



American Society of
Health-System Pharmacists
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July 23, 2008

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

Dear Mr. Weems:

The American Society of Health-System Pharmacists (ASHP) is requesting clarification regarding a Centers for Medicare & Medicaid Services (CMS) letter sent to State Survey Agency Directors from the Director of the Survey and Certification Group dated February 8, 2008 (Ref: S&C-08-12) (the letter). For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

The letter contains interpretive guidelines that correspond to the regulatory changes published on November 27, 2006 amending Hospital Conditions of Participation (CoPs) pertaining to requirements for history and physical examinations; authentication of verbal orders; securing medications; and post-anesthesia evaluations.

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...."

ASHP agrees that orders for drugs and biologicals must be documented and signed by an authorized practitioner who is responsible for the care of the patient. Additionally, ASHP policy supports the concept of therapeutic interchange of various drug products by pharmacists under arrangements where pharmacists and authorized prescribers interrelate

on behalf of patient care. However, the Society is concerned that the interpretive guidelines may be read to require a physician's order prior to instituting a protocol or standing order that has already been approved by the Pharmacy and Therapeutics Committee (P&T Committee). ASHP is also concerned that the interpretive guidelines might be interpreted to prevent a hospital from authorizing therapeutic interchange without a physician's order.

The interpretive guidelines state: "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."

ASHP seeks clarification from CMS that:

1. Orders for drugs and biologicals must be documented and signed by an authorized practitioner who is responsible for the care of the patient. The authorized practitioner may sign the patient's chart following the initiation of a protocol or standing order that has already been approved by the P&T Committee.
2. Therapeutic interchange of various drug products by pharmacists under arrangements where pharmacists and authorized prescribers interrelate on behalf of patient care is permitted when a hospital authorizes therapeutic interchange without a physician's order.

Without these clarifications, ASHP is very concerned that programs already existing in hospitals will no longer be permitted under the interpretive guidelines. Many hospitals have established protocols that enable pharmacists to convert eligible hospital inpatients from intravenous medications to therapeutically equivalent oral drugs without a specific physician's order. Because only the route of administration is changed, without compromising clinical efficacy, and because the conversion is timely without the delay associated with obtaining a physician's order, these programs have resulted in avoidance of adverse events associated with the IV route of administration, increased patient comfort and mobility, and decreased cost of care.

Other protocols allow pharmacist-initiated therapeutic substitution for safety, formulary management, or pharmacoeconomic reasons. As in the prior example, these protocols are medical staff-approved and do not require a specific physician's order to initiate. Studies have shown that these programs provide an equivalent level of care, and significantly reduce costs.

Furthermore, protocols for pharmacokinetic dosing and anticoagulation management allow pharmacists to adjust medication therapy for drugs where the therapeutic dose range, i.e. neither subtherapeutic nor toxic, is narrow and dependent on appropriately performed and closely monitored clinical laboratory tests. The benefits of these programs in reducing under- and over-treatment of high-risk medications, and the costs

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associated with suboptimal care and adverse drug events, have been extensively documented.

The examples above provide strategies to enhance care, improve safe medication use based on protocols that are medical staff-approved and do not require an initiating order from the physician, and reduce costs. Without the clarifications ASHP is seeking, the Society believes that these types of programs will be prohibited.

Feel free to contact Justine Coffey, Director of Federal Regulatory Affairs, if you have any questions regarding our comments. She can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian M. Meyer", with a long horizontal flourish extending to the right.

Brian M. Meyer
Director, Government Affairs Division

CC: Barry M. Straube, M.D.