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

Meeting Summary

October 6, 2004

Baltimore, Maryland

INTRODUCTION AND WELCOME

The PAOC meeting began with a welcome from Herb Kuhn, co-chair of the PAOC and director of the Center for Medicare Management at the Centers for Medicare and Medicaid Services (CMS) and Rita Hostak, co-chair of the PAOC and industry representative. Robin Williams, CMS moderator, provided an overview of the PAOC mission and meeting ground rules and reviewed the agenda. The agenda included six presentations, three by CMS staff and three by the RTI/Palmetto contractors. Each presentation was to be given in its entirety before opening the floor to PAOC discussion. The PAOC was informed that its mission is to advise CMS on design and implementation recommendations for the competitive bidding program and the quality standards that will be used in Medicare's DMEPOS benefit. This was followed by an introduction of committee members and a swearing-in ceremony.

MORNING SESSION

The three morning presentations by CMS staff were presented as a group; the PAOC then discussed all three presentations. The presentations included a review of the DMEPOS competitive bidding demonstration by Mark Wynn, an overview of the demonstration's evaluation by Ann Meadow, and a timeline of the Competitive Bidding program by Michael Keane.

Demonstrations

In the review of the competitive demonstrations, Mark Wynn, director in CMS' Office of Research, Development and Information (ORDI), presented an overview of the design and operation of the demonstrations that took place in San Antonio, Texas and Polk County, Florida. The demonstrations were authorized by the Balanced Budget Act of 1997, where Congress intended to achieve cost savings, discover market prices, and demonstrate the feasibility of using market methods for pricing certain DMEPOS products. The demonstrations included a broad range of products across the two sites. Bidding was conducted by Healthcare Common Procedural Coding System (HCPCS) codes, where bids for individual items in a product category were aggregated. Multiple suppliers were selected as winners in each product category. Quality and access evaluations were also important components of the demonstration. Mr. Wynn noted that

the history and reputation of bidding suppliers were considered, and that on-site inspections proved to be very important during bid evaluation. The demonstrations then relied on ongoing competition on the basis of quality to ensure continued quality and supplier performance. Another component of the demonstrations noted in the presentation was the importance of the transition policies for minimizing changeover and disruption of service.

Evaluation

Ann Meadow, CMS' project officer in ORDI, then presented an overview of the DMEPOS demonstration evaluation and the findings of the final Report to Congress. The evaluation was structured into key assessment areas, including expenditures, access, quality, market competitiveness, and implementation feasibility. Data for the evaluation was obtained through before and after surveys in demonstration and control sites; time series analyses of claims; bid analysis; and a supplier survey in the San Antonio site. The findings of the evaluation showed that overall expenditures were reduced by 19%, with variation in savings among the included products. Most quality and access measures remained stable, although a 24 percent reduction in portable oxygen use by new patients was reported in the survey, which was partially corroborated by a 12 percent reduction in claims for these products. However, the global satisfaction results remained stable throughout the demonstration, and the results were insufficient to determine if the reduction in portable oxygen use represented an access problem or was a result of other program changes and events. Most quality results were stable. As noted, most beneficiaries were satisfied with the supplier both before and during the demonstration. Some beneficiaries reported dissatisfaction with having to change brands for urologic supplies, and it appeared that some suppliers might have under-bid in this category. There were also anecdotes of changes in wheelchair service, such as suppliers charging for certain wheelchair accessories that they may have previously provided for free. Market competitiveness was also fairly stable. Market concentration measures were stable and market share changed slowly. Not all winning bidders increased market share, and it appeared that some did not make a marketing push to increase market share. Supplier views on the program were generally correlated with their winning status, with winning suppliers reporting positive results and losers reporting unfavorable views. The demonstration showed that competitive bidding could be successfully implemented from the lessons learned in the demonstrations.

Legislation/Timeline

In the final morning presentation, Michael Keane, CMS' project officer for the competitive bidding contract with RTI, illustrated the steps and timeline for the development of the DMEPOS competitive bidding program. Section 302 of the Medicare Modernization Act (MMA) requires bidding to occur in ten of the largest MSAs in 2007, in 80 of the largest MSAs in 2009, and additional areas after 2009. The process to design and implement competitive bidding began in the summer of 2004 with the awarding of a contract to RTI/Palmetto. By the spring of 2005 CMS will need to submit the notice of proposed rule making (NPRM) that will include the various provisions for the regulation. Some examples of the components that will be included in the regulation are: 1) the designation of bidding sites, 2) the selection of products, 3) the design of the bidding process, and 4) structure for implementation. CMS hopes to have these provisions be available for public comment by the summer of 2005. The final regulation will need to be published by the spring of 2006 so that time is available for supplier bidding to take place. During 2006, CMS will need to award an implementation contract(s), continue

with the educational programs for beneficiaries, suppliers, and referral sources, implement appropriate systems changes and conduct supplier bidding. Section 302 of the MMA also requires the establishment of quality standards for use across all of Medicare's DMEPOS benefit. Although these standards are not bound by the timeline for competitive bidding, CMS plans to implement the quality standards along with the competitive program.

Discussion

After the three morning presentations, the PAOC held a discussion period in which they asked the presenters for clarification on several issues. Committee members asked about the assessment of supplier quality, and in particular how a supplier could be rejected. Mark Wynn responded by mentioning that important information on quality was obtained through interviews with referral agents and site visits. Suppliers could be excluded if they had a formal citation or Inspector General (IG) reports indicating fraud or abuse. Committee members expressed some concern about the possibility that suppliers did not face uniform quality standards, and the fact that some suppliers were excluded based on their bid prices before they were assessed for quality. Committee members asked for clarification on product categories, quality criteria, the on-site inspection process, transition policies and program costs, and were generally told these results were listed in greater detail in the evaluation final report, which was provided to them at the meeting.

AFTERNOON SESSION

The committee meeting resumed in the afternoon with three presentations by RTI/Palmetto, each followed by a dedicated PAOC discussion period. Unlike the morning sessions, which focused on informing the PAOC about the history behind and tasks ahead for the project, these sessions were intended to present preliminary analyses and options for the consideration of the committee. The intent was to solicit ideas, suggestions, concerns and comments about various implementation issues.

Options for Implementation

Tom Hoerger, project director from RTI, presented the first presentation on program implementation structure. The PAOC was presented with options typifying a broad spectrum of implementation approaches for three stages; program design, bid evaluation and program operation. For program design, it was suggested that CMS or a single contractor produce the operational guidelines and program material templates. For the bid evaluation and operation stages, the committee was presented with three options, a centralized option involving CMS or a single contractor, a regional approach involving the four existing Durable Medical Equipment Regional Carriers (DMERC), or a localized approach based at the local level. For each option, advantages and disadvantages were presented based on certain criteria, including economies of scope, economies of scale, the learning curve, existing resources and infrastructure, and program time frame.

After the presentation, committee members discussed the presented options. Several members expressed opposition to the inclusion of DMERCs in bid evaluation and program operation. Some members expressed the view that bid evaluation should be managed internally by CMS and a few suggested that private industry approaches be considered. Two members with experience in competitive bidding expressed their opinion that bid evaluation and program operation must not be separated, and should be

done by the same people within an organization. Part of the session was devoted to a discussion on the merits and costs of program consistency, one of the criteria considered for the regional scope of the program. Several members stated that inconsistency in prices and access across regions would present ethical problems, while another expressed concern that manufacturers could find their products locked out of the Medicare program if bidding were done on a national basis.

Options for Quality Standards

The next item on the meeting agenda was a presentation by Shula Bernard, quality task leader at RTI, on quality standards. Section 302 of the MMA requires the establishment of quality standards for the entire Medicare DMEPOS benefit, and authorizes the agency to designate or authorize accrediting organizations to evaluate suppliers. The primary questions for the PAOC included in the presentation included how quality standards should be established, who should establish the standards, how they will be implemented, and how to define an accrediting organization. An important consideration was the limited capacity of accrediting organizations faced with the large number of unaccredited suppliers, and the time and cost requirements for accreditation. The panel was presented with the current work to date, which focused on interviews with accrediting organizations to review their processes and identify their quality standards. The committee was told that many of the standards were proprietary or copyrighted, but that in future PAOC meetings they may be provided a matrix of accreditation requirements cross-walked to the existing 21 DME standards.

The discussion period was marked with a general consensus that quality standards were important, and the current 21 standards were insufficient. Several committee members also spoke of the need for the DMEPOS industry to follow the lead of others and accept accreditation requirements. Some members mentioned the role of credentialing organizations for individuals. While there was near consensus on the need for accreditation and thorough quality standards, there was discussion about how to implement this requirement. Some members emphasized the importance of establishing uniform standards and not requiring some suppliers to meet these standards before others. Other members disagreed, noting that there was not enough capacity to accredit all suppliers at once. Several stated their opinions that the standards should be phased in by initially establishing requirements only for competitive bidding areas. Other issues that arose during the discussion were concerns over the impact of these requirements on pharmacies, and the concern that the accrediting organizations' standards may not be sufficiently consumer focused.

Options for Educating Beneficiaries, Suppliers, and Referral Sources

The final presentation of the day was made by Elaine Meyers of Palmetto, and focused on options for providing competitive bidding program education to suppliers, referral sources, and beneficiaries. The presentation was based on the education program of the demonstration, and listed the approach used to reach each of the target audiences. The presentation highlighted the role of the ombudsmen, who led education efforts in each site, and the press releases, fact sheets and other education materials used in the process. The education effort for suppliers included open meetings, contact with supplier associations, and contact through various communication channels with the implementing DMERC. Before the bidding occurred, suppliers were invited to a bidders' conference to provide materials and overview the process and requirements. After bid evaluation, all suppliers were provided a letter notifying them of their bidding results, and

inviting them to a debriefing session to obtain additional information. Referral sources, including discharge planners, physicians, and nursing facilities, were contacted by the ombudsmen, provided materials, and invited to workshops to learn about the program. Educational efforts targeted beneficiaries and social groups, residential facilities, community centers, and town-hall meetings to contact individual beneficiaries and provide them with the information necessary to obtain products and services under the competitive bidding demonstration. Perhaps the most important component of the education process for all target audiences was the provision of a supplier directory, which listed the winning suppliers for each product category and included instructions on program operation and contacts for questions or complaints. During the demonstration, it became apparent that releasing the supplier directory earlier would have been beneficial. The other major challenge of the education effort involved contacting physicians, who generally did not attend information sessions.

After this presentation, PAOC members made suggestions for other possible education resources and methods. There were no critical comments on the education program utilized in the demonstration, although one member thought that the focus on organizations for the aging represented a cultural bias in the program. Members mentioned that state Medicaid agencies would be a useful resource, as they have close contact with many dual eligible beneficiaries. It was noted that they were involved in the demonstration program. Another member mentioned that medical providers other than physicians should be a focus of the education effort, as providers such as physical therapists often have closer contact with and knowledge of DMEPOS products and services. A member with experience operating a competitive bidding program noted the importance of contacting losing suppliers, as beneficiaries are often very reliant on their suppliers for information, and these suppliers will need to direct their customers to other winning suppliers. This member also stated the importance of not “overloading” beneficiaries with information, and that many will need materials written simply and clearly and will still need personal assistance. This member noted that it is very important for program ombudsmen to have good local knowledge and communication, so that they are not just “another voice on the phone” to beneficiaries. Other suggestions included contacting congressional offices, which was done in the demonstration, contacting pharmacies, and involving manufacturers.

WRAP-UP

The PAOC meeting concluded with closing comments by the co-chairs, and a brief review of major issues. Members were then asked to provide their comments on the meeting, including what went well, what didn’t go well, and suggestions for future meetings. Several members made positive comments about the presentation format, the committee membership, and the moderation. Several members expressed some confusion over their role in the meeting and the committee’s role in the development and oversight of DMEPOS competitive bidding. Members also wanted to receive materials in advance, and Herb Kuhn indicated that they would attempt to do this for future meetings. PAOC members also asked if they could create a mechanism for out-of-meeting communication.

NEXT MEETING

It was announced that the next PAOC meeting is tentatively scheduled for December 6-7, 2004 in Baltimore.