



NORTH CAROLINA RESPIRATORY CARE BOARD

1100 Navaho Drive, Suite 242
Raleigh, NC 27609

May 19, 2010

William Mashburn, RCP
Respiratory Care Services
First Health Moore Regional Hospital
155 Memorial Drive
Pinehurst, NC 28374

Dear Mr. Mashburn,

This letter is sent on behalf of the North Carolina Respiratory Care Board in reference to your letter of March 30, 2010 requesting the Board's interpretation of state statutes and rules as it relates to respiratory care practitioners writing orders supported by a Protocol.

The Respiratory Care Board discussed your request during its regular scheduled meeting held on April 8, 2010 and approved the following interpretation of the Respiratory Care Practice Act and Board rules concerning your request:

The Board has determined the process your facility has in place is supported by the Respiratory Care Practice Act and that the RCP does not need to write orders to be counter signed by the physician if the treatment changes that are being made are within the limits set by the facility approved protocol. The RCP must document all changes to the treatment plan in the progress notes to inform the physician. Any changes outside the approved protocol must first be approved by the patient's physician, with all verbal orders written in the patient's chart. I have included a statement from Centers for Medicare and Medicaid (CMS) dated October 24, 2008, which clarifies standing orders.

Please advise if you have any other questions about this issue.

Regards,

Floyd E. Boyer, RRT, RCP
Executive Director



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.