

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 16, 2009

The Program Advisory and Oversight Committee (PAOC) met via teleconference on Friday, October 16, 2009, from 2 pm to 4 pm. PAOC members in attendance were: Tom Jeffers (co-chair); Peter Amico; Kendra Betz; Richard Boulger; Doran Edwards; Sue ElHessen; Joe Furlong; Walt Gorski; Rita Hostak; Jeff Mansell; Sharad Mansukani; Tom Milam; Barbara Rogers; Esta Willman; and Debra Zak. Ruben King-Shaw and Ann Kohler were absent.

The meeting opened with remarks from Jonathan Blum, Director of the Center for Medicare Management (CMM) at the Centers for Medicare & Medicaid Services (CMS), who thanked the PAOC members for attending the meeting and for submitting suggestions and feedback. He encouraged members to continue to send their ideas and questions to him, Laurence Wilson or Tom Jeffers so that CMS may ensure the program is as strong as possible. Mr. Blum reviewed key dates and said that CMS expects to meet the target date of October 21 to open bidding. He also announced that final guidelines on capacity should be released next week. Mr. Blum pointed out that, while certain issues are important to discuss, they would require a formal rulemaking process and therefore cannot be considered until round two. He acknowledged that the phone meetings have been beneficial and productive; however, he would like to schedule an in-person meeting in early 2010 at CMS to discuss the implementation process, specifically beneficiary education and outreach and formal interaction with the public.

Tom Jeffers, Vice President of Government Affairs at Hill-Rom, Inc., and co-chair of the PAOC, thanked members for their participation in the call and the CMS staff for arranging the meeting. He stated that he looked forward to the in-person meeting early next year and to today's robust dialog. He also reported that he had heard positive comments on the communication initiatives and improved education activities.

Laurence Wilson, Director, CMS Chronic Care Policy Group, CMM, reported that a formal announcement of the opening of bidding would be released next week. Registration has been open since August 17, and CMS has been pleased with the response. The number of registrants, however, cannot be released because it is considered procurement sensitive. Mr. Wilson thanked Mr. Jeffers for his remark about the education activities and noted that, on average, approximately 600 participants had attended each Special Open Door Forum Bidders' Conference. All education materials will be posted to the Competitive Bidding Implementation Contractor (CBIC) website prior to the opening of bidding, and CMS will continue to post answers to questions on the CBIC website as needed. A "What's New" feature will be added to the CBIC website so that newly added content can be easily identified. CMS expects to issue the final rule on round one termination of contracts and grandfathering around November 1, 2009. The next PAOC meeting will be in Baltimore in early 2010 to discuss beneficiary and supplier education prior to implementation. He encouraged members to submit agenda items for discussion.

Accreditation Update

Sandra Bastinelli, Senior Technical Advisor, Program Integrity Group, reported that the majority of suppliers have been accredited by the deadline. The exact number is not yet available. A process and guidance have been developed to assist beneficiaries in cases where a supplier's number has been revoked or deactivated and the beneficiary must change suppliers. A bill (HR3663) which extends the deadline for

pharmacies to be accredited to December 31, 2009 was signed into law on Tuesday, October 13. All large, chain pharmacies have been accredited.

PAOC Discussion

Barbara Rogers, a PAOC member, suggested that CMS offer site visits to beneficiaries' homes and DME businesses for CMS and those PAOC members who wish to participate so that they have a greater understanding of the process. Mr. Wilson thanked her for the suggestion and commented that it would be very useful. He stated that CMS has a preceptor program, and some CMS staff have already visited in some instances. He accompanied a supplier on the delivery of a wheelchair in Georgia last year. Mr. Wilson asked if the PAOC member would pursue the idea further and that CMS was open to the suggestion.

Another member reported that there were a number of small DME suppliers that had voluntarily deactivated their supplier numbers because they were not able to meet the accreditation deadline. Would it be possible for the National Supplier Clearinghouse (NSC) to expedite the reactivation of their billing numbers so that they could bid? Ms. Bastinelli responded that a priority process is being discussed for those suppliers with locations within a CBA. She asked that specifics be forwarded to her. A follow-up question was asked whether a supplier could still register if the billing number had been terminated. Martha Kuespert of CMS responded that suppliers must have an active NSC or billing number in order to register so this would present challenges.

DBidS Update

Carol Plum, Division Director, CMS Provider Communications Technology, Provider Communications Group, reported that the on-line bidding system (DBidS) is ready. System testing which validated that requirements had been met was completed in August 2009. Performance and stress testing have also been conducted and the system has been formally approved for bidding. The CBIC help desk will be available to assist suppliers with the bid submission requirements and any issues with the system. There were no questions or comments from the PAOC members.

Financial Standards for Determining Capacity Readiness

A PAOC member suggested that CMS consider adding a financial measure to demonstrate that the bidding supplier possessed the necessary capital to meet the terms of the contract. This would protect both the beneficiary and the program. He estimated that it would take approximately six months for a supplier to ramp up to meet expected demand. Furthermore, the economy has made a major difference as reflected on many suppliers' balance sheets. Therefore, the reported accounting period should immediately precede bidding, such as for the last quarter or period ending on September 30, 2009.

PAOC Discussion

One PAOC member questioned how liquid capital would be calculated and whether the "90 days of allowable value" as suggested was adequate. She offered that the measure should be based on an estimate of cost because acquisitions differ from item to item and margins are different. The PAOC member concurred that 90 days may not be enough. His premise was based on the 2009 allowables. He stated this was merely a starting point for discussion and asked that PAOC members run their own numbers using his proposed methodology as seen on the spreadsheet submitted with the agenda. Another member asked how CMS could ascertain that a service component was included in the bid. CMS responded that suppliers' locations must be accredited: Congress purposely required accreditation and the competitive bidding program to occur concurrently to ensure that only qualified suppliers were awarded contracts. Mr. Wilson reiterated that there would be close scrutiny and oversight to ensure that suppliers were operating in accordance with the contract terms and regulations. Contracts would be terminated if necessary. Another PAOC member suggested that any

new financial measure added to determine a realistic estimate of capacity not be used to disqualify a bidder but rather to only make any necessary adjustments to capacity. CMS indicated that this may be a useful approach for evaluating the expansion plan. Mr. Jeffers suggested that a supplier's ability to perform be added as a future agenda item.

IRS Form 4506-T

A PAOC member expressed concern that suppliers may attempt to fabricate required financial documents. He suggested that CMS require bidding suppliers to submit an IRS Form 4506-T granting CMS access to suppliers' actual tax extracts. Since there is no requirement to submit audited financial statements and only one year of financial documents is required, this would provide an independent verification from a trusted source. Mr. Wilson stated that CMS had talked with the IRS, and there are some challenges, such as the IRS having no set time to provide a response to a request and limiting requests to certain types of companies. However, he agreed it may offer a good tool, and CMS will work with the IRS on the logistical issues. An option may be to require the form be included with all hardcopy packages or conduct a sample such as on an audit basis.

PAOC Discussion

One member recommended that CMS verify the tax returns for all winning suppliers with the IRS. The 4506-T could be included in the contract package. If suppliers knew ahead of time that their tax extract may be verified with the IRS, it might eliminate any false bids.

Time Period for Financial Statements

Mr. Wilson noted that the requirements are for suppliers to submit financial statements and tax returns for the immediate one year prior to bid submission. The tax return and the financial statements must be for the same time period. This requirement cannot be altered for this bidding round.

PAOC Discussion

A member commented that the 2008 financial statements will look better than the period ending June 2009 because of the economy and the lower Medicare reimbursement rate. One member also expressed concern that financial statements ending December 31, 2008 will be quite different from those ending September 30, 2009. It was suggested that CMS request financial documents for the immediate previous quarter. Mr. Wilson asked that members submit suggestions for other documents that could be reviewed for subsequent bidding rounds.

Restriction of Contract Awards

A PAOC member stated that he had reviewed the Medicare Modernization Act of 2003 (MMA) and Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) for a reference on the limitation to the number of suppliers that could be awarded a contract and could find no mandate. He suggested that any supplier willing to accept the single payment amount (SPA) and that meets all other qualifications be considered a contract supplier. The supplier would still be required to submit a bid. Mr. Wilson questioned why a supplier would submit a bid amount much lower than the fee schedule amount if the supplier was guaranteed to be awarded a contract.

PAOC Discussion

One member expressed concern that many beneficiaries will be required to switch suppliers because of the small number of contract suppliers. CMS responded that a high percentage of noncontract suppliers choose to be grandfathered suppliers during round one, so CMS does not anticipate that this will be a problem. CMS intends to track grandfathering for the Round 1 Rebid to determine how

many suppliers elect to become grandfathered suppliers and how many beneficiaries choose to remain with their existing suppliers or change to a new contract supplier. A PAOC member stated that his concern was not specifically with grandfathering but rather over the life of the contract. Mr. Wilson assured the members that enough suppliers would be selected to address capacity and there will be an adequate cushion to absorb any fallout. Several members cautioned that the program cannot be compared to competitive bidding programs operated by the Department of Veterans Affairs (VA) or by private insurers. The VA prices are negotiated with manufacturers for the items and not for services.

Another member suggested that CMS track and establish a benchmark of the percentage of beneficiary turnover as a result of being required to change suppliers. He recommended there be a rational, objective tool to monitor excessive reported capacity based on the entry and exit of suppliers. CMS agreed this was a helpful suggestion and would be carefully considered. The member also suggested that additional CBAs be “rolled” into the process to make it more manageable rather than adding another 70 or 100 CBAs as suggested in Senator Max Baucus’ health reform bill.

Calculation of Single Payment Amount

A PAOC member suggested that the SPA be weighted rather than using an arithmetic mean.

PAOC Discussion

One member commented that the SPA may be much lower than the amount that a supplier bid. He suggested that CMS should be more liberal in its approach to allow for a margin of error. Another member agreed with the comment and stated an additional issue to consider is the SPA does not change if additional contracts are offered. Mr. Wilson stated that the methodology for determining the SPA was discussed in the initial regulation and must be implemented for the Round 1 Rebid as described in that regulation. There is no flexibility under the rule for this bidding round.

Diabetic Test Strip Products (50 percent Rule)

A PAOC member questioned whether the requirements in MIPPA for national mail order for diabetic testing supplies could apply to the Round 1 Rebid as there appeared to be time to implement the process before program implementation in January 2011. Mr. Wilson responded that MIPPA requires that any national mail order program be implemented after the Round 1 Rebid. MIPPA also outlines a process for developing national mail order requirements that includes a study conducted by the Office of Inspector General (OIG) for Health and Human Services (HHS). The study has not yet been completed. A formal rulemaking process, which includes soliciting comments, is also required. CMS plans to work closely with the PAOC on this process in the future.

Other Agenda Topics

Mr. Wilson opened the meeting up for discussion on other issues.

Coding: One member stated that approximately 50 percent of the Healthcare Common Procedure Coding System (HCPCS) codes include items that vary widely on costs. It was suggested tying pricing or billing modifier tiers (i.e., high, medium, low) based on manufacturer suggested retail price (MSRP) to track and stratify the types of items being dispensed. It was suggested that this would be a simple process to implement and could be done through a policy update article. The process would not affect bidding and would be for reporting and tracking purposes only. CMS asked the member to

submit an example of how this would work and will discuss the process further in terms of a monitoring strategy. One member believed that the HCPCS code descriptors are vague and the use of an Advance Beneficiary Notice (ABN) to provide an upgrade is not clear. CMS will discuss the anti-discrimination clause further internally and report to the PAOC.

Price Fixing or Bid Rigging: Mr. Wilson stressed that CMS has serious concerns about any bidding that violates antitrust regulations. Suspected violations should be reported to the CBIC, and CMS will work with law enforcement.

Oxygen Payment Policy: A member asked whether any guidance had been provided on the new oxygen policy and how it relates to the competitive bidding rules. CMS responded that responses to oxygen questions had been posted to the CBIC website under "Payment Policies." Walt Gorski of AAHomecare stated that this information would be forwarded to their association's members.

After no additional issues were raised for discussion, Mr. Blum thanked the PAOC members for the helpful discussion. He stated that a summary of this meeting would be provided to members and posted on the CMS website. An in-person meeting will be scheduled in Baltimore early next year. Mr. Jeffers thanked all for their assistance and asked that agenda topics for future meetings be submitted to him, Jon or Laurence.