American Hospital Association

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

June 27, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies and Other Issues (CMS-1270-P)

Dear Dr. McClellan:

The American Hospital Association (AHA), on behalf of our 4,800 member hospitals and health care systems, and 35,000 individual members, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule concerning competitive bidding for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). This proposal is of great interest among hospital-based DMEPOS providers and could adversely impact the continuity of care for post-acute patients and hospitals. CMS must ensure that hospital discharge planners assisting patients' transition from the hospital to home/community are not hindered by being forced to deal with multiple external DMEPOS vendors, which would delay discharge and increase the cost of care.

Background on Hospital-based DMEPOS Programs

Hospitals providing DMEPOS differ significantly from commercial vendors that provide only DMEPOS. For hospitals, DMEPOS are integrated into a multi-disciplinary package of medical services, which often involves complex care, continues beyond the inpatient setting and may include a combination of outpatient services, home health care, inpatient rehabilitation, skilled nursing, DMEPOS delivery/service/education, and other services. Timely access to the DMEPOS prescribed by hospital physicians is essential for proper execution of a patient's plan of care, including a return to home and community with maximum function and quality of life.

Hospitals also differ from commercial DMEPOS suppliers because they must preserve a positive, ongoing relationship with the community, and meet extensive mandatory certification and quality criteria in order to participate in the Medicare program.

Hospitals provide DMEPOS to patients in several ways. Some hospitals operate a DMEPOS operation that serves only their patients, others provide DMEPOS for the community-at-large, others rely solely on external DMEPOS vendors, and the remaining hospital-based DMEPOS programs are hybrids.

General Concerns

The proposed rule raises several broad concerns about CMS' plans to phase-in competitive bidding for selected DMEPOS items. First, the proposed rule lacks specificity for many key components of the agency's competitive bidding program, such as an explicit recommendation on the DMEPOS items to be included in Phase I, a targeted list of metropolitan areas to be included in Phase I, specific quality criteria and a concrete description of the price-setting methodology, among other provisions. These should be clearly articulated in a proposed rule and subjected to public comment, which has not been done in this case. Second, CMS' effort to collect direct beneficiary input on DMEPOS priorities and needs, as discussed at the recent DMEPOS Payment Advisory and Oversight Committee meeting, was limited and unrepresentative of the patient population. Finally, the AHA is concerned that CMS treats hospital-based DMEPOS programs the same as commercial suppliers when they are not, and when hospitals were not part of the competitive bidding pilot demonstrations in Florida and Texas.

Although hospital-based DMEPOS providers were not included in the billing pilots, several questions and concerns about unintended consequences remain. The medically complex patients served by hospital-based DMEPOS are more sensitive to disruptions in DMEPOS access, and product selection could adversely impact the recovery and healing process, as well as delay discharge from the hospital.

Given these issues, CMS should implement the following recommendations:

- Issue an interim final rule to allow CMS to present a more detailed proposal for public comment and to garner further input from stakeholders. The lack of detail in the proposed rule makes it difficult for stakeholders to meaningfully comment.

- Proceed cautiously in implementing competitive bidding for DMEPOS providers that also are health care providers since they were not involved in the pilot. In particular, CMS should give consideration to the hospital-specific recommendations made below, which preserve continuity of care for Medicare beneficiaries in hospitals who need DMEPOS.

Hospital-specific Recommendations

Payment Basis
CMS intends to use its statutory authority to adjust Medicare payments for DMEPOS products in other parts of the country that do not participate in competitive bidding based on the agency's experience with products included in the competitive bidding program. For example, if CMS

achieves a 20 percent savings on hospital beds through competitive bidding in participating metropolitan areas, the agency could reduce Medicare payments throughout the country (not necessarily by 20 percent) without requiring a competitive bidding process in the new areas. CMS notes that it has "not yet developed a detailed methodology" for using this authority and invites comments on this issue. **Without a specific proposal to comment on, we strongly object to CMS using the final rule (or a manual instruction) to spell out the agency's detailed plan for using this authority.** Instead, CMS should develop a detailed methodology and issue a comprehensive description of its proposal for public comment.

Criteria for Item Selection

The proposed rule notes that CMS "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." **We urge CMS to forgo applying competitive bidding to any DMEPOS not included in the two Medicare demonstration projects.** CMS first should fine-tune the competitive bidding methodology using only piloted DMEPOS before deciding whether to expand competitive bidding to products not included in the demonstrations.

We are especially concerned about preserving high-quality care for medically complex patients needing DMEPOS. For these patients, DMEPOS requiring clinical intervention (e.g., requiring support from a licensed clinician including on-site care and evaluation; consultations with the treating physician; patient education on disease management and equipment use and maintenance; 24-hour coverage for medical issues or questions that may arise) is often part of the patient's care plan and, therefore, there is greater sensitivity to disruptions in DMEPOS access and quality that could delay discharge from the hospital, or, once home, restrict healing and create clinical complications. These types of DMEPOS products are used by more medically acute patients who should not be subject to the early stages of DMEPOS competitive bidding, which is certain to involve trial-and-error that could negatively impact DMEPOS access and quality for these vulnerable patients. **CMS should exclude from the competitive bidding program those DMEPOS products that require clinical interventions.**

Under the proposed rule, CMS plans to group DMEPOS into product categories composed of related items and to require a contract to provide all items within a product category. However, this approach is likely to result in product categories that include items that both do and do not require clinical intervention. For instance, if CMS groups all respiratory DMEPOS into one competitive bidding product category, it would inappropriately include certain DMEPOS that are used by very sick patients. For example, continuous positive airway pressure (CPAP) services for sleep apnea patients requires oversight from a state-licensed respiratory care practitioner, and should not be grouped with lower-level respiratory DMEPOS. It would be similarly inappropriate to include bi-level therapy devices that provide pressure to maintain an open airway during sleep for patients with various neuromuscular diseases. And, competitive bidding would be inappropriate for ventilator services for patients with respiratory failure or chronic respiratory disease.

Submission of Bids under the Competitive Bidding Program
The competitive bidding pilots highlighted the extensive administrative resources required by the participating DMEPOS chain organizations to develop a bid. However, some hospitals operating effective DMEPOS programs may not have the resources to develop a bid without detracting from patient care. Therefore, **hospital-based DMEPOS programs should be eligible to participate in the competitive bidding program, if they communicate to CMS that they are not submitting a bid price, but accept the single price determined through the bidding process.**

Conditions for Awarding Contracts
Quality Certification. Many hospitals with certified DMEPOS programs have acquired external certification from organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) through one of two means: They have either received external certification specifically for the DMEPOS operation or the DMEPOS operation has been included within the hospital's overall certification due to its integrated relationship with other hospital operations. **To avoid duplicative effort and cost, hospital-based DMEPOS programs that are integrated within the hospital's broader quality accreditation should be allowed to fill this requirement through the hospital's comprehensive accreditation. In addition, hospital-based DMEPOS programs that are not included in the overall hospital quality accreditation, but are certified separately by an external accreditation entity, should not be required to obtain new certification until the current one expires.** We can provide more detailed input regarding the final DMEPOS supplier quality standards after CMS publishes them.

Opt Out for Health Care Providers. The proposed rule would require that competitively bid DMEPOS under Medicare Part B be provided by contract suppliers that serve the entire competitive bidding area. These suppliers must submit bids and attain certification that quality standards have been met. To access DMEPOS for their patients, health care providers that are not awarded contracts must use contract suppliers to furnish DMEPOS items subject to competitive bidding. The proposed rule would allow skilled nursing facilities (SNFs) and physician practices to opt out of the requirement that the entire competitive bidding area be served and would thereby be eligible to serve only their patients. Like SNFs and physician practices, most hospitals also focus on providing DMEPOS to their own patients. As such, **we recommend that hospitals also be given the option to participate in the competitive bidding program by electing to provide DMEPOS products solely to their patients, rather than requiring hospital-based DMEPOS suppliers to serve the community-at-large.**

Adequate Selection of Brands and Products. According to the proposed rule, individual products subject to competitive bidding will be identified by HCPCS codes and further described at the time of CMS' request for a bid. Hospitals are concerned that DMEPOS competitive bidding will severely limit beneficiary choice of brands and products due to new cost pressures on suppliers that could lower quality and lessen variety in DMEPOS inventories. **To uphold high quality of care, CMS must require that suppliers provide an adequate selection of brands or products within each HCPCS code subject to competitive bidding.** DMEPOS brands are not always

interchangeable. We acknowledge the enormous challenge in addressing this issue, but we urge CMS to minimize the unintended consequence of reduced beneficiary access, choice and quality. This is especially important for medically complex patients, including patients with one or more chronic diseases. These patients often require a specific brand or product to meet their clinical needs and maximize their quality of life.

Determining Single Payment Amounts for Individual Items

CMS expects to set the single payment amount at the median of the bids for each DMEPOS product selected for competitive bidding. We oppose this method because it favors national chain suppliers that deliver a large volume of DMEPOS. It is unreasonable to adopt a methodology that guarantees that half of "winning" bidders, those with bids above the median price, would be paid less than their bid. In addition, since the submitted bids apparently will not be weighted by supplier capacity, the bid from a supplier with very limited capacity would have the same impact on the single payment amount calculation as a supplier with a large capacity. Therefore, **we urge CMS to adopt a payment methodology similar to the approach used in the pilot programs, which ensures that most contract suppliers are paid no less than their bid amount. We also are concerned that the median price would be capped at the fee schedule price, which does not account for costs associated with complying with quality standards and acquiring quality accreditation.**

Terms of Contracts

Lack of timely DMEPOS access would be harmful for patients who are clinically ready to return to home or the community. In particular, timely DMEPOS access is critical for medically complex patients with very specific DMEPOS needs, such as high-flow oxygen via a tracheostomy tube. Delaying the discharge of Medicare beneficiaries due to restricted and untimely availability of specific DMEPOS would produce serious problems for patients' continuity of care and also for the hospital. Therefore, preserving the ability of hospitals to provide DMEPOS to their patients is essential for patient continuity of care and the efficiency of hospital operations. CMS' plans to require that certain DMEPOS be provided by mail-order DMEPOS companies would be especially detrimental to timely hospital discharge due to slow access. **Therefore, from the hospital perspective, it is essential for CMS to ensure that DMEPOS be made available on a timely basis and to sanction providers for untimely service.**

In addition, CMS must ensure that DMEPOS suppliers do not implement shortcuts in response to new competitive bidding cost constraints by reducing the quality of their DMEPOS inventory, excessively limiting the range of products offered or reducing their customer service resources needed to respond to special requests and questions. Such actions would delay discharge and jeopardize patients' clinical progress. The final rule needs to take additional steps to prevent these problems, including specific sanctions that would apply to contract suppliers failing to meet these needs.

Physician Authorization/Treating Practitioner

CMS proposes to implement a physician authorization mechanism that allows a physician or treating practitioner to specify that a particular DMEPOS item is necessary to avoid an adverse

medical outcome, but the agency provides few details on this provision. The specific requirements of this provision will significantly impact the new competitive bidding program, especially for medically complex patients. **We urge CMS to develop a streamlined and expeditious process that facilitates the role of physicians as the key decision-makers for each patient.**

We also urge CMS to clarify "adverse medical outcome" in a manner that recognizes the harm of delays that cause untimely discharge for patients. Further, CMS should provide for expedited appeals to ensure disputes are settled quickly in order to facilitate timely DMEPOS access upon discharge from a hospital. The failure of this provision would cause unnecessary delays for the patient and, in many communities, would exacerbate back-ups in the hospital that can needlessly postpone the admission of new patients requiring acute care.

Quality Standards and Accreditation for Suppliers of DMEPOS
As discussed earlier, many hospital-based DMEPOS have certification from an external entity such as JCAHO, the Community Health Accreditation Program, and the Accreditation Commission for Health Care, Inc. **Hospitals and other health care providers with certified DME programs should not be required to acquire new certification until the current certification expires.** By allowing this grace period, CMS would avoid imposing a redundant cost on DMEPOS providers. However, since the final quality standards are not yet published, it is impossible to comment at this time.

The AHA appreciates this opportunity to submit comments on CMS' plans to implement competitive bidding for selected DMEPOS. Please address any questions about our comments and recommendations to me or Rochelle Archuleta, senior associate director of policy, at (202) 626-2320 or rarchuleta@aha.org.

Sincerely,

Rick Pollack
Executive Vice President