

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S3-02-01  
Baltimore, Maryland 21244-1850



**Office of Clinical Standards and Quality**

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OCT 12 2010

David T. Tayloe, Jr., MD, FAAP  
Immediate Past President  
American Academy of Pediatrics  
Department of Federal Affairs  
Homer Building, Suite 400 N  
601 13<sup>th</sup> Street NW  
Washington, DC 20005

Dear Dr. Tayloe:

Thank you for your letter on behalf of your organization's members requesting guidance on the Medicare requirements for standing orders, particularly those for healthy term newborns. Thank you also for the supporting documentation that you enclosed. The use of standing orders in the hospital setting is an issue in which CMS is currently and actively engaged, and we welcome the opportunity to help clarify our position on it.

In the October 24, 2008 CMS memorandum (CMS S&C-09-10) that you mention in your letter, CMS pointed out its strong support of the use of evidence-based protocols, developed by the medical staff and based on recognized standards of practice, that advance the quality of care provided to patients. The nationally recognized guidelines and recommendations for administration of hepatitis B vaccine, Vitamin K, and prophylactic ophthalmic antibiotic to a healthy newborn immediately upon admission to a hospital term nursery that you mention are a prime example of the type of evidence-based medicine that CMS hopes all hospitals are using to develop written protocols, treatment regimens, and orders (including standing orders) to enhance and optimize patient care.

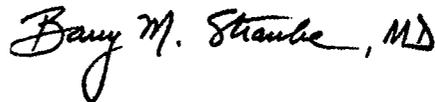
As was discussed in S&C-09-10, often these protocols are formalized by the hospital through the development and use of pre-printed order sets or computerized programs that are the equivalent of hard-copy order sets. These order sets are permitted under the CMS conditions of participation (CoPs). Furthermore, CMS recognizes that these order sets can be used to great effect by hospitals attempting to promote evidence-based patient care. **A physician, or other qualified and licensed practitioner authorized by the hospital and the State to write orders, can use these order sets to quickly and effectively implement patient care protocols. The practitioner may issue the order to implement a particular protocol, and its included order set, for a patient either in writing or verbally. Or the hospital may have a policy, approved by the medical staff, which allows for the initiation of an order set for a specific type of patient (e.g., a healthy term newborn being admitted to the term nursery), provided that the order set is reviewed and authenticated by the responsible practitioner as soon as possible after its initiation.** Under

the CoPs, all orders, whether written, pre-printed, electronic, or verbal, must be authenticated and documented in the patient's medical record by a practitioner responsible for the care of the patient. But, as was stated in the above mentioned memorandum, "the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances." While the healthy newborn interventions that you mention are clearly not part of an emergency response, they are excellent examples of both "timely and necessary care" and "patient safety advances," and clearly fulfill the intent of the language included in the 2008 CMS memorandum.

I want to thank you for sharing the concerns that the members of your organization have regarding this issue. Thank you also for the commitment that the American Academy of Pediatrics has shown toward advancing the use of evidence-based recommendations and guidelines in order to provide safe and effective care for newborns. I hope that I have helped to clarify the CMS position on the use of standing orders in this context.

Should you have any further questions regarding this issue or any of the other Medicare hospital CoPs, please feel free to contact either me or the member of my staff responsible for this area, Scott Cooper, at 410-786-9465 or via e-mail at [Scott.Cooper@cms.hhs.gov](mailto:Scott.Cooper@cms.hhs.gov).

Sincerely,

A handwritten signature in black ink that reads "Barry M. Straube, MD". The signature is written in a cursive style with a large, looped initial 'B'.

Barry M. Straube, M.D.  
CMS Chief Medical Officer  
Director, Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services