

**2006-2007 BOARD**

**PRESIDENT**

Gabriel N. Hortobagyi, MD

**IMMEDIATE PAST PRESIDENT**

Sandra J. Horning, MD

**PRESIDENT-ELECT**

Nancy E. Davidson, MD

**SECRETARY/TREASURER**

Bruce J. Roth, MD

**INTERIM EXECUTIVE**

**VICE PRESIDENT AND CEO**

Joseph S. Bailles, MD

**DIRECTORS**

Howard A. Burris, III, MD

S. Gail Eckhardt, MD

Alexander M. Eggermont, MD, PhD

Peter D. Eisenberg, MD

Waun Ki Hong, MD

Thomas A. Marsland, MD

Barbara L. McAneny, MD

Bruce D. Minsky, MD

Hyman B. Muss, MD

Martine J. Piccart-Gebhart, MD, PhD

Gregory H. Reaman, MD

Nagahiro Saijo, MD, PhD

George W. Sledge, Jr., MD

Jamie Hayden Von Roenn, MD

June 28, 2006

Mark McClellan, MD, PhD  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1270-P  
Humphrey Building, Room 445-G  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: Proposed Rules on Competitive Acquisition for Durable Medical Equipment  
(CMS-1270-P)

Dear Dr. McClellan:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed rules on the competitive acquisition program for durable medical equipment (DME) published in the Federal Register on May 1, 2006. ASCO is the national organization representing physicians who specialize in the treatment of cancer.

As discussed below, ASCO has two concerns with the proposed rules related to the use of ambulatory infusion pumps, which oncologists use to administer certain types of chemotherapy to patients:

- Although physicians are permitted to submit bids to become vendors under the program, it seems likely that physicians will fail to qualify if there is a large vendor with substantial capacity that is also bidding. ASCO requests that physicians who furnish ambulatory infusion pumps only to their own patients should be permitted to do so if they are willing to accept the Medicare payment amount determined in the competition.
- The proposal appears to require vendors of ambulatory infusion pumps to supply the drugs involved as well as the pumps. This approach could be disruptive to appropriate cancer care, and ASCO requests that physicians should be permitted to continue furnishing the drugs even if the pump is obtained from a vendor.

2007 Annual Meeting  
June 1-June 5, 2007  
Chicago, Illinois

For more information  
about ASCO Meetings  
Phone: (703) 631-6200  
Fax: (703) 818-6425  
Website: [www.asco.org](http://www.asco.org)

## **Background**

Under the proposed rules, CMS would phase in a competitive acquisition program for DME. In the case of items subject to the program that are furnished in the geographical areas covered by the program, Medicare would reimburse for an item only if it is obtained from one of the vendors selected in the competitive bidding process.

The proposed bidding process would require each bidder to specify the volume of items that it is capable of supplying. CMS would select as winning bidders the vendors with the lowest bids but only as many such bidders as is necessary to fulfill the estimated quantity required. The law requires that there be at least two vendors selected. If the lowest bidding vendors have a large capacity to provide items, it seems likely that only the minimum two would be approved.

The proposal specifies that bidders would have to furnish supplies used in connection with the DME, including drugs. Thus, in the case of ambulatory infusion pumps, the vendors would apparently be required to supply the drugs administered through the pumps.

Physicians who furnish DME to their patients would be required to bid successfully in order to continue doing so if the DME at issue is subject to the competitive acquisition program. Unlike other bidders, who must furnish DME to the general community, physicians who are successful bidders may furnish DME only to their own patients.

## **Ambulatory Infusion Pumps**

Oncologists often furnish ambulatory infusion pumps to their patients. These pumps are used in certain chemotherapy regimens that call for continuous infusion by pump. The so-called Stark law, which generally prohibits physicians from furnishing DME to their patients, expressly allows physicians to furnish infusion pumps.

ASCO is concerned about how the proposed rules would affect the ability of oncologists to furnish ambulatory infusion pumps to their patients. First, under the proposal, if the lowest bidders are able to satisfy the volume of DME needed, no further bidders will be selected. If there is a bidder with a large capacity, this method seems likely, as a practical matter, to exclude physicians from the possibility of bidding successfully. ASCO suggests that physicians who intend to serve only their own patients should not be subject to selection in the same manner as vendors who intend to serve the general community. The rules should permit physicians who are willing to provide ambulatory infusion pumps at the rate approved for successful bidders to continue to do so.

Second, we question the proposed requirement that vendors of ambulatory infusion pumps must supply the drugs involved. Currently, even if a pump is obtained from an outside vendor, the drugs involved are typically prepared in the oncologist's office. Under this approach, oncologists have confidence in the integrity of the drugs and the accuracy of the amount of drug



in the pump. The logistics of requiring the pump vendor to prepare the drugs for specific patients would also seem to present practical problems that could be disruptive to appropriate patient care. ASCO requests that, even if a pump is obtained from an outside vendor, physicians should be permitted to furnish the drugs involved.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD  
Interim Executive Vice President and CEO