety
- Make sure they are dated, timed, and authenticated promptly in the medical record
 - Signed off by the ordering practitioner of another practitioner on the case
 - Could be signed off by non-physician if allowed by hospital policy, state law, the person state law scope of practice, and MS bylaws or R/R

Subq Insulin Order Set

The screenshot displays the SHM website interface. At the top, the SHM logo is accompanied by the tagline "Hospitalists. Transforming Healthcare. Revolutionizing Patient Care." Navigation links include Home, Log-in, Community, Career Center, and QI Resource Rooms. A search bar is located in the top right corner. The left sidebar contains a menu with categories such as About SHM, Membership, Education, Quality Initiatives, Practice Management, and Advocacy. The main content area shows a breadcrumb trail: Home → Quality Improvement → QI Clinical Tools. An advertisement for Xarelto (rivaroxaban tablets) is featured, promoting "The New DVT and PE Treatment" with a link to "EXPLORE THE BENEFITS". Below the ad, the title "Subcutaneous Insulin Order Set" is displayed, followed by a link to "Guidelines for Insulin Use and Care of the Hospitalized Patient with Hyperglycemia". The tool's purpose is to encourage proper use of inpatient insulin by promoting long-acting scheduled (basal) insulin and pre-meal scheduled insulin, while discouraging traditional sliding scale insulin. The submitter is Greg Maynard MD, MS, and the tool author is the same. E-mail contact information is provided as gmaynard@ucsd.edu. A URL is also present: www.hospitalmedicine.org/AM/Template.cfm?Section=QI_Clinical_Tools&Template=/CM/HTMLDisplay.cfm&ContentID=4239

Insulin Drip Protocol



THE NEW* YALE INSULIN DRIP PROTOCOL



The following insulin drip protocol is intended for use in hyperglycemic adult patients in an ICU setting, but is not specifically tailored for those individuals with diabetic emergencies, such as diabetic ketoacidosis (DKA) or hyperglycemic hyperosmolar syndrome (HHS). When these diagnoses are being considered, or if $BG \geq 500$ mg/dL, an MD should be consulted for specific orders. Also, please notify an MD if the response to the insulin drip is unusual/unexpected, or if any situation arises that is not adequately addressed by these guidelines. The starting dose, adjustments, and glucose targets have been intensified.

Initiating An Insulin Drip

- 1.) **INSULIN INFUSION:** Mix 1 units Regular Human Insulin per 1 cc 0.9 % NaCl. Administer via infusion pump (in increments of 0.5 U/hr).
- 2.) **PRIMING:** Flush 50 cc of Insulin/NS drip through all IV tubing, before infusion begins (to saturate the insulin binding sites in the tubing)
- 3.) **THRESHOLD:** IV insulin is indicated in any critically ill patient with persistent $BG \geq 140$ mg/dL; consider use if $BG \geq 110$ mg/dL.
- 4.) **TARGET BLOOD GLUCOSE (BG) LEVELS:** **90-119 mg/dL***.
- 5.) **BOLUS & INITIAL INSULIN DRIP RATE:** If initial $BG \geq 150$, divide initial BG level (mg/dL) by 70, then round to nearest 0.5 units for bolus AND initial drip rate. If initial $BG < 150$ mg/dL, divide by 70 for initial drip rate only (i.e., NO bolus)
Examples: 1) Initial BG 335 mg/dL: $335 : 70 = 4.78$, rounded \uparrow to 5: 5 units IV bolus + start drip @ 5 units/hr.
2) Initial BG 148 mg/dL: $148 : 70 = 2.11$, rounded \downarrow to 2: start drip @ 2 units/hr (NO bolus)

Fingerstick (FS) Blood Glucose Monitoring

- 1.) Check FS hourly until stable (defined as 3 consecutive values in target range). In hypotensive patients, capillary blood glucose (i.e., fingersticks) may be inaccurate and obtaining a blood sample from an indwelling vascular catheter may be preferable.
- 2.) Once stable, check FS q 2 hours; once stable x 12-24 hours, FS checks can be spaced to q 4 hours **IF:**
 - a) no significant change in clinical condition
 - AND
 - b) no significant change in nutritional intake
- 3.) If any of the following occur, consider the temporary resumption of hourly FS monitoring, until BG is again stable:
 - a) any change in insulin drip rate (i.e. BG out of target range)
 - b) significant changes in clinical condition
 - c) initiation or cessation of pressor or steroid therapy
 - d) initiation or cessation of dialysis or CVVH
 - e) initiation, cessation, or rate change of nutritional support (TPN, PPN, tube feedings, etc.)

Changing the Insulin Drip Rate

If $BG < 50$ mg/dL:
D/C INSULIN DRIP

Give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes

⇒ When $BG \geq 90$ mg/dL, wait 1 hour, recheck BG, then restart drip at 50% of most recent rate (if BG still ≥ 90 mg/dL)

If BG 50-69 mg/dL:
D/C INSULIN DRIP

If asymptomatic (or difficult to access), give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes

Alcohol Withdrawal Treatment Protocol

Evidence-Based Revision of an Alcohol Withdrawal Order Set Treatment Protocol

Background: Every year several hundred thousand hospitalized patients are treated with alcohol withdrawal, either as a primary or secondary diagnosis. In 2003, due to high numbers of our patient population experiencing alcohol withdrawal, the Medical ICU at the XXXX Hospital, implemented a symptom triggered alcohol withdrawal order set protocol which incorporated the standardized CIWA scale (Clinical Institute Withdrawal Assessment), and treated primarily with oral clorazepate or oral or intravenous (IV) lorazepam. The order set was expanded in 2005 to include all inpatient areas, dividing the orders into treatment of intensive Emergency/ICU patients and less intensive Medical/Surgical patients. In May 2008, because of concerns among several of the MICU physicians and nurses, the MICU Outcomes Committee reviewed the most current alcohol withdrawal literature for evidence-based best practice protocols and subsequently modified the alcohol withdrawal order set. Physician concerns included: 1) Patients receiving large benzodiazepines doses on the current protocol causing over sedation which required intubation to protect the patient's airway; 2) Patients receiving a continuous infusion of lorazepam which delayed extubation by several days. Nursing concerns included increasing benzodiazepine usage due to the lack of adjunct medications to manage associated alcohol withdrawal symptoms such as agitation, delirium, and adrenergic stimulation with hypertension and tachycardia.

Purpose: The purpose of this evidence-based project was to revise the XXXX alcohol withdrawal treatment practice order set based on the evidence and to include adjunct medications to improve patient safety and outcomes.

Methods: The Multidisciplinary MICU Outcomes Committee revised the alcohol withdrawal order set to include additional evidence-based adjunct medications to reduce

Guidelines www.guidelines.gov

The screenshot shows the National Guideline Clearinghouse website. At the top, there is a search bar with the text "definition protocol" and a "Search" button. To the right of the search bar are links for "Help", "RSS", "Subscribe to weekly e-mail", "Site map", "Contact us", and "For web developers". Below the search bar, there are links for "Search Tips", "Advanced Search", and "About Search".

The main content area is titled "Guideline Syntheses >" and features a "Print" button. The primary heading is "Chronic Obstructive Pulmonary Disease (COPD): Diagnosis and Management of Acute Exacerbations". Underneath, it lists "Guidelines Being Compared:"

- Global Initiative for Chronic Obstructive Lung Disease (GOLD).** Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Vancouver (WA): Global Initiative for Chronic Obstructive Lung Disease (GOLD); 2011. 78 p. [503 references]
- University of Michigan Health System (UMHS).** Chronic obstructive pulmonary disease. Ann Arbor (MI): University of Michigan Health System; 2010 May. 17 p. [7 references]

Below the list are several tabs for comparison: "Areas of Agreement and Difference", "Comparison of Recommendations", "Strength of Evidence and Recommendation Grading Schemes", "Methodology", "Source(s) of Funding", "Benefits and Harms", "Contra-indications", "Abbreviations", and "Status".

The text under the "Areas of Agreement and Difference" tab reads: "A direct comparison of recommendations presented in the above guidelines for the diagnosis and management of acute exacerbation of COPD is provided below. The UMHS guideline provides recommendations for the outpatient setting; GOLD addresses both hospital and home settings."

The section is titled "Areas of Agreement" and begins with "Diagnosis and Initial Assessment".

The left sidebar contains navigation links: Home, Guidelines, Expert Commentaries, Guideline Syntheses (highlighted), Guideline Resources, Annotated Bibliographies, Compare Guidelines, FAQ, Submit Guidelines, About, and My NGC.

Joint Commission Standards on Protocols, Standing Orders and Order Sets

What Hospitals Need to Know



Joint Commission Standards MM.04.01.01

- No definition of standing order, protocol, or order set in the glossary
- However, MM.04.01.01 EP1 defines standing order
- Standing orders:
 - A pre-written medication order and specific instructions from the licensed independent practitioner (LIP) to administer a medication to a person in clearly defined circumstances

Joint Commission Standards MM.04.01.01

- Added MM.04.01.01, EP 15, effective September 1, 2012 regarding pre-printed and standing orders
- To bring TJC standards into compliance with CMS changes that went into effect June 7, 2013
- Standard: Medication orders are clear and accurate
- For hospitals that use TJC for deemed status (DS)
- Processes for the use of pre-printed and electronic standing orders, order sets, and protocols for medications orders must include the following:

TJC Standing Orders, Order Sets MM.04.01.01

- The Medical Staff (MS), Nursing and Pharmacy need to review and approve all standing orders and protocols
- The hospital must evaluate standing orders and protocols to ensure they are consistent with nationally recognized and evidence based guidelines
- There must be a regular review of standing orders and protocols by MS, Nursing, and Pharmacy to determine their continued usefulness and safety

TJC Standing Orders, Order Sets MM.04.01.01

- Standing orders and protocols
 - Must be dated and timed
 - Must be signed off or authenticated by the ordering practitioner or a practitioner responsible for the patient's care
 - Must be in accordance with professional standards of practice, and law and regulation
 - Must be consistent with hospital policies and procedures and MS bylaws and rules & regulations

MM.02.01.01 Hospital Selects Medications

- **Standard:** The hospital selects and obtains medications
- Recently, hospitals have experienced many problems related to drug shortages and outages
- EP 12 States that's the hospitals develops and approves written medication **substitution protocols** to be use in the event of a medication shortage or outage
- EP 13 States hospital must implement its approved **medication substitution protocols**

MM.02.01.01 Medication Substitution Protocol

- EP14 Hospital needs to have a process to communicate to the physicians and LIPs and staff about the **medication substitute protocol** for shortages and outages
- EP 15 Hospital implements its process to communicate to all of the above who participate in medication management about the **medication substitution protocols** for shortages and outages
- Hospitals can sign up to get email updates on drug shortages and outages from the FDA
- ASHP also has good resources on the same



Drugs

www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

Home Drugs Drug Safety and Availability Drug Shortages



Drug Safety and Availability

Drug Shortages

Current Drug Shortages Index

Current Drug Shortages A - D

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Current Drug Shortages O - R

Current Drug Shortages S - Z

Resolved Drug Shortages

Drugs to be Discontinued

How to Report a Shortage or Supply Issue

Frequently Asked Questions About Drug Shortages

Drug Shortages

FDA takes great efforts, within its legal authority, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. The agency works closely with manufacturers of drugs in short supply to communicate the issue and to help restore availability. FDA also works with other firms who manufacturer the same drug, asking them to increase production, if possible, in order to prevent or reduce the impact of a shortage.

Manufacturers are not required to report information, such as reasons for shortages or the expected duration of shortages. However, many companies voluntarily provide shortage information that FDA posts on its website. FDA encourages and appreciates all reporting of shortages by manufacturers. Shortage notifications and updates may be reported to FDA at drugshortages@fda.hhs.gov.



Spotlight

- 2012-2013 Influenza Season: Availability of Antivirals
- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information
- Fact Sheet: Drug Products in Shortage in the United States
- FDA Report: A Review of FDA's Approach to Medical Product Shortages
- Statement from FDA and HHS on Drug Shortages

Drug Shortages Information

Email Updates on Drug Shortages



U.S. Food and Drug Administration
Protecting and Promoting Your Health

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ASHP Drug Shortages Resources



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HOME > DRUG SHORTAGES

Drug Shortages

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Print Share

Welcome to the ASHP Drug Shortages Resource Center, the first stop for information and resources on drug product shortages and management. Drug shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors. ASHP and its partners work to keep the public informed of the most current drug shortages.

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ASHP Resources on Managing

ASHP REPORT

ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems

DEVELOPED BY AN ASHP EXPERT PANEL ON DRUG PRODUCT SHORTAGES: ERIN R. FOX, ANNETTE BIRT, KEN B. JAMES, HEATHER KOKKO, SANDRA SALVERSON, AND DONNA L. SOFLIN

Ann J Health-Syst Pharm. 2009; 66:1399-406

Purpose

Drug product shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors.^{1,2} Health care professionals are increasingly concerned about the clinical effect that shortages have on patients and the tremendous resources required to address shortages.³⁻⁵ Adverse patient outcomes related to drug product shortages^{1,2,6-9} have prompted aggressive management strategies by health care providers and gained the attention of the Joint

Commission,¹⁰ the government,^{11,12} and the media.^{13,14} Drug product shortages adversely affect health-system finances by increasing the cost of delivering patient care, largely through higher drug acquisition and personnel costs.⁶ In addition, shortages create a high level of frustration for everyone involved, including purchasing agents, pharmacists, nurses, physicians, and patients.⁷

Managing drug product shortages is particularly complex for practitioners in hospitals and health systems (hereinafter, "health systems"),

because these facilities routinely treat patients with acute or emergent conditions, use a significant number of medically necessary or single-source products, and use high-cost new drug technologies. These health care providers are challenged during drug product shortages to ensure the provision of seamless, safe, and therapeutically equivalent drug therapy, preferably at comparable costs. The pharmacy department must take a leadership role in efforts to develop and implement appropriate strategies and processes for inform-

Developed through the ASHP Council on Pharmacy Management and approved by the ASHP Board of Directors on January 15, 2009. These guidelines supersede the ASHP Guidelines on Managing Drug Product Shortages dated March 28, 2001.

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NPSG.03.05.01 Anticoagulant Protocols

- **Standard:** Reduce the likelihood of patient harm associated with anticoagulant therapy
- This standard applies to hospitals that provide anticoagulant therapy or long term prophylaxis for things like atrial fibrillation where it is expected lab values will remain outside normal values
- Does not apply to short term use to prevent DVTs
- EP2 Hospitals must use approved **protocols** for the initiation and maintenance of anticoagulant therapy

University of Washington Anticoagulation

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- Neuraxial Anesthesia in the Anticoagulated Patient >
- Heparin Protocols for UWMC >
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- Central Venous Catheter Management >
- Alternative Monitoring for Antithrombotic Agents at UWMC >
- Permissions Request >

About UW Medicine Department of Pharmacy Anticoagulation Services

The anticoagulation services program at UW Medicine is operated by the [Department of Pharmacy](#). Services encompass the management of anticoagulant therapy in pharmacist-managed anticoagulation clinics as well as coordination of the use of antithrombotic agents in the inpatient setting. Pharmacist providers are involved in clinical practice, training and education, and research activities consistent with the mission of UW Medicine and the Department of Pharmacy.

"The goals of pharmacist-managed anticoagulation services include treatment and prevention of thromboembolic disease and minimization of complications of antithrombotic therapy."

Use the links to the left to navigate through the major sections of this site. The links at the top are the most frequently visited areas. BY USING THE SITE, YOU AGREE TO THE TERMS OF USE; IF YOU DO NOT AGREE, DO NOT USE THE SITE.

WHAT'S NEW

[Rivaroxaban \(Xarelto\)](#)

[Dabigatran \(Pradaxa\)](#)

[Warfarin drug interactions](#)

<http://www.uwmcacc.org>

Heparin Protocol

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Venous Thromboembolism
(Diagnosis, Prevention
Treatment) >

Recommendations for
Chronic Antithrombotic
Therapy >

Warfarin >

Dabigatran (Pradaxa) >

Rivaroxaban (Xarelto) >

Guidelines for Reversal of
Anticoagulation >

Guidelines for Dosing and
Monitoring of Low-Molecular
Weight Heparin (LMWH) >

Guidelines for Management
of Fondaparinux >

Peri-Procedural
Anticoagulation >

Neuraxial Anesthesia in the
Anticoagulated Patient >

Heparin Protocols for
UWMC >

Heparin-Induced
Thrombocytopenia >

Central Venous Catheter
Management >

Alternative Monitoring for
Antithrombotic Agents at
UWMC >

Permissions Request >

Heparin Protocols for UWMC

[Intravenous Heparin Administration Orders \(pdf\)](#)

[Low-Range IV Heparin Administration Orders \(pdf\)](#)

for use in patients with excessive bleeding risk
******Do NOT USE for patients with acute thromboembolism, including
DVT or PE******

GUIDELINES FOR MANAGEMENT OF FULL INTENSITY SQ HEPARIN

Fixed Dosing

- Unfractionated heparin (UFH) 250 units/kg SQ q12h with no aPTT monitoring
- Consider 333 units/kg SQ loading dose for treatment of acute thrombosis
- Do not use for treatment of arterial thrombosis (eg. AF, valve replacement, etc.)

Adjusted Dosing

- Initial Dosing
 - Initial therapy with adjusted-dose SQ UHF

Other Sections Mentioning Protocols

- MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders to be dispensed in the hospital
 - EP1 An exception to the rule is if the medication delay would harm the patient
 - The radiology department is expected to define through a protocol or a policy the role of the LIP in the direct supervision of a patient during and after IV contrast
- MM.06.01.05 Must have written process for use of investigational medication that specifies if patient involved in investigational protocol

Other Sections Mentioning Protocols

- NPSG.07.04.01 Related to central line associated bloodstream infections
 - Need **standardized protocol** and checklist
 - Need **standardized protocol** for sterile barrier precautions
 - Use **standardized protocol** to disinfect catheter hubs and injection ports
- PC.01.02.15 Hospitals in California must make sure dose of CT scan is recorded in the medical record or on the protocol page that lists the radiation dose

The End! Questions?



- Sue Dill Calloway RN, Esq.
CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and
Education Consulting
- Board Member
Emergency Medicine
Patient Safety Foundation
- 614 791-1468
- sdill1@columbus.rr.com
(Call with Questions, No emails)

CHA Guidelines and Standing Orders

- 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

CHA GUIDELINES FOR STANDING ORDERS, STANDARDIZED PROCEDURES AND OTHER DELEGATION TOOLS

This is intended as a tool to provide generalized guidance; please seek advice of counsel when utilizing delegation tools.

**Regulations and laws are constantly changing, the following summary is based on today's regulations.*

	What are they and who do they apply to?	What can or can't they be used for?	Special conditions for Medicare/Medi-Cal:
Standing Orders	<ul style="list-style-type: none"> • Standing orders are 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.¹ • Standing orders are conditioned upon the occurrence of certain clinical events, initiated by the treating health care practitioner. All patients who meet the criteria for the order receive the same treatment. Once the triggering event is identified, an allied health professional (A.H.P) or licensed independent practitioner (L.I.P) may initiate treatment pursuant to a standing order.² • Standing orders can be used by a physician to authorize a nurse practitioner ("NP"),³ or physician assistant ("PA")⁴ to provide specified services. • Use of standing orders for medical assistants are limited and subject to specific rules and settings.⁵ <p>For example, a standing order is one of two ways to meet the statutory requirement for medical</p>	<ul style="list-style-type: none"> • <i>Note: While the statutes and regulations described below deal almost exclusively with the use of standing orders in the context of administering drugs to patients, standing orders have a much broader application than just drug administration.</i> Final rules at 42 CFR §482.24 allow hospitals flexibility to use standing orders. Added requirement for medical staff, nursing, and pharmacy to approve written and electronic standing orders, orders sets and protocols. Orders and protocols must be based on nationally recognized and evidence-based guidelines and recommendations.⁶ • In a hospital, standing orders for drugs may be used for specified patients when authorized by a person licensed to prescribe. A copy of the standing orders for a specific patient must be dated, timed, promptly signed by the prescriber, and included in the patient's medical record. Such standing orders shall: 	<ul style="list-style-type: none"> • Services billed to Medi-Cal that are the result of routine or standing orders for admission to a hospital are not reimbursable when applied indiscriminately to all patients. All patient orders, including standing orders for particular types of cases, must be specific to the patient and must represent necessary medical care for the diagnosis or treatment of a particular condition.⁷ • While historically CMS has generally frowned on the use of standing orders, CMS recently proposed a rule that would allow hospitals to use standing orders under certain circumstances.⁸

CHA GUIDELINES FOR STANDING ORDERS, STANDARDIZED PROCEDURES AND OTHER DELEGATION TOOLS

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	What are they and who do they apply to?	What can or can't they be used for?	Special conditions for Medicare/Medi-Cal:
<p>Standardized Procedures</p>	<p>Standardized procedures can be used by RNs, nurse-midwives, or NPs,¹⁴ and mean <u>either</u> of the following:</p> <p>(1) Policies and protocols developed by a health facility licensed pursuant to Chapter 2 (commencing with § 1250) of Division 2 of the Health and Safety Code through collaboration among administrators and health professionals including physicians and nurses (e.g., an interdisciplinary committee).</p> <p>(2) Policies and protocols developed through collaboration among administrators and health professionals, including physicians and nurses, by an organized health care system which is not a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.</p> <p>The policies and protocols shall be subject to any guidelines jointly promulgated by the Medical Board of California and the Board of Registered Nursing.¹⁵</p>	<ul style="list-style-type: none"> • <i>Note: While many of the statutes and regulations described below deal exclusively with the use of standardized procedures in the context of administering drugs to patients, we believe that standardized procedures have a much broader application than just drug administration.¹⁶</i> • Standardized procedures may be used to legally allow RNs and NPs to perform some functions that would otherwise be considered the practice of medicine.¹⁷ • The administration of dimethyl sulfoxide may be performed pursuant to standardized procedures developed by an organized health care system through collaboration among administrators and health professionals.¹⁸ • A certified nurse-midwife or a NP following standardized procedures may dispense substances included in the California Uniform Controlled Substances 	<ul style="list-style-type: none"> • Under both the Medi-Cal and Medicare programs, standing orders <u>cannot</u> be used to authorize the restraint of a patient, including when using drugs that meet the definition of a restraint.²⁰

	What are they and who do they apply to?	What can or can't they be used for?	Special conditions for Medicare/Medi-Cal:
Protocols	<p>(7) Specify the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a physician.</p> <p>(8) Set forth any specialized circumstances under which the RN is to immediately communicate with a patient's physician concerning the patient's condition.</p> <p>(9) State the limitations on settings, if any, in which standardized procedure functions may be performed.</p> <p>(10) Specify patient record keeping requirements.</p> <p>(11) Provide for a method of periodic review of the Standardized procedures.²⁷</p> <ul style="list-style-type: none"> • Protocols typically apply to PAs, but may also apply to nurse mid-wives, NPs,²⁸ or polysomnographic technologists.²⁹ • With regard to PAs, a PA and his or her supervising physician shall establish written guidelines for the adequate supervision of the PA. This requirement may be satisfied by the supervising physician and surgeon adopting protocols for some or all of the tasks performed by the PA. The PA protocols shall comply with the following requirements: 	<ul style="list-style-type: none"> • Note: While many of the statutes and regulations described below deal exclusively with the use of protocols in the context of administering drugs to patients, we believe that protocols have a much broader application than just drug administration.³⁰ • A certified nurse-midwife or a NP following protocol may dispense substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).³¹ • Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or condition for which the Schedule II controlled substance is being administered, provided, or issued. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon.³² 	<ul style="list-style-type: none"> • Under the Medi-Cal program, a single physician is limited to supervising four PAs (full-time equivalents). The supervising physician and surgeon shall review, countersign and date a sample consisting of, at minimum, five percent of the medical records of patients treated by the PA functioning under the protocols within 30 days of the date of treatment by the PA.³³ • CMS suggests that a hospital's anesthesia services policy should include protocols for supportive life functions, e.g., cardiac and respiratory emergencies.³⁴ • CMS suggests that hospitals develop substitution protocols to address medication shortages.³⁵

ICSI Instit for Clinical Systems Improvement

GUIDELINES AND ORDER SETS

January 2013

- ▶ [Headache, Diagnosis and Treatment of](#)
- ▶ [Immunizations](#)
- ▶ [Respiratory Illness in Children and Adults, Diagnosis and Treatment of](#)
- ▶ [Venous Thromboembolism Diagnosis and Treatment](#)

December 2012

- ▶ None

www.icsi.org/guidelines__more/new__recently_revised_guidelines/

November 2012

- ▶ [ACS: Chest Pain and Acute Coronary Syndrome, Diagnosis and Treatment of](#)
- ▶ [Hypertension Diagnosis and Treatment](#)
- ▶ [Low Back Pain, Adult Acute and Subacute](#)
- ▶ [Venous Thromboembolism Prophylaxis](#)

PROTOCOLS

January 2013

Standing Orders, Protocols, Order Sets

- Tag 405 was amended November 18, 2011 and finalized in a transmittal issued December 22, 2011 but March 15, 2013 moved standing order material to 457 and **provided for reference only at the end**
- As mentioned hospitals need to read all of these sections to fully understand the interpretive guidelines for
 - Order sets
 - Pre-printed orders
 - Protocols and
 - Standing orders

Standing Orders November 18, 2011 Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Office of Clinical Standards and Quality / Survey & Certification Group

Ref: S&C-12- 05-Hospital

DATE: November 18, 2011
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Updated Guidance on Medication Administration, Hospital Appendix A of the State Operations Manual (SOM)

Memorandum Summary

- **Medication Administration Guidance Updated:** SOM Appendix A guidance concerning medication administration in hospitals is being updated to:
 - Reflect current standards of practice related to timeliness of medications. Hospitals are expected to establish policies and procedures for the timing of medication administration that appropriately balance patient safety with the need for flexibility in work processes.
 - Incorporate policy regarding standing orders from S&C-09-10.
- **ASPEN Changes:** Tags A-404 and A-405 have been combined. It will take time for this guidance to be incorporated into a future ASPEN release. Prior to this conversion citations should be made only to Tag A-404.

Background

Final Transmittal Standing Orders

CMS Manual System **Pub. 100-07 State Operations** **Provider Certification**

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 77

(Advance Copy)

Date: December 22, 2011

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for 42 CFR 482.23(c), concerning medication administration.

REVISED MATERIAL - **EFFECTIVE DATE*:** December 22, 2011
IMPLEMENTATION DATE: December 22, 2011

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.23(c) Standard: Preparation and Administration of Drugs/A-0405

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their current operating budgets.

IV. ATTACHMENTS:

Business Requirements

Standing Orders Tag 405 (See 457)

- Standard: Drugs and biologicals must be prepared and administered in accordance with federal and state laws, practitioner's orders and the acceptable standards of practice **(moved to 457)**
- Drugs and biologicals can be prepared and administered on the orders of other practitioners only
 - If the practitioner is acting in accordance with state law
 - This includes their state scope of practice
 - In accordance with hospital P&P and MS bylaws and rules and regulations

Note Regarding 405

- March 15, 2013, CMS moved the section on standing orders to tag 457
 - See June 7, 2013 manual for final section
- However, the memo issued on November 18, 2011 and finalized in a transmittal December 11, 2011 has good information
- Is helpful to understanding the issue of standing orders
- So presented here for reference only

CMS Memo Standing Orders

Standing orders

As discussed in S&C-09-10, issued on October 24, 2008, it is permissible for hospitals to use standing orders to address well-defined clinical scenarios involving medication administration. The guidance in Hospital Appendix A is being updated to incorporate the principles of this prior memorandum. Hospital policies and procedures must address the process by which each standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by the physician or practitioner responsible for the care of the patient. In addition, the standing order must be entered into the medical record at the time of initiation or as soon as possible thereafter.

Page 3 – State Survey Agency Directors

Consolidation of ASPEN Tags

We are consolidating the regulatory text in ASPEN Tag A-404 into Tag A-405. It will take time for this guidance to be incorporated into a future ASPEN release. Prior to this conversion, citations should be made only to Tag A-405.

Section in Memo on Standing Orders

Standing orders

Hospitals may adopt policies and procedures that permit the use of standing orders to address well- defined clinical scenarios involving medication administration. The policies and procedures 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 care of the patient.

8

The specific criteria for a nurse or other authorized personnel to initiate the execution of a particular standing order must be clearly identified in the protocol for the order, i.e., the specific clinical situations, patient conditions or diagnoses in which initiating the order would be appropriate. Policies and procedures must address the education of the medical, nursing, and other applicable professional staff on the conditions and criteria for using standing orders and the individual staff responsibilities associated with their initiation and execution. An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter. Likewise, standing order policies and procedures must specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal polysaccharide vaccines, which do not require such authentication in accordance with §482.23(c)(2).

The policies and procedures must also establish a process for monitoring and evaluating the use of standing orders, including proper adherence to the order's protocol. There must also be a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions.

Note Regarding 405

- In 2013, CMS moved some of the language on standing orders to another section
- Created tag number 457
- Amended tag 406
- However, the memo issued on November 2011 and finalized in a transmittal Dec 2011 has good information
- Is very helpful to understanding the issue of standing orders

Standing Orders Tag 405

- Example, the pharmacy board in X state allows a pharmacist to manage the anticoagulant clinic and the pharmacist writes the order for the warfarin
- This has a section on standing orders
- Hospitals may adopt P&P that permit the use of standing orders to well-defined clinical scenarios involving medication administration
 - Example; ED nurse is allowed to start an IV on a patient having chest pain
 - Code blue team administers ACLS medications in a code

Revised Tag 405 and 406 March 15, 2013

Old Tag	New Tag
<p>A -0404 – combine with A-0405 §482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).</p> <p>A -0405 (1) - All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p>	<p>A-0405</p> <p>§482.23(c) Standard: Preparation and administration of drugs.</p> <p>(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under §482.12(c), and accepted standards of practice.</p> <p><i>(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p> <p>§482.23(c)(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p>
<p>A-0406</p>	<p>A-0406</p> <p><i>§482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).</i></p> <p>§482.23(c)(3)- With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy and who is responsible for the care of the patient as specified under §482.12(c).</p> <p><i>§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p>

Standing Orders P&P Tag 405

- CMS says nursing must follow the standing order P&P
- The standing order P&P must address the following:
 - Process by which standing order is developed
 - Process to approve
 - Process standing order is monitored
 - Process to have authorized staff initiate
 - Subsequent authentication by physicians or practitioners responsible for the care of the patient

Standing Orders Tag 405

- Example of compliance
 - Hospital has an interdisciplinary committee that reviews all of the standing orders on an annual basis
 - Committee documents review
 - A literature search is done to ensure the standing order is still current with the evidenced based literature
 - The standing orders for medications are approved by the Medical Staff (MEC) in conjunction with pharmacy and nursing
 - The nurse documents the standing order in the chart and it is signed off, dated and timed by the LIP or physician

Standing Orders Tag 405

- CMS says the specific criteria for a nurse or other authorized person to initiate the standing order must be identified in the protocol for the order
- CMS states the specific clinical situations, patient condition or diagnosis initiating the order has to be appropriate
 - Example; Standing order allows RN in the ED to give an adult patient a tetanus shot (TDaP) if a break in the skin and the last one was over five years ago
 - Asthmatic patient is sent to a bed and the respiratory therapist administers Atrovent/Albuteral breathing treatment

Standing Orders P&P Tag 405

- CMS requires that P&P address the education of the medical, nursing, and other staff on the conditions and criteria for using standing orders
- This includes the requirement regarding individual staff responsibilities associated with initiation and execution
- Example; Any new physician to the ED is educated on what standing orders exist and the need for the ED physician to sign off the standing order even if approved by the MEC
 - Includes time and date order signed off also

Standing Orders Tag 405

- CMS is specific that if you have a standing order you must write the order in the chart at the time it is initiated or asap
- The standing order P&P must state that the physician or practitioner who is responsible for the patient's care will sign off or authenticate the order
- An exception is the flu and pneumococcal vaccine which the nurse can give per approved protocol after clarifying there are no contraindications
 - Many will still write these in the order section but both TJC and CMS does not require the order to be signed off

Standing Orders P&P Tag 405

- The standing order P&P must:
 - Establish a process for monitoring and evaluating the use of standing orders
 - This includes 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

Standing Orders P&P Tag 405

- Standing orders must be approved by the Medical Staff even if they are only used in one department
- Make sure you do not have a more strict state law
- It is important that every order be placed in the chart and the order signed off later by the physician or LIP
- Don't forget to time and date the entry
- CMS was concerned because would see protocol approved, like trauma protocol, but what was being done was not documented in the order sheet

Standing Orders Survey Procedure 405

- Surveyor to verify there is a standing order P&P to address how the standing order is developed and approved, monitored, initiated and order signed off
- Surveyors to ask to see an example of standing orders related to medication administration
 - Will make sure evidence of training and periodic evaluation of the use of the standing order
- Surveyor to interview nursing staff to determine if they initiated any medication standing orders
- Will make sure nursing familiar with standing order P&P and that they are following it

Standing Orders Survey Procedure 405

- 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 protocols for patients having surgery

Standing Orders Survey Procedure 405

- 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

Resources

- 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

Resources

- See also www.guidelines.org
- 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_AppendixA.pdf
- Institute for Clinical Systems Improvement (ICSI) website has order sets and guidelines at <https://www.icsi.org/>
 - Has updated monthly list of guidelines, orders sets, protocols etc.

Resources

- Promoting Best Practice and Safety Through Preprinted Orders at www.ahrq.gov/downloads/pub/advances2/vol2/Advances-Ehringer_17.pdf
- ISMP Standard Order Sets at www.ismp.org/newsletters/acutecare/articles/20100311.asp
- Preprinted Order Sets as a Safety Intervention in Pediatric Sedation, J Pediatrics 2009, June:154(6):865-8 at <http://www.ncbi.nlm.nih.gov/pubmed/19181332>

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Thank you for attending!!



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