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

Wednesday, February 12th, 2014

Speaker

- 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 www.empsf.org
- 614 791-1468
- sdill1@columbus.rr.com
Learning Objectives

1. Recall hospital compliance requirements with the CMS CoP
2. Explain the CMS requirements for standing orders and protocols

You Don’t Want One of These
The Conditions of Participation (CoPs)

- Many revisions in past to respiratory and rehab orders, visitation, IV medication and blood, anesthesia, pharmacy, timing of medications, confidentiality & privacy, insulin pens, humidity, PI program, Complaint manual, deficiencies, discharge planning and telemedicine
- Hospital CoP Manual updated August 30, 2013
- First regulations are published in the Federal Register then CMS publishes the Interpretive Guidelines and some have survey procedures.
  - Hospitals should check this website once a month for changes


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
- So now in sections 405, 406, 450, and 457
- Published in the May 16, 2012 Federal Register effective July 16, 2012 and final interpretive guidelines published March 15, 2013 and 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
CMS Memo on Changes

CENTER FOR MEDICARE & MEDICARE SERVICES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Center for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C52-A1-16
Baltimore, Maryland 21244-1010

Center for Clinical Standards and Quality/Survey & Certification Group:

Ref: S&C 13-20-Acute Care

DATE: March 15, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Guidance for Hospitals, Critical Access Hospitals (CAHs) and Ambulatory Surgical Centers (ASCs) Related to Various Rules Reducing Provider/Supplier Burden

Memorandum

Memorandum

Summary

- Various Burden Reduction Regulations: adopted
  - On October 24, 2011, the Centers for Medicare & Medicaid Services (CMS) published a final rule revising the ASC Patient Rights regulation at 42 CFR 416.50, effective December 23, 2011 (76 FR 65886).
  - On November 30, 2011, CMS published the Hospital Outpatient Prospective Payment System rule, effective January 1, 2012 (76 FR 74122). The rule included revisions to 42 CFR 489.20(e), governing required notice to patients by hospitals and CAHs that do not have a doctor of medicine (MD) or doctor of osteopathy (DO) present in the hospital or CAH at all times.
  - On May 16, 2012, CMS published two final rules (77 FR 29002 & 77 FR 29034) which included provisions:
    - For Hospitals: Revisions of the Conditions of Participation (CoPs) concerning governing body, patient’s rights, medical staff, nursing services, medical records, pharmaceutical

---

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 29032, May 15, 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
Memo Outlining CMS Changes  www.empsf.org

CMS Final Hospital CoP Changes
Sue Dill Calloway RN MSN JD CPHRM
July 16, 2012

There are important changes that hospital should know about. These changes were published in the Federal Register on May 18, 2012 and become effective on July 16, 2012 and affect every hospital that receives Medicare or Medicaid reimbursement. They make over two dozen changes to the hospital conditions of participation (CoPs). CMS will publish interpretive guidelines on these at a later date. Many of these standards have some impact on the emergency department.

CMS said these changes would modernize the CoPs. In fact, CMS stated these are the most significant changes in over two decades. CMS

CMS Hospital CoP Manual

State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 39, 08-10-13)

Transmittals for Appendix A
Survey Protocol
Introduction
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
Task 3 - Information Gathering/Investigation
Task 4 - Preliminary Decision Making and Analysis of Findings
Task 5 - Exit Conference
Task 6 - Post-Survey Activities
Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module
Regulations and Interpretive Guidelines
§482.2 Provision of Emergency Services by Nonparticipating Hospitals

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
- Will update quarterly and updated June & Nov 2013
  - 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
## Updated Deficiency Data Reports

**CMS.gov**

Updated Deficiency Data Reports

**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 of a specialized nature. Officially, a hospital is a facility owned, operated, and certified by a health care organization that provides health care services to the public.

### Deficiency Data CMS Hospitals Nov 2013

<table>
<thead>
<tr>
<th>Section</th>
<th>Tag Number</th>
<th>Number of Deficiencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration of Drugs/Standing Orders</td>
<td>405</td>
<td>218</td>
</tr>
<tr>
<td>Standing Orders</td>
<td>457</td>
<td>29</td>
</tr>
<tr>
<td>Standing Orders</td>
<td>406</td>
<td>23</td>
</tr>
<tr>
<td>MR Services/Standing Orders/ Date and Time of Order</td>
<td>450</td>
<td>117</td>
</tr>
</tbody>
</table>

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

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?

- **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

Criteria for consideration when creating or revising preprinted physician orders:

<table>
<thead>
<tr>
<th>Content and Format</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Orders reflect current “best practice”</td>
<td></td>
</tr>
<tr>
<td>2. Orders are created in Arial 10- or 12-point font</td>
<td></td>
</tr>
<tr>
<td>3. Orders do not contain unapproved abbreviations</td>
<td></td>
</tr>
<tr>
<td>4. Orders do not contain confusing symbols (e.g., %, ⅛)</td>
<td></td>
</tr>
<tr>
<td>5. Blanket orders are not used. (i.e., Resume home meds)</td>
<td></td>
</tr>
<tr>
<td>6. Order contains space for physician signature, physician ID #, and date</td>
<td></td>
</tr>
<tr>
<td>7. Admission orders include “Admit as Inpatient,” “Outpatient,” or “Observation Status,” as appropriate</td>
<td></td>
</tr>
<tr>
<td>8. Orders are single-sided (Reverse side of sheet should contain additional information or references only)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication Safety</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Abbreviations, when used, are kept to a minimum</td>
<td></td>
</tr>
<tr>
<td>11. Medication orders are not numbered</td>
<td></td>
</tr>
<tr>
<td>12. Medication orders contain drug name, dose, route, and frequency</td>
<td></td>
</tr>
<tr>
<td>13. If multiple routes are listed, order contains criteria to determine which route to use</td>
<td></td>
</tr>
<tr>
<td>14. When possible, order contains dose written as mg. and not as tablets or ml.</td>
<td></td>
</tr>
<tr>
<td>15. Order does not contain multiple ranges</td>
<td></td>
</tr>
<tr>
<td>16. Order contains indication for PRN medications</td>
<td></td>
</tr>
<tr>
<td>17. Time frame is written for IV bolus / IV push orders</td>
<td></td>
</tr>
<tr>
<td>18. Generic and trade names (if applicable) of medication are used</td>
<td></td>
</tr>
</tbody>
</table>

Actions by the Clinical “Best Practice” Committee (CEP) 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.
- Other suggestions from clinical experts.
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 Order Set Standardization and Implementation Workgroup (POSS).
- 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 practice.
- 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

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 that may be important but not be visible to the prescriber, 3) either specify monitoring requirements, 4) reflect current best practices, and 5) are accurate. This section offers examples of commonly observed problems and guidelines to help avoid these errors. (1-5)

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, formulary 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 minimize confusion regarding how inactivated/selected 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 the 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, procedures, 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 “OK” 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 propranolol 20 mg, which may look like 120 mg”).
- 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 July 16, 2012 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
    - 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 Drop: 05-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

DATE: October 24, 2008
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

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

Memorandum Summary

A. Standing Order Clarification: We are clarifying a portion of S&C-09-12 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

<table>
<thead>
<tr>
<th>Old Tag</th>
<th>New Tag</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-404</td>
<td>A-404X</td>
</tr>
<tr>
<td>A-406</td>
<td>A-406X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A-404X</th>
<th>Standard: Preparation and administration of drugs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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 §482.23(c)(5), and accepted standards of practice.</td>
<td></td>
</tr>
<tr>
<td>(6) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.23(c)(5) 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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A-406X</th>
<th>Standard: Preparation and administration of drugs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-406X</td>
<td>Standard: Preparation and administration of drugs.</td>
</tr>
<tr>
<td>(5) 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 §482.23(c)(5), and accepted standards of practice.</td>
<td></td>
</tr>
<tr>
<td>(6) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.23(c)(5) 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.</td>
<td></td>
</tr>
</tbody>
</table>
Tag 405 Standing Orders

- 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 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 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.

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)(4)

What is covered by this regulation?

There is no standard definition of a “standing order” in the hospital community at large (77 FR 29953, 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...
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 July 16, 2012 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 stoke.
- Again the ED staff would need to enter the order in the chart and sign off the orders as discussed.
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
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 2013

- 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

[Image of Subq Insulin Order Set from the Society of Hospital Medicine]
Insulin Drip Protocol

**THE NEW® YALE INSULIN DIP PROTOCOL**

The following insulin drip protocol is intended for use in hyperglycemic adult patients in an ICU setting. It is not specifically tailored for these individuals with diabetes emergencies, such as ketoacidosis. Hyperglycemia (SGLT2) or hyperglycemia hyperosmolar state (HHS).

When these conditions are being considered, or if HHS > 250 mg/dL, an MD should be consulted for further orders. Please notify an MD if the insulin drip is unsuccessful or if any intervention occur that is not adequately addressed by these policies.

- **Insulin Drip**
  1. **Insulin Regimen:** Mix 1 unit Regular Humulin insulin per 1, 000 mg/dL SI level. This regimen may range from increments of 5 to 15 units.
  2. **Initial Dose:** Initial is 20 units of insulin drip through 14-gv tubing, followed by 20 units (2 new sets of insulin tubing, 5 units in the tubing).
  3. **Threshold:** IV insulin titrated in any elderly or patient with comorbidities. If insulin > 150 mg/dL, consider titrate to 150 mg/dL.
  4. **Objective:** Read glucose levels, 90-110 mg/dL.
  5. **Insulin drip rate:** Initial is 25 units of insulin drip per hour. Drip rate should be adjusted to maintain glucose levels between 100-180 mg/dL.

- **Rapid Glucose Monitoring**
  1. Check glucose hourly until stable (defined as 3 consecutive values in target range). In patients on insulin, blood glucose should be monitored every hour.
  2. Once stable, check insulin drip hourly. In patients on insulin, if glucose can be reduced by < 40 mg/dL.
  3. If any of the following occur, consider the following adjustments: insulin drip rate, insulin dose, or other interventions (e.g., fluid restriction, dietary changes, etc.)

- **Changing the Insulin Drip Rate**

- **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 patient experiencing alcohol withdrawal, the Medical ICU at the XXXX Hospital, implemented a symptom triggered alcohol withdrawal order set protocol which incorporated the standardized CIWA-S scale (Clinical Institute Withdrawal Assessment), and treated primarily with oral dosing 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 2006, because of concerns on 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 benzodiazipines 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 benzodiazipine usage due to the lack of adjunct medications to manage associated alcohol withdrawal symptoms such as agitation, delirium, and diaphoresis 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 additional evidence-based 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

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
- References standing orders under PC.03.05.05, EP 1, which states the hospital uses standing orders for restraints

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:
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.

Standing orders and protocols need to be:

- Dated and timed
- Signed off or authenticated by the ordering practitioner or a practitioner responsible for the patient’s care
- In accordance with professional standards of practice, and law and regulation
- 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
Email Updates on Drug Shortages

https://public.govdelivery.com/accounts/USFDA/subscriber/new?pop=t&topic_id=USFDA_22

Email Updates

Welcome to the U.S. Food & Drug Administration (FDA) free e-mail subscription service. When you subscribe to this service, you will receive an e-mail message each time there is an update on the FDA page(s) you select.

To subscribe to this service or update your subscriber preferences, please enter your e-mail address below. You may change your subscriber preferences or cancel your subscription at any time.

We have a strict privacy policy. FDA does not collect personally identifiable information other than your e-mail address which is needed in order to provide the service. FDA will not use or share your e-mail address for any other purpose. The GovDelivery service FDA employs to provide this e-mail subscription service is not a government entity. Information you provide may be made available to GovDelivery and other non-governmental parties.

Email Address *

Submit Cancel

Your contact information is used to deliver requested updates or to access your subscriber preferences.

Privacy Policy · Help
MAPP Drug Shortage Manual

MANUAL OF POLICIES AND PROCEDURES
CENTER FOR DRUG EVALUATION AND RESEARCH

POLICY AND PROCEDURES

OFFICE OF NEW DRUGS
Drug Shortage Management

Table of Contents
PURPOSE ......................................................... 1
BACKGROUND ............................................... 1
POLICY .......................................................... 2
RESPONSIBILITIES AND PROCEDURES ..................... 3
REFERENCES .................................................. 7
DEFINITIONS ................................................ 7
EFFECTIVE DATE ............................................. 8
ATTACHMENT A .............................................. 18
ATTACHMENT B .............................................. 18

PURPOSE
- This MAPP establishes the Center for Drug Evaluation and Research (CDER) procedure for notification, evaluation, and management of drug shortage situations for all CDER products (e.g., investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and clinical products from anywhere).
- This MAPP also establishes the CDER Drug Shortage Program (DSP).


ASHP Drug Shortages Resources

American Society of Health-System Pharmacists

Drug Shortages
Current Shortages
Drugs No Longer Available
Resolved Shortages
Guidelines and Resources
Report a Drug Shortage

Drug Shortages
Welcome to the ASHP Drug Shortages Resource Center. The first step 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.

Subscribe to RSS | Report a Drug Shortage

http://www.ashp.org/shortages

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

**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 label 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

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. Pharmacists 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."

WHAT'S NEW
- Rivaroxaban (Xarelto)
- Dabigatran (Pradaxa)
- Warfarin drug interactions

http://www.uwmcacc.org

Heparin Protocol

Heparin Protocols for UWMC

Intavenous Heparin Administration Orders use
Low/Standard IV Heparin Administration Orders use
for use in patients with excessive bleeding risk

"DO NOT USE for patients with acute thromboembolism, including EVT 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 UFH
### 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 www.empsf.org
- 614 791-1468
- sdill1@columbus.rr.com

(Call with Questions, No emails)

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

Office of Clinical Standards and Quality / Survey & Certification Group

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
  - Reflecet current standards of practice related to loowerrs 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

<table>
<thead>
<tr>
<th>Subject: Revised Appendix A, Interpretive Guidelines for Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revised Material Summary: Classification is provided for 42 CFR 482.23(c), concerning medication administration.</td>
</tr>
<tr>
<td>Effective Date: December 22, 2011</td>
</tr>
<tr>
<td>Implementation Date: December 22, 2011</td>
</tr>
</tbody>
</table>

The revision date and transmittal number apply to the red indicated 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: (N/A if manual not updated.) |
<table>
<thead>
<tr>
<th>R/N/D</th>
<th>Chapter/Section/Subsection/Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>Appendix A(482.43) Standard: Preparation and Administration of Drugs/A-402</td>
</tr>
</tbody>
</table>

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.

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(b)(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

<table>
<thead>
<tr>
<th>Old Tag</th>
<th>New Tag</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-4040</td>
<td>A-4040</td>
</tr>
<tr>
<td>§482.23(a)(1)(ii)</td>
<td>§482.23(c) Standard: Preparation and administration of drugs.</td>
</tr>
<tr>
<td>(1) Drugs and biologicals must 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(a)(1)</td>
<td></td>
</tr>
<tr>
<td>(2)</td>
<td></td>
</tr>
<tr>
<td>A-4040</td>
<td>(2)</td>
</tr>
<tr>
<td>(2) 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.</td>
<td></td>
</tr>
</tbody>
</table>

§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.

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 stricter 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

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.

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.
### CHA Guidelines for Standing Orders, Standardized Procedures and Other Delegation Tools

This is intended as a tool to provide general 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.

<table>
<thead>
<tr>
<th>Standing Orders</th>
<th>What are they and who do they apply to?</th>
<th>What can or can’t they be used for?</th>
<th>Special conditions for Medicare/Medi-Cal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standing orders</td>
<td>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 license.</td>
<td>A 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.</td>
<td>Services billed to Medi-Cal that are the result of routine or standing orders for admission to a hospital are not reimbursable when supplied inadvertently to all patients. All patient orders, including standing orders for particular types of drugs, must be specific to the patient and must represent necessary medical care for the diagnosis or treatment of a particular condition.</td>
</tr>
<tr>
<td>Standing orders</td>
<td>Condensed 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 (AHP) or licensed independent practitioner (LIP) may initiate treatment pursuant to a standing order.</td>
<td></td>
<td>While internally CMS has generally focused on the use of standing orders, CMS recently proposed a rule that would allow hospitals to use standing orders under certain circumstances.</td>
</tr>
<tr>
<td>Standing orders</td>
<td>May be issued by a physician to authorize a nurse practitioner (“NP”), or physician assistant (“PA”), to provide specified services.</td>
<td>In a hospital, standing orders for drugs may be used for specified patients when prescribed by a person licensed to prescribe. A copy of the standing order for a specific patient must be dated, time-stamped, signed by the prescriber, and included in the patient’s medical record. Each standing order must include:</td>
<td></td>
</tr>
<tr>
<td>Standing orders</td>
<td>May be used to medical assistants are limited and subject to specific rules and regulations.</td>
<td></td>
<td>Standing orders must be updated periodically and be subject to any guidelines jointly promulgated by the Medical Board of California and the Board of Registered Nursing.</td>
</tr>
</tbody>
</table>

### CHA Guidelines for Standing Orders, Standardized Procedures and Other Delegation Tools

This is intended as a tool to provide general 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.

<table>
<thead>
<tr>
<th>Standardized Procedures</th>
<th>What are they and who do they apply to?</th>
<th>What can or can’t they be used for?</th>
<th>Special conditions for Medicare/Medi-Cal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardized procedures</td>
<td>Standardized procedures may be used by RNs, nurse practitioners, and physician assistants to authorize the use of standardized procedures in the context of administering drugs to patients, we believe that standardized procedures may have a much broader application than just drug administration.</td>
<td>Note: While many of the statutes and regulations described below deal almost exclusively with the use of standardized procedures in the context of administering drugs to patients, we believe that standardized procedures may have a much broader application than just drug administration.</td>
<td>Under both the Medi-Cal and Medicare programs, standing orders cannot be used to authorize the restraint of a patient, including when using drugs that meet the definition of a restraint.</td>
</tr>
</tbody>
</table>

(1) Policies and procedures 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.

(2) Policies and procedures 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.

The policies and procedures shall be subject to any guidelines jointly promulgated by the Medical Board of California and the Board of Registered Nursing.
## 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

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_Appendixtoc.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.

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

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
Resources


This presentation is intended solely to provide general information and does not constitute legal advice. Attendance at the presentation or later review of these printed materials does not create an attorney-client relationship with the presenter(s). You should not take any action based upon any information in this presentation without first consulting legal counsel familiar with your particular circumstances.
? QUESTIONS ?

Do you have a question that you would like answered during the Q&A session? Simply follow the instructions below.

You may enter your question in the chat box in the webinar room.

OR

If you are listening to the conference via streaming audio through your computer, you must dial in on the telephone at 1-866-543-4746 to ask your question live. After dialing-in (or if you are already dialed-in):

1. Press *1 on your touchtone phone. If you are using a speaker phone, please lift the receiver and then press *1.

2. If you would like to withdraw your question, press *1.

The End!

- Sue Dill Calloway RN, Esq. CPHRM
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education Consulting
- Chief Learning Officer of the Emergency Medicine Patient Safety Foundation at www.empsf.org
- 614 791-1468
- sdill1@columbus.rr.com