



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
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 community to advance safe practices and develop a common understanding of both best practices and important operational definitions as they pertain to standing orders, preprinted order sets, and effective methods to promote evidence-based medicine.
- C. Signatures on Order Sets:** We are also clarifying the circumstances under which signatures are required on pre-printed order sets.
- D. Use of Rubber Stamps:** We add an information-only note to the Guidance as an alert to note that some payers, including Medicare, do not accept the use of rubber stamps for payment purposes. The Conditions of Participation (CoPs), however, do not prohibit such use.

A. Standing Orders

On February 8, 2008 and April 11, 2008 we issued via memoranda S&C-08-12 and S&C-08-18 an advance copy of updates to the State Operations Manual (SOM) for the SOM Hospital Appendix A. The official version of these updates was issued on October 17, 2008 (Transmittal 37, CMS Manual System, Publication 100-07, State Operations Provider Certification). We are taking this opportunity to clarify expectations regarding standing orders as they pertain to the following regulation:

§482.23(c)(2) 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 by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).

The February 8th and April 11th advance copies of surveyor guidance for the SOM Hospital Appendix A each contained the following additional note:

Note: If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care

We have removed this note from the on-line versions of the S&C memoranda as well as from the final edition of the SOM Hospital Appendix A. We concluded that the note may cause confusion about the ability of rapid response teams and other health care professionals in hospitals to initiate effective responses to emergency situations and/or to implement best practices for providing necessary patient care in a timely fashion under the aegis of standing orders.

The use of standing orders must be documented as an order in the patient's medical record and authenticated by the practitioner responsible for the care of the patient, as the regulations at 42 CFR §482.23(c)(2) and §482.24(c)(1) require, but the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances. We would expect to see that the standing order had been entered into the order entry section of the patient's medical record as soon as possible after implementation of the order (much like a verbal order would be entered), with authentication by the patient's physician.

We also note that there may be a misconception that CMS regulations require all orders to be written by a "community" physician who admitted the patient to the hospital. This is incorrect. 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. This includes not only the attending physician, but also hospitalists, intensivists, and residents. In addition, 42 CFR 482.12(c)(1)(i) recognizes the authority of a doctor of medicine or osteopathy to delegate tasks, including writing orders, to other qualified health care personnel, such as nurse practitioners and physician assistants, to the extent recognized under State law.

B. Future Directions on Standing Orders

CMS strongly supports the use of evidence-based protocols to enhance the quality of care provided to hospital patients. Many hospitals employ such protocols developed by physicians and other clinical staff that are designed to standardize and optimize patient care in accordance with current clinical guidelines or standards of practice.

CMS, through its policies, payments and “*Hospital Compare*” Web site, promotes hospital-specific compliance with evidence-based standards of practice for treatment of certain conditions and/or prevention of infection. Many hospitals have developed protocols and preprinted (or computerized) order sets that are ready to be used with patients diagnosed with acute myocardial infarction, congestive heart failure, or community-acquired pneumonia, or for patients undergoing surgery. Many protocols help enhance hospital performance in important areas of care that are measured and reported as part of the CMS measurement and reporting of hospital quality data.

Hospitals also have created formal protocols for a number of other scenarios, e.g., for “Rapid Response Teams.” Such protocols are designed to bring hospital staff with critical care skills to the bedside of patients when clinical changes (that may portend the patient’s deterioration) are recognized by staff (or by the patient or patient’s family) in the patient’s unit.

While there is significant merit to the use of standing orders, there is also the potential for harm to patients if hospitals use such orders so that nurses or other clinical staff are routinely expected to make clinical decisions outside their scope of practice. This is a complex issue which requires careful consideration by hospitals, physicians, nurses and other licensed health care professionals, experts in patient safety and quality improvement, and patients.

We therefore intend to engage with the professional community in consensus-building efforts to advance safe practices and develop a common understanding of both best practices and important operational definitions as they pertain to standing orders, pre-printed order sets, and effective methods to promote evidence-based medicine. We further intend to build on the results of such a process to inform CMS decision-making. In the next several months we hope to formulate the specific steps and partnerships necessary to accomplish these goals.

C. Preprinted Order Sets

We refer to a “preprinted order set” as a tool generally designed to assist qualified practitioners as they write orders. Order sets may include computerized programs that are the functional equivalent of hard copy preprinted order sets. Such tools may include a menu of medications or actions from which the qualified practitioner makes selections to be applied to a particular patient. They sometimes include a standard combination of medications and actions to be followed without amendment whenever the physician selects that order.

Preprinted order sets are permitted under the CMS Conditions of Participation (CoPs). CMS recognizes the role that pre-printed order sets can play in reducing medication errors and promoting optimal treatments for patients with certain conditions.

Preprinted order sets should be reviewed and approved by the hospital’s medical staff. Under the CoPs at §482.24(c)(1), “all orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering physician or another practitioner who is responsible for the care of the patient as specified under 482.12(c)...” We consider this requirement to include orders employing preprinted order sets.

In the February 8th and April 11th advance copies of the updated SOM we stated the following in interpreting §482.24(c)(1): “Where a practitioner has written a set of orders or is using a preprinted order set contained on one page, or on several pages, the physician must sign, date, and time each page of orders.”

Upon closer review we find agreement with commenters that CMS has discretion under the regulation at §482.24(c)(1) to interpret the requirement in a manner that is less burdensome but is still consistent with the regulation and ensures that the ordering practitioner’s intent is clear on those order sets that provide a menu of choices for a physician to make, or where portions of the preprinted order set may have been amended.

We are therefore revising the guidance (revised advance copy attached) to read as follows:

“When a practitioner is using a preprinted order set, the ordering practitioner may be in compliance with the requirement at §482.24(c)(1) to date, time and authenticate an order if the practitioner accomplishes the following:

- ***Last page:*** Sign, date, and time the last page of the orders, with the last page also identifying the total number of pages in the order set.
- ***Pages with Internal Selections:*** Sign or initial any other (internal) pages of the order set where selections or changes have been made.
 - The practitioner should initial/sign the top or bottom of the pertinent page(s)
 - The practitioner should also initial each place in the preprinted order set where changes, such as additions, deletions, or strike-outs of components that do not apply, have been made
 - It is not necessary to initial every preprinted box that is checked to indicate selection of an order option, so long as there are no changes made to the option(s) selected.

In the case of a pre-established electronic order set, the same principles would apply, so that the practitioner would date, time and authenticate the final order that resulted from the electronic selection/annotation process, with the exception that pages with internal changes would not need to be initialed or signed if they are part of an integrated single electronic document.”

D. Use of Rubber Stamps

The CoPs do not prohibit the use of rubber stamps in a hospital setting, when properly controlled, for authentication of medical record entries. However, as a point of information for surveyors and providers, we are taking this opportunity to add an information-only statement to the interpretive guidance for §482.24(c)(1) to note that some payers, including Medicare, may not accept such stamps as sufficient documentation to support a claim for payment.

If you have additional questions or concerns, please contact David Eddinger at 410-786-3429 or via email at david.eddinger@cms.hhs.gov.

Page 5 – State Survey Agency Directors

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management
Attachment: (1)

Revised Interpretive Guidelines – Advance Copy

§482.23(c) Standard: Preparation and Administration of Drugs

* * *

A-0406

482.23(c)(2) 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 by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).

Interpretive Guidelines §482.23(c)(2)

All orders for drugs and biologicals, with the exception of influenza and pneumococcal polysaccharide vaccines, must be documented and signed by a practitioner who is authorized by hospital policy, and in accordance with State law, to write orders and who is responsible for the care of the patient as specified under §482.12(c). In accordance with §482.12(c)(1), practitioners who are authorized to provide care for Medicare patients include:

- A doctor of medicine or osteopathy;
- A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;
- A doctor of optometry who is legally authorized to practice optometry by the State;
- A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist;
- A clinical psychologist as defined in §410.71, but only with respect to clinical psychologist services as defined in §410.71 and only to the extent permitted by law.
- A doctor of dental surgery or dental medicine.

Consistent with delegation agreements, collaborative practice agreements, hospital policy, and the requirements of State law, Nurse Practitioners and Physician Assistants responsible for the care of specific patients are also permitted to order drugs and biologicals.

Influenza and pneumococcal polysaccharide vaccines may be administered per physician-approved hospital policy after an assessment of contraindications.

In accordance with standard practice, elements that must be present in orders for all drugs and biologicals to ensure safe preparation and administration include:

- Name of patient (present on order sheet or prescription);
- Age and weight of patient, when applicable;
- Date and time of the order;
- Drug name;

- Dose, frequency, and route;
- Exact strength or concentration, when applicable;
- Quantity and/or duration, when applicable;
- Specific instructions for use, when applicable; and
- Name of prescriber.

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding orders. Any questions about orders for drugs or biologicals are expected to be resolved prior to the preparation, or dispensing, or administration of the medication.

* * *

§482.24(c) Standard: Content of Record

The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

* * *

A-0450

482.24(c)(1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

Interpretive Guidelines §482.24(c)(1)

All entries in the medical record must be **legible**. Orders, progress notes, nursing notes, or other entries in the medical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.

All entries in the medical record must be **complete**. A medical record is considered complete if it contains sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers. With these criteria in mind, an individual entry into the medical record must contain sufficient information on the matter that is the subject of the entry to permit the medical record to satisfy the completeness standard.

All entries in the medical record must be **dated, timed, and authenticated**, in written or electronic form, by the person responsible for providing or evaluating the service provided.

- The time and date of each entry (orders, reports, notes, etc.) must be accurately documented. Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or timelines of various signs, symptoms, or events. (71 FR 68687)
- The hospital must have a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
- The hospital must have a method to require that each author takes a specific action to verify that the entry being authenticated is his/her entry or that he/she is responsible for the entry, and that the entry is accurate.

The requirements for dating and timing do not apply to orders or prescriptions that are generated outside of the hospital until they are presented to the hospital at the time of service. Once the hospital begins processing such an order or prescription, it is responsible for ensuring that the implementation of the order or prescription by the hospital is promptly dated, and timed in the patient's medical record.

When a practitioner is using a preprinted order set, the ordering practitioner may be in compliance with the requirement at §482.24(c)(1) to date, time and authenticate an order if the practitioner accomplishes the following:

- **Last page:** Sign, date, and time the last page of the orders, with the last page also identifying the total number of pages in the order set.
- **Pages with Internal Selections:** Sign or initial any other (internal) pages of the order set where selections or changes have been made.
 - The practitioner should initial/sign the top or bottom of the pertinent page(s)
 - The practitioner should also initial each place in the preprinted order set where changes, such as additions, deletions, or strike-outs of components that do not apply, have been made.
 - It is not necessary to initial every preprinted box that is checked to indicate selection of an order option, so long as there are no changes made to the option(s) selected.

In the case of a pre-established electronic order set, the same principles would apply, so that the practitioner would date, time and authenticate the final order that resulted from the electronic selection/annotation process, with the exception that pages with internal changes would not need to be initialed or signed if they are part of an integrated single electronic document.

Authentication of medical record entries may include written signatures, initials, computer key, or other code. For authentication, in written or electronic form, a method must be established to identify the author. When rubber stamps or electronic authorizations are used for authentication, the hospital must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals whose signature they represent. There shall be no delegation of stamps or authentication codes to another individual. *It should be noted that some insurers and*

other payers may have a policy prohibiting the use of rubber stamps as a means of authenticating the medical records that support a claim for payment. Medicare payment policy, for example, no longer permits such use of rubber stamps. Thus, while the use of a rubber stamp for signature authentication is not prohibited under the CoPs and analysis of the rubber stamp method per se is not an element of the survey process, hospitals may wish to eliminate their usage in order to avoid denial of claims for payment.

Where an electronic medical record is in use, the hospital must demonstrate how it prevents alterations of record entries after they have been authenticated. Information needed to review an electronic medical record, including pertinent codes and security features, must be readily available to surveyors to permit their review of sampled medical records while on-site in the hospital.

When State law and/or hospital policy requires that entries in the medical record made by residents or non-physicians be countersigned by supervisory or attending medical staff members, then the medical staff rules and regulations must address counter-signature requirements and processes.

A system of auto-authentication in which a physician or other practitioner authenticates an entry that he or she cannot review, e.g., because it has not yet been transcribed, or the electronic entry cannot be displayed, is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the entry after it was created. In addition, failure to disapprove an entry within a specific time period is not acceptable as authentication.

The practitioner must separately date and time his/her signature authenticating an entry, even though there may already be a date and time on the document, since the latter may not reflect when the entry was authenticated. For certain electronically-generated documents, where the date and time that the physician reviewed the electronic transcription is automatically printed on the document, the requirements of this section would be satisfied. However, if the electronically-generated document only prints the date and time that an event occurred (e.g., EKG printouts, lab results, etc.) and does not print the date and time that the practitioner actually reviewed the document, then the practitioner must either authenticate, date, and time this document itself or incorporate an acknowledgment that the document was reviewed into another document (such as the H&P, a progress note, etc.), which would then be authenticated, dated, and timed by the practitioner.

Survey Procedures §482.24(c)(1)

Review a sample of open and closed medical records.

- Determine whether all medical record entries are legible. Are they clearly written in such a way that they are not likely to be misread or misinterpreted?
- Determine whether orders, progress notes, nursing notes, or other entries in the medical record are complete. Does the medical record contain sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers?

- Determine whether medical record entries are dated, timed, and appropriately authenticated by the person who is responsible for ordering, providing, or evaluating the service provided.
- Determine whether all orders, including verbal orders, are written in the medical record and signed by the practitioner who is caring for the patient and who is authorized by hospital policy and in accordance with State law to write orders.
- Determine whether the hospital has a means for verifying signatures, both written and electronic, written initials, codes, and stamps when such are used for authorship identification. For electronic medical records, ask the hospital to demonstrate the security features that maintain the integrity of entries and verification of electronic signatures and authorizations. Examine the hospital's policies and procedures for using the system, and determine if documents are being authenticated after they are created.