



Liberty Place, Suite 700  
325 Seventh Street, NW  
Washington, DC 20004-2802  
(202) 638-1100 Phone  
[www.aha.org](http://www.aha.org)

April 11, 2008

Kerry N. Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., 314G  
Washington, DC 20201

Dear Mr. Weems:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) wishes to express its concern over a Centers for Medicare & Medicaid Services (CMS) survey and certification letter sent to state survey agency directors on February 8, 2008 (S&C-08-12). The interpretive guidelines contained in the letter pertaining to regulatory changes to the Hospital Conditions of Participation (CoPs) contradict accepted standards of care in hospitals and have the potential to place patient safety in jeopardy. As written, the guidelines could halt hospitals' progress on the very quality improvement initiatives CMS is advocating.

Section 482.23(c)(2) of the CoPs states, "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..." This essentially requires that all orders for drugs and biologicals must be documented and signed by a practitioner responsible for the patient's care. This is appropriate; orders should be documented and signed.

However, in CMS' February 8 letter to the state survey agencies, the interpretive guidelines for this CoP contain an additional note that states, "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." This note implies that *all* protocols and standing orders require a physician's order prior to initiation of treatment for each patient. This interpretation is clearly beyond the scope of the language of the CoP.



The note's language likely will lead to patient harm, is counter to accepted standards of care and will impede hospitals' progress on quality improvement initiatives. The guidance runs counter to standards of care for triage protocols in the emergency department, individual physician standing orders, and medical staff-approved protocols. Standing orders are used throughout the hospital to help ensure patients get the care they need, particularly when care is needed urgently. Our ability to deliver care quickly would be affected by the language in the interpretive guideline. For example:

- Triage protocols are used in the emergency department so that nurses can start a rapid infusion of intravenous fluids to children who are severely dehydrated because they have been vomiting, and that can be done before the patient sees a physician.
- Patients presenting in the emergency department with asthma symptoms are treated per protocol with albuterol and atrovent inhalers immediately.
- In a code situation, the responding code team administers emergency medications per protocol and does not wait for a physician to give the order.

These are just a few of the most serious situations in which the necessity to wait for a physician's order to initiate a standing order or medical staff-approved protocol could place a patient's life in danger. Clearly, such protocols have not been adopted simply for convenience, but as practical solutions to providing the best care possible to every patient. All protocols and standing orders are approved by a hospital's medical staff, and many now are considered by professional organizations to be best practices of care.

In addition, the interpretive guideline may actually prevent hospitals from successfully engaging in quality initiatives. For example, the quality measures used under the annual payment update pay-for-reporting program include a measure for giving heart attack patients aspirin on arrival at the emergency department. Many hospitals have established chest pain protocols that allow nurses to give aspirin to chest pain patients before they are seen by a physician. Such protocols would be halted by the new interpretive guideline.

We believe that the intent of the CoP is for all standing orders and medical staff orders for drugs and biologicals to be written in the patient's chart and later signed by a practitioner responsible for the care of the patient. Again we note that this is an appropriate requirement. However, we urge CMS to take immediate action to change the language in the interpretive guideline, which goes beyond the requirements of the CoP, and to provide clarification to the hospital field and to state survey agencies about the change.

Kerry Weems  
April 11, 2008  
Page 3 of 3

I will follow up with your office to schedule a time to discuss this issue. Should you have any questions, please contact me or Nancy Foster, vice president for quality and patient safety, at (202) 626-2337 or [nfoster@aha.org](mailto:nfoster@aha.org).

Sincerely,

Rick Pollack  
Executive Vice President

Cc: Barry Straube, M.D.