

Program Advisory and Oversight Committee (PAOC) for Quality Standards and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Meeting 4 Summary

September 26-27, 2005

Pikesville, Maryland

MONDAY, SEPTEMBER 26, 2005

The first day of the PAOC meeting began with a welcome and introduction by Herb Kuhn, Director for the Center for Medicare Management at the Centers for Medicare & Medicaid Services (CMS). It was noted that two PAOC members were no longer members of the committee. Dr. Ken Viste, former Medical Director at the Physical Rehabilitation Unit at Mercy Medical Center and staff physician at St. Agnes Hospital, passed away in August. Dan Waldmann, former Director of Federal Affairs at Johnson & Johnson, Inc., recently accepted a new position at another company. Rita Hostak, chairperson of the PAOC, welcomed Michael Tootell, Director of Health Policy for the Ross Products Division of Abbott Laboratories, as a new committee member.

The first day's presentations focused on an overview of findings from small supplier focus groups and DMEPOS supplier quality standards. Due to time constraints, a topic originally scheduled for the first day of the meeting, the impact of quality standards and accreditation on rural areas, was postponed until the next PAOC meeting. The afternoon sessions included stakeholder presentations pertaining to DMEPOS competitive bidding from the perspective of beneficiary organizations and blood glucose systems. The afternoon concluded with a public, open door conference call.

OVERVIEW OF SMALL DME SUPPLIER FOCUS GROUPS

Shulamit Bernard of RTI International presented an overview of findings from nine focus groups conducted with small DME suppliers earlier this year. The purpose of the focus groups was to explore small DME suppliers' thoughts and opinions on aspects of quality standards, accreditation, and competitive bidding, and the potential impact of these requirements on their businesses. Four focus groups were conducted in Las Vegas (in conjunction with the Medtrade Spring conference), two in Texas, two in Illinois, and one telephone focus group. Focus group participants worked for or owned businesses with an

annual gross revenue of less than \$3 million and/or employed up to 10 FTEs. A total of 98 participants comprised the nine focus groups, with representation from 28 states.

Focus group topics focused on four key areas: quality standards, accreditation, competitive bidding, and financial standards. Findings pertaining to the latter two areas will be presented at the next PAOC meeting. The quality standard domains presented to the focus group participants were the same as those presented to the PAOC at the last meeting in February. Consequently, participants' responses pertained to the preliminary draft quality standards domains and predate the standards presented to the PAOC at the current meeting. Subject to this caveat, many participants noted that the quality standards were similar overall to requirements for accreditation. Moreover, the majority of participants (both accredited and non-accredited), already collect information for the quality domains that were presented to them. However, providing actual documentation for quality standards poses challenges for small suppliers given reduced profits and increase administrative burden. The quality domains perceived as problematic by the participants include financial management, human resources, assessment and evaluation of quality, and facility/patient environmental safety management. Participants desired additional information regarding interpretation of both the quality standards and data expectations.

Among the 98 focus group participants, 17 worked for or owned businesses that were accredited. The participants had many questions regarding the identification and number of accrediting bodies, grandfathering policies, and the timeline for accreditation. There was also distrust/discomfort with allowing private companies to serve as accrediting organizations. There was a tendency by some participants to delay accreditation until additional details about the CMS-approved accrediting organizations were identified.

Perceived pros of accreditation included: helping businesses develop and implement policies and procedures; promoting a set of standards for conducting business; providing credibility/serving as a requirement by some payers; and setting businesses apart from their competitors. Perceived cons of accreditation included: high expense (estimates ranged from \$6,000-\$50,000), considered a time-consuming and labor-intensive process; some of the standards appeared to be geared towards hospitals or home health agencies and were considered inappropriate for the DME industry; questionable utility of some of the data for patients/suppliers.

During discussion, Committee members acknowledged that many of the focus group findings correlated with their expectations. However, one member noted that it was difficult to provide many comments since the latest quality standards have not yet been published for public comment and were not included in the focus group discussions. On the other hand, findings from the focus groups may be useful in the development of the regulation to help ensure that all relevant issues are captured during the regulatory process. Other Committee members inquired about whether provisions would be made to accommodate small suppliers. Grandfathering was recommended as a means of accelerating the accreditation process and preventing/alleviating a tremendous backlog of businesses trying to meet the impending accreditation deadline.

QUALITY STANDARDS FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIERS (DMEPOS)

The next presentation, by Debra Frankel (Abt Associates, Inc.), Steve Levenson (President-Elect of the American Medical Directors Association), and Linda Smith (CMS) highlighted the challenges, consumer impact, and approach/format of the quality standards. Accreditation and next steps were also discussed briefly during the presentation. Section 1834(a)(20) of the MMA requires suppliers of DMEPOS and other items and services to comply with quality standards established by the Secretary. There are several challenges in developing these quality standards, including: the scope and complexity of home care; the varying scope of needs of beneficiaries; the need for integration of services; variation in the size of supplier businesses; operation of capable, compliant, financially viable home care businesses; ensuring quality in multiple locations and chains; ensuring that personnel qualifications are met and personnel are sufficiently knowledgeable in the products and services provided; and the limitations of accounting personnel and computer systems.

The quality standards are expected to impact consumers in the following ways: improved access to information/education; improved customer service; assurance that equipment is appropriate to medical need; assurance that equipment is of high quality and promptly delivered; assurance that conditions in the home are appropriate and safe for equipment; greater emphasis on education and training in the use of equipment by the supplier in the home; and provision of guidance for follow-up.

Primary goals of the quality standards include: assuring that appropriate equipment is provided; maximizing safe and appropriate use of DMEPOS via training/education of beneficiary and caregiver; maximizing health outcomes for beneficiaries; and describing expected services from suppliers. The standards were developed as a collaborative effort among Abt Associates, physicians, clinicians, consultants, DMEPOS suppliers, and Homecare Association experts. Interviews with DME suppliers, manufacturers, trade association representatives, home health agencies, rehabilitation therapists, and other clinicians, internet research, and review of consumer educational handbooks/materials and CMS conditions of Participation and Coverage Standards were also key components of the development process for the draft recommendations for standards.

Beneficiary services in any setting requires: integration of individual services, attention to the “big picture,” and coordination/integration and communication between suppliers, physicians, and other healthcare team members. Hence, the quality standards should be pertinent to beneficiary service quality, supplier specialization, Medicare requirements, and should meet the needs of accreditation. The standards are organized in two parts: business quality standards (which apply to all suppliers regardless of specialization) and product-specific service quality standards. The business quality standards are categorized into eight domains: administration, financial management, human resource management,

beneficiary services, performance management, equipment and safety, beneficiary rights and services, and information management. The presenters proceeded to review aspects of the standards under each of the eight business quality standards domains based on a document prepared by Abt Associates entitled, "Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Suppliers (DMEPOS) and Other Items and Services: Draft of Proposed Recommendations."

Using the same document as a basis for discussion, the presenters then highlighted product-specific service requirements for the following: oxygen and oxygen equipment; invasive mechanical ventilation therapy, CPAP and BiPAP, Intermittent Positive Pressure Breathing (IPPB), power wheelchairs, manual wheelchairs, diabetes equipment and supplies; customized orthotics and prosthetics; enteral nutrition therapy; electric and manual hospital beds; support surfaces; walkers, canes and crutches; commodes; and bedpans and urinals. Product-specific standards are divided into four sections from the perspective of what beneficiaries could expect from suppliers: preparation and inspection; delivery/setup; training/education of beneficiary and caregivers; and follow-up.

Suppliers will be accredited upon meeting business quality standards and product-specific quality standards that it has disclosed to Medicare on the CMS Form 855S. Selection of the accreditation organizations will occur after the final rule is published. Feedback on the draft standards from the PAOC and public is allowed during a 60-day comment period that will end on 11/28/05. Comments may be submitted to: [DMEPOS Quality Standards Public Comments@cms.hhs.gov](mailto:DMEPOS_Quality_Standards_Public_Comments@cms.hhs.gov). Individuals interested in serving as volunteers for workgroups may contact Debra Frankel at: debra_frankel@abtassoc.com.

The Committee raised several questions/concerns during the discussion period. One member noted that integration of services is a goal of the beneficiary service domain. Given that beneficiaries often receive services from a number of different facilities and providers, concern was raised about suppliers being held responsible for this task since the responsibilities appear to be similar to the role and responsibilities of a case manager. While it is unclear at this point who should hold the ultimate responsibility for ensuring integration of services, it was stated that many things fall through the cracks to the detriment of the patient. When there is no coordination, there is an expectation that the supplier will try to coordinate services. However, no one entity can handle the full responsibility. One Committee member indicated that while she supports the need for home visits, new/first time purchases of items such as wheelchairs have a more critical need for a home visit than repeat purchases of similar items. Moreover, if after a home visit, a determination is made that it is an inaccessible area or if a sale is not possible, the implications of such a finding should also be recognized and accounted for.

Another Committee member commented on the absence of consultation with a consumer group during the standards development process. His concerns pertained to low quality and lack of significant improvement in patient outcomes as a result of the proposed standards. He suggested working with individuals in the community to develop standards as a starting point so that their interests are addressed. He also questioned the feasibility

and appropriateness of a provider going into a home to decide if it is safe, particularly if the person is not someone intimately involved in the beneficiary's life. The committee member also suggested involving a consumer group (e.g. wheelchair users) so that end users are involved in the development of standards. This entails going beyond evidence that may be seen in the literature pertaining to consumer input. He went on to emphasize the importance of care coordination and recommended looking at competitive acquisition based on individual's needs and ensuring that there is some coordination with other services or devices that the individual will rely upon. He added that bulk purchases may cost Medicare more in the long run unless efforts are made to examine how different components interface with other devices.

Another Committee member pointed out that not enough has been done to encourage small suppliers and added that "one size does not fit all" – all suppliers are not alike. In terms of conducting business in a "business correct manner" according to GAAP principles, said that some suppliers likely do not know what GAAP stands for. Proceeding with a one size fits all philosophy will likely eliminate many small suppliers and possibly create access issues. A proposal of a tiered approach was raised for consideration.

One Committee member pointed out that part of the problem is the chicken vs. the egg. Less than 20% of providers are accredited so 80% of providers are not accredited and likely do not know their costs going into the process. How do you develop a program that takes this into consideration?

Referring back to coordination challenges, a Committee member noted that there are HIPAA issues to contend with when trying to obtain patient information from physicians. Many noted that communication with physicians is very difficult.

Another member commended the draft standards and raised the following issues for consideration: delivery of low-level equipment often occurs through a hospital consignment closet; CPAP users frequently prefer to come in to pick up their equipment; the timeline for delivery requirements should be revisited to determine feasibility and appropriateness; an excessive amount of documentation is required for smaller-end items; the definition of "qualified staff" should be clarified since the definition varies for beneficiaries needing a cane vs. oxygen.

Many members voiced concern over the impact of the standards on small suppliers in particular. In reference to an enteral and diabetes training program, a member pointed out that nurses are paid from Part A for these services. As a result, such a requirement would result in mixing money from Parts A and B. Dealers may need to hire additional staff to provide training, which could be problematic for small suppliers. Some members felt that the restrictive content of the standards would limit the number of small suppliers that would be able to comply. One member pointed out that the bar is raised too high and that standards should be at a level that would work for small suppliers. For example, having a licensed/credentialed practitioner for customized orthotics and prosthetics available within 60 minutes is not feasible when the beneficiary is located 300 miles away. A

suggestion was made to lower the current level of standards for accreditation with the possibility of adjusting the level of the standards at another time for those involved in bidding.

One Committee member stated that it currently takes approximately 6 months to complete the accreditation process. While all accreditation organizations are currently preparing for the influx of applications, they are concerned about the timeline and the fact that the MSAs have yet to be identified.

Regarding the financial standards, one member indicated that preparing profit and loss statements would be a financial burden in itself and could cost an \$8 million organization as much as \$5,000. It was also noted that since some accreditation organizations ask about budget status as part of their accreditation process, requiring a CPA-audited statement may be unnecessary.

A question was raised as to whether items such as canes and walkers must be delivered to the home. Perhaps a dispensing fee should be considered if a van is required to deliver items to the homebound. Reimbursement rates should be examined to potentially incorporate another rate for sending a live person out to a home.

A Committee member closed the morning session by recommending the fielding of a survey to suppliers to determine their willingness to still participate if given the current proposed list of quality standards. Results may indicate whether there may be access issues to contend with in the near future.

AFTERNOON SESSIONS

The afternoon session began with a continuation of final comments on the proposed quality standards. The Committee urged CMS to enforce achievable, measurable standards and to avoid creating additional bureaucratic layers and added costs. Stakeholder presentations on beneficiary organizations and blood glucose systems followed. The afternoon session concluded with a public open door conference telephone call on quality standards.

STAKEHOLDER PANEL: BENEFICIARY ORGANIZATIONS

Peter Thomas, Esq. (Powers, Pyles, Sutter and Verville, P.C.) gave a presentation on behalf of beneficiary organizations including the American Association of People with Disabilities (AAPD). The presentation encouraged CMS to consider the impact that competitive bidding will have on two very different populations: Medicare beneficiaries with acute medical conditions that entail a short-term, one-time or occasional need for

DMEPOS vs. beneficiaries with chronic conditions and disabilities who may have a long-term and extensive need for DMEPOS. Few beneficiaries have any idea that competitive

bidding is on the way, which may be disruptive and disturbing to beneficiaries that rely on and have developed a trust with their existing supplier over a period months, years, or decades for some beneficiaries, as their condition has progressed.

The presenter noted that competitive bidding has the potential to restrict access to items and services that improve health and function, enhance quality of life, and promote independent living within the Medicare population. Consequently, fairly modest decreases in beneficiaries' co-payments for DMEPOS could be outweighed by the potential negatives that may result from competitive bidding. Major issues from the consumer perspective include: quality, choice of provider, choice of item, and additional burdens on the beneficiary.

It was indicated that when the fee schedule is constant, providers compete on dimensions such as the quality of services, relationship building within the community and satisfying referral sources and beneficiaries, and meeting the patients' needs and preferences through patient care. However, when the price is variable, providers primarily compete on price with the following potential consequences, quality and service become secondary considerations, referrals are more or less guaranteed, and low-ball bidders may provide substandard care after gaining market share. Concern was expressed that it may require egregiously poor quality and detriment to beneficiaries before a supplier's contract is nullified.

Price alone should not be the sole determinant for a competitively bid contract – quality standards are critical. However, the standards must be enforceable and measurable with a user-friendly complaint reporting system and mechanisms in place to actively investigate complaints. A lack of substantive quality benchmarks and variability in patients' conditions pose significant challenges in the measurement of quality in DMEPOS. The presenter suggested that choice of provider and specific product or brand provide the ultimate quality control under competitive bidding and advocated that implementation of competitive bidding is done in such a manner that:

- f* Preserves long-standing relationships between beneficiaries and familiar suppliers, as well as between suppliers and physicians that service a disproportionate amount of beneficiaries with complex conditions or disabilities
- f* Minimizes interruptions in service
- f* Ensures access to a wide range of products, not just those with the widest margins for suppliers.
- f* Meets the patients' needs and preferences
- f* Preserves access to community-based, independent suppliers and small, innovative businesses

Moreover, efforts should be made to ensure that there is no increased burden on beneficiaries and that innovation of DMEPOS products and services is preserved. To this end, the presenter proposed a scenario in which all beneficiaries are allowed to opt-out of the competitively bid network and select the provider of their choice at the Medicare DMEPOS fee schedule amount. This situation would operate similar to a point-of-service option in a managed care environment in which the beneficiary would pay an additional

co-payment for the ability to use an out-of-network supplier. Enabling beneficiaries to opt-out of competitive bidding offers the following proposed advantages:

- f* Maximizes beneficiary choice
- f* Permits beneficiaries to maintain long-standing relationships with specific suppliers
- f* Permits beneficiaries to obtain a specific brand of product if competitively bid suppliers do not carry the brand
- f* Minimizes inconvenience for patients if their routine supplier is located nearby and the network supplier is not
- f* Keeps selected suppliers focused on quality and service
- f* Permits small business and independent suppliers who do not secure contracts to have some ability to see Medicare patients if the patient chooses them
- f* Would not compromise the competitive bidding process in securing reduced reimbursement rates since the majority of beneficiaries would continue to receive their DMEPOS from competitively bid suppliers
- f* Potential to reduce the incidence of beneficiary complaints

Following the presentation, many Committee members viewed the opt-out proposal for beneficiaries as promising and expressed support for such a scenario. One member noted that empowering beneficiaries by allowing them to have choice enables those with complex needs a way to work around equipment that they know will not work for them. Another added that the proposal meets the needs of two communities – patients with complex needs and small suppliers. The additional cost (co-payment) could function as a safeguard to ensure that there is not a tremendous effort to work around the competitive bidding program. However, one member cautioned that some suppliers may waive the co-payment to attract business. Another suggested requiring an explanation in cases where beneficiaries prefer to go out-of-network as a protective measure, particularly for elderly patients and patients who may respond to emotional pleas from out-of-network suppliers.

One Committee member suggested that the proposal was similar to an any willing provider clause. He disliked the idea of allowing non-participating bidders to receive higher reimbursement and was concerned that it may lead many suppliers away from the competitive bidding program. A suggestion was made to try and identify beneficiaries with chronic issues and disabilities that may require complex technology and allow this subset to participate in an opt-out program. However, it may be difficult to justify only allowing some beneficiaries to opt-out of the competitive bidding program.

STAKEHOLDER PANEL: BLOOD GLUCOSE SYSTEMS

Nicole Johnson Baker, MA, Bruce Bode, MD, FACE, Seth Lundy, and Virginia Valentine, CNS, BC-ADM, CDE, provided panel presentations on Blood Glucose Systems. As a person with Type 1 diabetes and a diabetes advocate, Ms. Baker noted that seniors living with diabetes are vulnerable and need support. Limiting their supplier

choices may weaken the system and make it difficult for them if they are forced to make changes such as switching to a new glucose monitor. If seniors are not allowed to use preferred testing supplies that fit with their lifestyles, many may cease testing altogether. Allowing choice in suppliers and products promotes comfort and security for many seniors. Competitive bidding may lead to more complications and higher costs by potentially limiting extra services such as educational materials and counseling, which are often not billed. Driving compliance and providing support to help patients better manage the disease should be the first priority, with health improvement as the objective.

During the comment period, a Committee member inquired whether Ms. Baker was affiliated with any diabetes testing/supply company. She indicated that she did not serve as a spokesperson for a particular organization during the presentation.

In the next presentation, Dr. Bode, a diabetes specialist, indicated that the Medicare Modernization Act took steps in the right direction by including screening for diabetes, coverage of insulin, and implementing chronic care improvement programs. However, he stated, competitive bidding of blood glucose test strips is an aspect of the Act that is not a step in the right direction, indicating that it is inconsistent with the objectives of chronic care improvement programs; will result in dramatically increased costs due to long-term complications; and will hurt an already vulnerable segment of Medicare beneficiaries. Active managing and monitoring of diabetes will significantly reduce overall costs to the system. Dr. Bode stated that the objective should be to drive compliance with physicians' orders. While new technology is on the horizon that may dramatically improve the quality of life for beneficiaries, he stated that a reduction in reimbursement due to competitive bidding may threaten future advancements in technology.

Seth Lundy (Fulbright & Jaworski, LLP) provided the next presentation on behalf of the Diabetic Product Suppliers Coalition. He began the presentation with an overview of diabetes statistics:

- f* 18.2 million people in the US (6.3% of the population) have diabetes
- f* 13 million have been diagnosed with diabetes
- f* 8.6 million (18.3%) of the US population ages 60 and older have diabetes
- f* \$132 billion is estimated as the total annual economic cost of diabetes in 2002 (1 in every 10 health care dollars spent in the US)

Mail order suppliers, retail pharmacies, and local DME suppliers comprise the major sources of diabetes supplies and purchases. Suppliers are trusted health care professionals that respond to beneficiary questions and often interact with beneficiaries more frequently than physicians. Compliance with testing is critical for persons with diabetes and forced changes in suppliers and brands will likely lead to more non-compliance with prescribed testing regimens. The competitive bidding process may have serious implications on beneficiary access, reimbursement rates, and quality. Significant reductions in suppliers could mean millions of displaced beneficiaries. Competitive reimbursement for diabetes testing supplies must allow smaller, local suppliers to survive, particularly since margins on such products are already low. Additionally, costs

associated with increased quality should be considered, as implementation of the quality standards will result in additional costs to suppliers.

Mr. Lundy indicated that nationwide competitive bidding will not work for the following reasons:

- f* Access will be affected
- f* Smaller, local suppliers cannot compete nationwide, but are particularly important in rural areas
- f* Significant reductions in the number of suppliers could affect availability of brands and models
- f* Effects on diabetes testing supplies have not been proven in demonstration projects

Mr. Lundy advocated exclusion of diabetes testing supplies from competitive bidding and/or beginning with other product areas. He also advised consideration of additional demonstration projects on a more limited basis since diabetes supply data was not provided from the demonstration projects and many unanswered questions still remain.

Virginia Valentine, CNS, BC-ADM, CDE gave the final presentation on the Blood Glucose Systems panel. She began the presentation with a brief overview of diabetes care, complications, treatment, and management. The patient is key in interpreting results and determining clinical intervention. Patients' tracking of results of glucose monitoring over time are often followed by efforts to detect patterns and select appropriate interventions such as diet, activity level, and drug therapy. Frequent use of self monitoring blood glucose systems (SMBG) systems by patients facilitates prevention and reduction of diabetes-related complications. If such systems do not meet patient needs, there is a greater risk of patient non-compliance or error.

The following issues and concerns related to competitive bidding and glucose monitoring systems were raised:

- f* Competitive bidding may deny access to the full range of available glucose monitoring products and related services
- f* It may potentially reduce local suppliers sufficient to meet need or make it more difficult for beneficiaries to obtain needed products and services
- f* It may work at cross-purposes to Medicare disease management efforts
- f* It could reduce patient compliance with diabetes self-monitoring regimens, leading to diminished health outcomes and increased use of expensive health care services

The following considerations were mentioned with regard to the competitive bidding process:

- f* Competitive bidding design should maintain a patient-centered approach to diabetes care management and should consider the goal of patient compliance with SMBG systems
- f* Competitive bidding should preserve current access to products
- f* Competitive bidding should consider Medicare disease management goals

- f* Competitive bidding should preserve innovation and quality standards
- f* Clinical discretion of healthcare professionals should be preserved in matching patients to glucose monitoring systems
- f* Patients' individual medical and functional needs must be addressed in care plans
- f* Access to customary sources of care must be preserved

During discussion, one Committee member raised the concern of how A1C will be affected if patients are told where they can get their supplies. There are instances where mail order is not feasible. He suggested creation of a carve-out for diabetes since some pharmacies are solely devoted to diabetes testing and supplies. An observation was made that the diabetes testing industry is experiencing tremendous and dynamic change with significant advances in technology expected to occur within the next three years.

PUBLIC OPEN DOOR CONFERENCE TELEPHONE CALL

The afternoon closed with a Public Open Door Conference Call. During the call, Linda Smith (CMS), Debra Frankel (Abt Associates), and Steve Levenson (President-Elect of the American Medical Directors Association), presented an abridged version of their morning presentation on quality standards. Over 400 people participated in the call via telephone, and more than 50 people listened to the presentation in person.

Following the presentation, participants made a number of comments and asked questions. Several participants were concerned about the 60-minute response time proposed for oxygen equipment, noting that this time would be especially difficult to achieve in rural areas where patients might live 100 miles or more away from the supplier. Linda Smith responded that they appreciated this comment and were likely to revise this requirement in the final standards. Participants were also concerned that the standards for in-person or in-home visits could unnecessarily increase costs for glucometers, canes and walkers, and oxygen equipment (visits every 2 weeks for the first month were viewed as too frequent). A participant stated that the proposed credentialing requirements for providing some services would be difficult to achieve because there simply are not enough credentialed individuals to serve all areas.

Several participants were concerned that the financial standards might be difficult for small suppliers to comply with. One participant objected to the proposed standard requiring a written order prior to delivery. Currently, suppliers can provide equipment on verbal order and then get a written order prior to billing Medicare.

Several participants were concerned about the timeline for adoption of the quality standards and accreditation. One participant urged CMS to make decisions as quickly as possible.

Linda Smith closed the session by reiterating that the proposed standards are a starting point; the standards will be revised based on public comment during the next 60 days. The quality standards will be issued as program instructions, allowing CMS to modify the

standards as technology and practice change. She also reviewed the timeline for accreditation. Selection of accreditation organizations will occur after publication of the final rule on competitive bidding. After the rule is final, there will be a *Federal Register* notice for applications for accreditation organizations. Selection of the accreditation organizations and announcement of the first 10 MSAs for competitive bidding will then occur.

TUESDAY, SEPTEMBER 2, 2005

The second day of the PAOC meeting included stakeholder panel presentations on home medical equipment, respiratory equipment (including oxygen), rehabilitation equipment and assistive technology, prosthetics and orthotics, and enteral nutrition. Five meeting participants then made remarks during a public comment period. Herb Kuhn and Rita Hostak closed the meeting with brief comments.

STAKEHOLDER PANEL: HOME MEDICAL EQUIPMENT

George Taler, Sharon Baranoski, Thomas Jeffers, and Jeff Wills made a panel presentation on home medical equipment. Dr. Taler, Director of Long-Term Care at the Washington Hospital Center and a house call doctor, provided a physician's perspective on home medical equipment in general and wound care in particular. He emphasized the complexity of wound care patients, the need for a patient team, physician expectations for equipment and medical equipment suppliers, and physician concerns about competitive bidding. Ms. Baranoski, MSN, RN, CWOCN, FAAN, and Administrator of Home Health at Silver Cross Hospital in Joliet, Illinois, discussed the clinician's role in home care, the need for appropriate home medical equipment, and clinician concerns about competitive bidding. Mr. Jeffers, Director of Government Affairs at the Hill-Rom Company, provided a manufacturer's perspective and discussed manufacturers' concerns about competitive bidding. Manufacturers are concerned that competitive bidding could stifle innovation; in addition, they believe that HCPCS codes need to be expanded to accommodate differences in technology and features. Mr. Wills, Chief Operating Officer and Owner of Canadian Valley Medical Solutions, provided the perspective of an 85-employee equipment supplier in Oklahoma. He described the supplier's role in patient care, the key service components provided by suppliers, and provider concerns about competitive bidding. All of the speakers discussed the central role of the patient and noted that quality home medical equipment and excellent service lead to good patient outcomes and avert ER and hospital visits.

During discussion a Committee member noted that Hill-Rom offered a relatively narrow product line with respect to HME and asked Mr. Jeffers whether that put his company into a special condition for competitive bidding. Mr. Jeffers replied that the competitive bidding program should allow firms to bid by HCPCS code.

A Committee member asked Mr. Wills how many employees he would still employ if he was selected as a winner. Mr. Wills noted that in advance of recent 19% reimbursement reductions, he lost 2 of 7 service personnel, the area that seems most susceptible to reductions in reimbursement.

Mr. Wills commented on the quality standards for walkers, noting that the initial standards called for 1 delivery to the home and 1 or 2 consults with occupational or physical therapists. He thought that these requirements would lead to lower quality walkers being supplied.

A Committee member noted that home care is one of the major ways to reduce overall health care costs. He thought that an advisory committee could be formed on documentation. He also thought that a lot of angst about competitive bidding could be reduced by clearly defining rural areas that would be exempt from competitive bidding. Dr. Taler noted that deep urban areas also face major challenges for access.

A Committee member noted that we want quality with cost savings and suggested that it would be useful to measure the rate of rehospitalization under competitive bidding.

STAKEHOLDER PANEL: RESPIRATORY EQUIPMENT (INCLUDING OXYGEN)

The speakers were:

- Vernon Pertelle, Apria Healthcare, Corporate Director of Respiratory & HME Services
- Joseph Lewarski, Inogen, Inc, Vice President of Clinical & Government Affairs
- Dr. William Denman, Tyco Healthcare, Vice President of Medical Affairs
- Robert Keith, National Home Oxygen Patient's Association
- Barbara Rogers, President and Board Chair National Emphysema/COPD Association

Mr. Pertelle began the presentation by repeating a theme prevalent throughout the meeting, "Expand the HCPCS codes". He stated that this was necessary to identify the new technologies and products. Furthermore he expressed that these new products, required to meet the clinical needs of beneficiaries, once identified, would require the establishment of product standards. He strongly recommended that those standards become a part of the competitive bidding program.

Mr. Pertelle elaborated on the need for service review, not just concern about the product. He told the panel that two states currently don't even require credentialing, even though it would better ensure that the needs of the patients were met. He spoke of follow-up and monitoring that does not occur without credentialing. He stressed the need for oversight by Respiratory therapists, rather than family members. He feels that the service or credentialed therapist would save hospital time and thus monies.

Mr. Lewarski was nominated by other respiratory providers to speak for their diverse perspectives. His focus included the complexity of certain respiratory equipment for use by seniors and thus the inappropriateness of certain services for competitive bidding. He echoed the need for expansion of HCPCS descriptions and coding, exacerbated by technology increases since the Balanced Budget Act. He cited examples of technologically complex home equipment and lower tech equipment whose use is complex. The primary concern of the providers he represented is the standard of care. He stated that the current provider standards of participation are inadequate to serve the needs of the respiratory patients today. Mr. Lewarski noted that it is not beneficial to the patient to have equipment sitting in the home without the recipient able to utilize it.

Mr. Lewarski referred to a GAO report citing significant variance of device cost, quality, and capabilities within the same code. He addressed product standards and the concern that without them, equipment gets “lumped into lower codes or E1399”. He concluded that competitive bidding will eliminate local market competition, referral and patient choice. He foresees a decrease in the use of ambulatory oxygen technologies as well as an increase, driven by price, in the use of least costly alternatives within the current HCPCS codes.

Dr. Denman recommended that competitive bidding not go forward until there is an expansion of HCPCS codes for respiratory technologies. He echoed the opinion that complex home respiratory services may be compromised in a competitive bidding system. He spoke at length on the value of ambulatory oxygen. He addressed the flaws of least costly alternative. He concluded with a concern for the patient’s access to respiratory technologies if competitive bidding goes forth modeled after CMS demonstrations.

Mr. Keith provided a consumer’s perspective. As a 24/7 oxygen user and a member of the Board of Director’s of NHOPA, he was able to provide a unique outlook from the user’s standpoint. He passed around photographs of the oxygen package with which he travels. It can be charged in a wall socket or a cigarette lighter. He can take trips without canisters. He made the request personal, providing a tale of a trip he was able to take due to the advent of the new concentrators, and speaking of his liberation. He spoke of oxygen users able to travel to climates more beneficial to their needs and requested that bidders be required to make available systems suited for travel. Mr. Keith authored an article, “Traveling Tank-less: New technology puts COPD patients back on the road” which will be published in the next month’s issue of AARC times.

Mr. Keith recommended collaboration with the users. He spoke of the broad spectrum of user needs and noted that it was short sighted to stop with providing systems. He requested that CMS realize the importance of preserving the right and need of the patient to have choice and access.

Ms. Rogers, who relies on a ventilator, was this group’s last speaker. Her focus was based on the premise that equipment is not a commodity. She stated that it could not be

interchanged or replaced, that the equipment keeps her alive. She expressed that the patient must be able to choose the interface that works for them and that this is a very personal choice. Ms Rogers stated, “Homecare is the future of our country. People are sent home sooner and sicker and left to fend for themselves”. She felt it crucial that the service is there. Ms Rogers told the panel that support and services are a requirement and much more than just dropping off the equipment. Ms Rogers felt strongly that the user must retain the ability to change providers. She told of her personal case where she had utilized one provider for 10 years and then when portable equipment became available and her provider did not provide that equipment, she was forced to change. Her suggested solution was to require all winning bidders to supply the full range of options. Her plea at the end was, as she pointed out, that of a disabled America asking CMS to protect her.

STAKEHOLDER PANEL: REHAB AND ASSISTIVE TECHNOLOGY PANEL

Panel Speakers:

Chris Chovan

Barbara Crane, PhD

Gary Giberti

Dan Lipka

Jack Pivar, Esq.

The first speaker, Dan Lipka, represented the supplier’s perspective for the Rehab and Assistive Technology product category. His portion of the presentation described the panel’s objectives: (1) describe which items are really considered Rehab and Assistive Technology, (2) explain which items within Rehab and Assistive Technology that should be exempted from competitive bidding while others should only be considered after delay, and (3) suggest that this category of products will require quality standards for the company and for the individuals providing them.

Mr. Lipka described the Rehab and Assistive Technology product category. He emphasized that this product category and the necessary accessories are very individualized for the user. Most users require multiple adjustments and fittings throughout the usage of these products in size and as their health needs change.

Mr. Chovan reiterated Mr. Lipka’s points that this product category is very different than other HME product categories. He described the typical rehab consumer and stressed the patients’ individualized needs, continuous servicing and adjustments required by the patients and how the total system for the consumer is not considered “catalog type supplying”.

Mr. Lipka then described speech generating devices. This group of products was described as having very low utilization. Like other product categories presentations

throughout the meeting, a request was made to modify the HCPCS code set—which was described as very small for speech generating devices.

Dr. Krane explained the team approach in providing the proper items for patients within these product categories. She described the team as including the physician, clinicians (i.e., Occupational Therapists, etc.), the rehab suppliers, caregivers and patients. Dr. Krane described the importance of the team approach in order for the patients to receive the necessary outcome. She stressed the concern of competitive bidding jeopardizing these long-standing relationships and causing disruptions in care to the patients. She suggested exempting certain items such as: (1) all pediatric mobility, (2) all speech generating devices, (3) certain adult power chairs, and (4) certain seating. She also suggested a delay until 2009 for certain products. Again, a request was made to modify HCPCS code set specifically for adult manual wheelchairs.

The panel then concluded by giving supporting reasons for delaying competitive bidding within the product categories, exempting certain items and suggesting areas to develop quality standards. Attorney Jack Pivar stated that a delay should be considered because of the number of changes and the possible affects of these changes. Mr. Pivar presented the concern that recent changes such as changes in HCPCS coding and pricing for power wheelchairs and general purpose seats and backs will require adjustments by the industry. He stressed the need to delay to establish a baseline for measurement in sight of the recent changes and their unknown affects to the industry.

Mr. Gilberti gave suggestions for quality standards. Mr. Gilberti is a rehab provider and stated that the rehab field is unique in its processes, staff needs, and physical structure because of certain diagnosis groups and conditions of patients for a rehab provider. He outlined recommendations to include within the quality standards. For example, one recommendation included phasing in certain credentials for rehab specialists and mandatory inclusion of ATS/CRTS in assessments for high end rehab consumers. Simply stated, the panel maintained that any staff involved should have certain requirements to include areas such as customer service, repair and administration.

The recommendations for facilities included compliance with accessibility standards of the Americans with Disabilities Act, inventory levels to ensure timely service and delivery and inclusion of fitting rooms that are private, clean and safe for rehab patients.

Mr. Pivar summarized the panel's points and reiterated the dependence of patients to their particular rehab equipment. He also emphasized their opinion that any disruption to the team approach and relationships within these teams would minimize any potential savings obtained by competitive bidding.

During the discussion, the PAOC committee raised several issues and questions. There seemed to be a general concern about the level of certification/accreditation requirements that should be placed on rehab providers and their employees. It was also implied that new regulations and standards would alleviate examples of incorrect products being delivered to rehab patients that are not suited for their specific conditions or physical

specifications. One of the panel members added to the discussion that personnel requirements are also needed for speech generation devices. It was stated that such requirements would also limit fraud and abuse.

STAKEHOLDER PANEL: PROSTHETICS AND ORTHOTICS

Four speakers presented, including:

- Nancy Cannon, OTR, CHT – a practicing occupational therapist with over 25 years of experience. Ms. Cannon is the Director of the Hand Rehabilitation Center of Indiana and was a past president of the American Society of Hand Therapists.
- Teresa Kelchi, PhD, RN – a certified wound care nurse who developed and teaches foot care education courses for RN's. She is a gerontological clinical nurse specialist with over 24 years of experience.
- Jeffrey Yakovich, CO – who was speaking for a number of organizations including the American Academy of Orthotists and Prosthetists (AAOP), the American Board for Certification in Orthotics and Prosthetics, Inc. (ABC), the American Orthotic and Prosthetic Association (AOPA) and the National Association for the Advancement of Orthotics and Prosthetics (NAAOP).
- Michael Madden, BOCPO – who was speaking for the Board for Orthotist-Prosthetist Certification (BOC).

Their presentations focused on how the competitive bidding may impact the products and services that they render. Ms. Cannon argued that the 8 suppliers that were included in the San Antonio demonstration site were too few for the population served and that this ratio would present an access issue for beneficiaries. Another concern voiced by Ms. Cannon was that competitive bidding places therapists at a huge disadvantage. Therapists both fit and dispense off-the-shelf orthotics, however, their volume is too small to enable them to compete on price with the large suppliers. In addition, serving a population beyond their patients would be difficult for therapists. Under competitive bidding these professionals are concerned that clinics that fit patients for custom orthotics would not be able to fit and dispense off-the-shelf orthotics as part of the treatment plan. Finally, Ms. Cannon stated that occupational therapists need to be better represented in the development of quality standards.

Dr. Kelechi emphasized the need to include suppliers who know the local community and provide culturally sensitive services to minority populations. She expressed concern that competitive bidding would disrupt established relationships between minority populations and trusted suppliers with whom they have worked successfully. From a clinician's perspective, Dr. Kelechi emphasized the difficulty for both referral agents and patients to keep up with approved providers as well as access to products and services.

Mr. Yakovich and Mr. Madden recommended exempting O & P from competitive bidding, arguing that off-the-shelf products also need to be provided with expertise and

knowledge. They emphasized their belief that the patient can be harmed if we assume

that the off-the-shelf orthotics can be used for only less complex needs. They remain concerned about the quality of devices under competitive bidding, access to medically appropriate care and continuity of care for the medically complex patient when they have to go to one provider for custom orthotics and another for off-the-shelf orthotics. In their view, the impact on access to care will be significant resulting in fewer facilities available to patients, and the reduced reimbursement will result in curtailed innovation for products and clinical techniques. They further expressed concern that patients will need to go to more than one location and that a store front location would not have personnel with the needed expertise to provide proper fit or advice regarding the off-the-shelf orthotics. The organizations they represent are opposed to competitive bidding as they believe that it will reduce access and reduce quality – “a relatively simple device is not simple when used to treat complex patients.”

Mr. Madden stated that DME suppliers are product based while prosthetics and orthotics are clinically based services where the product is only one part of the combined product and clinical service. Reimbursement needs to reflect the expertise needed to achieve successful outcomes that should be taken into consideration. The clinical aspect is important requiring adjustments and alterations made to best meet the needs of the patient needing orthotics, including off-the-shelf products. Competitive bidding would threaten the elimination of the clinical component, it would threaten the quality of the products, and it would threaten access to the service needed for the product. He argued that even off-the-shelf orthotics need to be used correctly, which requires assessment by a professional and appropriate training of the patient. Reduction in reimbursement to the lowest common provider resulting from competitive bidding threatens to eliminate the type of clinical practice that promotes proper assessment and training. All four speakers recommended that off-the-shelf orthotics be removed from consideration for competitive bidding.

The following questions were posed to the speakers from the PAOC members:

- Do you feel that current providers can bid competitively?

The response was that OT/PT would not have access to manufacturers that would enable them to obtain competitive prices. Clinicians in the clinical environment do not have these relationships. Also, a small business provider can not do that because from a clinical standpoint they could not compromise standards and would provide the patient the item they needed even if it cost more than the reimbursement.

- Are different manufacturers needed for different results?

The response was that there are options for breathable materials that cost more but are in the same code and sometimes are more appropriate but under competitive bidding the incentive would be to provide the low cost products rather than the more costly breathable products.

- The legislation assumes no education or fit is required for the off-the-shelf orthotics so what is the main concern? That therapists will spend a great deal of time without reimbursement?

The response was that the basic concern is that they (therapists in business) will go out of business because they won't compromise their clinical practice.

- If the device under consideration is a shoe insert for a person with diabetes would that be ok?

The response was that this would be even more of a problem because a practitioner needs to be involved. The quality of the product is the bottom line. Patients will go to discount places to get products but they don't know how to use them. A simple device in a shoe that is not meant to accommodate the device can result in more harm than good.

STAKEHOLDER PANEL: ENTERAL NUTRITION

Patricia Sirois, Jane Hardman, Alan Parver, and Rose Pereg made a panel presentation on enteral nutrition and competitive acquisition. Dr. Sirois, a doctor of pharmacy from the University of Michigan provided an overview of enteral nutrition and its coverage by Medicare. Enteral nutrition is the provision of nutritional formula via a tube inserted into a patient's stomach or intestine. Premixed formulas, tubing, and enteral pumps are covered under the Part B prosthetics benefit (the feeding tube is considered to be a replacement for a body part).

Jane Hardman, RN, Vice President of Reimbursement for Nutritional Support Services described the typical enteral patient profile. Enteral treatment is determined by patient characteristics, variation in comorbidities, and the setting of care. Unlike many DMEPOS services, enteral nutrition is covered in both home and nursing home settings. Enteral nutrition treatment involves assessment services; delivery, handling of formula, supplies and equipment; equipment management; education and training; and monitoring of the feeding regimen.

Rose Pereg, CEO and owner of Stonebridge Medical, noted that suppliers have significant operational differences between nursing homes and home care. Patients in nursing homes are often sicker, and nursing homes expect enteral nutritional suppliers to have clinical support resources to collaborate with the nursing home's resident team. About 60 percent of Medicare Part B enteral patients reside in nursing homes, while 40 percent receive enteral nutrition in their homes.

Alan Parver, Esq., President of the National Alliance for Infusion Therapy, argued that enteral nutrition is not a good candidate for the initial phase of the competitive acquisition program. Key concerns included the demonstration project's experience with enteral nutrition; difference in treatment between nursing homes and home care; the lack

of quality standards for enteral nutrition in nursing homes; and multiple formulas being billed under the same HCPCS code.

During the comment period, a PAOC member asked whether there were bids in the nursing homes during the demonstration. During the demonstration, nursing homes were encouraged to use demonstration suppliers, but they could continue to be served by an existing, nondemonstration supplier. A PAOC member asked whether separate quality standards should be developed for enteral nutrition suppliers serving nursing homes. The panel indicated that there should be special standards for nursing home care.

PUBLIC COMMENT

Karyn Estrella, Executive Director of the New England Medical Equipment group, an organization of 145 predominantly small medical equipment suppliers expressed concern about the proposed timeline for the program. She said that either competitive bidding is not appropriate for the industry or the timeline is not appropriate. She was also concerned that the financial standards would be too much for small suppliers and would have the effect of increasing costs while decreasing revenue. In addition, she believed that the standards need to clearly define service components. She stated that “competitive bidding has been a dark cloud hanging over us, and now the storm is upon us,” and urged CMS to do competitive bidding in a way that is the best possible.

Marcia Nusgart, Executive Director of a coalition of DME manufacturers emphasized that it is important for CMS to carefully review and update HCPCS codes quickly. She stated that the collaborative nature of physicians, clinicians, and suppliers are not always clearly reflected in the quality standards. She also called for the standardization of documentation.

David Deutsch stated that quality of life is the most important thing for the patient. He thought that CMS needs to fix HCPCS coding and carefully evaluate the effects of the quality standards and competitive bidding on the small supplier.

Wendy Beattie, Vice President of the American Academy of Prosthetics and Orthotics, stated that many prostheticians would not be able to bid or win the bid for off-the-shelf orthotics and predicted that many facilities would have to close. He noted that such facilities are needed so patients can try orthotics on and determine whether they are appropriate for the patient.

Daniel Berish, from Aircast LLC, a manufacturer of orthotics, thanked the PAOC for the opportunity to comment on the standards. He commented that the quality standards focused on the quality of services, but provided relatively little discussion of the quality of the products. He stated that the panels had done a great job of educating about the importance of service.

CLOSING COMMENTS

Herb Kuhn from CMS closed the meeting by thanking everyone for their participation, and noting the great attendance at this PAOC meeting. He said the panel presentations made it clear that suppliers have an absolute passion for the patient. The goal for CMS is to help patients restore patient functionality as much as possible. Mr. Kuhn stated that he would like to convene the PAOC during the comment period soon after the NPRM for the competitive bidding program is released.

Rita Hostak noted several recurring themes from the meeting: the complexity of matching products and patients, the interrelated roles and responsibilities of the team members providing equipment and care to the patient, and the fear that the team could be disrupted by competitive bidding.