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

Meeting 5 Summary

May 22-23, 2006

Baltimore, Maryland

MONDAY, MAY 22, 2006

The 5th meeting of the Program Advisory and Oversight Committee was centered on summarizing and discussing the provisions of the proposed rule for the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues:

http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1270p.pdf

The stated purpose of the meeting was to brief the members of the committee on the proposals forwarded for each issue, the alternatives considered, and the rationale for evaluating the alternatives, and to seek comment and suggestions for consideration before beginning work on the final rule.

The meeting was opened with a welcome by Herb Kuhn and Rita Hostak, thanking the committee members as well as the attendees for their continued participation and assistance and stating that CMS was looking forward to hearing comments and suggestions from all stakeholders. All presentations were conducted by CMS staff, and CMS's entire competitive bidding implementation team was present for the duration of the meeting.

BACKGROUND OF CMS'S PROGRESS,

UPDATE ON DMEPOS QUALITY STANDARDS,

DMEPOS ACCREDITATION

The first three presentations of the morning focused on a background of the status of tasks other than rule-making that were required for the implementation of competitive bidding, an update on the resolution of the comment period on the

draft supplier standards, and an update on the status of the development of requirements for accreditation organizations.

Laurence Wilson began by providing an overview of the current state of the regulation development process and other related issues and work ongoing at CMS. He stated that the release of the NPRM was a major, visible milestone reached towards the goal of implementation of the requirements of the MMA concerning competitive bidding for certain DMEPOS, but that many other tasks were ongoing as well. He indicated that work has already begun to prepare CMS and its contractors for implementation of this program. The program would require the development of a major new information technology system, and work had already begun on this task. The existing Medicare claims processing contractors, Medicare statistical analysis contractor, and Medicare provider enrollment contractors were also already working on ensuring that their systems would accommodate the deployment of this program. Mr. Wilson also announced that CMS planned to contract with a Competitive Bidding Implementation Contractor (CBIC) and a solicitation for bids had already been posted on www.fedbizopps.gov. Finally, he mentioned that CMS had already begun the development of manuals for the CBIC and for DMEPOS suppliers.

Linda Smith then provided the PAOC with a summary of the resolution of the public comment period and the results of beneficiary focus groups conducted by CMS's quality standards and accreditation support contractor, Abt Associates.

Barry Bromberg, who is the current program director for the National Supplier Clearinghouse (NSC) provided the last of the three initial presentations, focusing on accreditation. Mr. Bromberg focused his presentation on clarifying how the new accreditation requirement would be applied, the continuing role of the NSC and the current 21 Medicare standards, and that plans were in effect to ensure that suppliers who needed accreditation first due to proposed competitive bidding requirements would receive priority.

PAOC DISCUSSION

Following these three presentations, the PAOC members were given the opportunity to ask questions and discuss the presentations. The most common comments involved questioning why only 44 beneficiaries were surveyed, with several questioning why this appeared to be a very small number. Two members stated that they did not believe the somewhat negative findings of the focus groups were viable because of the small size and the lack of reimbursement may have led to beneficiaries with negative experiences to be more likely to participate. One member mentioned that his organization could provide the results of large surveys of their customers which were claimed to prove that the customers were very satisfied with their service. Ms. Smith responded by stating that the focus groups were not intended to be a large survey, but was intended to allow the people developing quality standards to discuss in detail the importance of different facets of quality with engaged beneficiaries. (NOTE: the contractor was also likely hindered by OMB requirements limiting the size of data collection

without undergoing a long approval process.) Other comments largely centered on the accreditation requirement. Some members expressed concerns about the timing of the enforcement of accreditation requirements. Mr. Bromberg responded that accreditation for contract suppliers will be required before implementation of the competitive bidding contracts. It was also noted that CMS will work with the approved accreditation organizations to ensure that suppliers facing competitive bidding in early rounds "will be taken care of". Other comments concerned requesting clarification that retail pharmacies, physicians and skilled nursing facilities that provide DMEPOS would require accreditation, and under competitive bidding, a contract. Several members expressed a high level of concern about these requirements. One noted the importance of the 51,000 existing retail pharmacies in providing access to DMEPOS even though it may be a small portion of their business. Two members discussed the complexities involved in enteral nutrition delivery with regards to SNFs, and that bidding could disrupt their existing service procedures. One member who manages a competitive bidding program expressed grave concern that the requirements for physicians were overreach and could interfere with patient care.

COMPETITIVE BIDDING AREAS,

CRITERIA FOR ITEM SELECTION

The next two presentations were given by Joel Kaiser on the selection of bidding areas and the selection of items for competitive bidding.

PAOC DISCUSSION

The PAOC discussion period included numerous questions about many specific facets of the presentations, many centering on how or why CMS would alter the bidding area from the MSA boundary and how items would be selected or excluded. One member wanted to know when MSAs would be announced, and was told they would be released when the final rule was released. Several members asked how or why CMS was proposing to expand the competitive bidding area beyond the boundary of a selected MSA. Mr. Kaiser reiterated that due to programmatic issues the boundary may not exactly correlate with MSA counties. He stated that while the OMB defines the counties and cities in an MSA based on general economic and commuting ties, that this is not always reflective of the realities of the DME market, including beneficiary population, supplier locations and supplier service areas. He said that CMS will use its authority to exempt uncompetitive areas from within an MSA, and while they may never add an area, CMS wants to have the option to add contiguous areas if this would result in maintaining current supplier service areas. One member expressed significant concern over the requirement that all contract suppliers agree to service beneficiaries in an entire bidding area, stating that small suppliers simply could not do this and advising CMS to take care when defining the bidding area to ensure all beneficiaries maintain access.

PAOC members brought up a wide range of issues related to item selection. Several asked questions related to the inclusion of items, such as orthotics. Several members asked questions related to how specific orthotics codes would be selected, and who would determine what constitutes “minimal self adjustment”. Mr. Kaiser responded that they propose to base the definition on items that do not require fitment by a certified orthotist, but that CMS would welcome comments and suggestions for revising this definition. A PAOC member then noted that CMS must consider the importance of preserving patient care when considering the inclusion of items. Mr. Kaiser said that the use of contracts will serve as a new tool at CMS’s disposal for determining and enforcing patient care, noting that contract suppliers must live up to the terms of their contract.

Other questions related to the use of product categories of HCPCS codes for the basis of contracts. Members wanted to know how product categories would be defined, and how CMS proposed to combine items from different medical policy groups. Others wanted to know when they would be released and if they could be commented on. Another PAOC member asked if beneficiaries would need to go to multiple suppliers to obtain all of their items if their supplier doesn’t win all product categories. Mr. Kaiser replied that this is possible and that it is a result of the proposed use of product categories, and reminded the PAOC that they had considered 3 choices earlier – bidding by category, for all HCPCS codes,,or for individual items and that each had advantages and disadvantages but this was the one most members were in favor of. Some members also discussed the current HCPCS system, with some noting that they felt there should be brand and product specificity and others noting the effect that recoding can have if such items are included in competitive bidding before suppliers gain experience with them.

PAYMENT RULES UNDER COMPETITIVE BIDDING

After lunch, the PAOC meeting resumed with another presentation by Joel Kaiser on Payment Rules Under Competitive Bidding. This presentation summarized proposed aspects of the regulation that would govern certain facets of bidding, program participation and supplier grandfathering and payment adjustments.

PAOC DISCUSSION

PAOC members discussed the payment issues and several raised objections to provisions of the grandfathering provisions and maintenance and repair requirements. Several members expressed concern over the scenario of contract suppliers being required to accept beneficiaries near the end of their capped rental term and conceivably only receiving one monthly payment before they had to turn over the title for a new item. While CMS responded that this would be a cost that suppliers would need to factor into their bid, some members said that this would be impossible to anticipate. One PAOC member suggested

that they were setting up a scenario where both beneficiaries and non-contract suppliers had an incentive to break capped rental agreements. Beneficiaries would be incentivized to switch to save co-payments or to obtain a new item at the end of the rental term. In addition, non-contract suppliers would have motivation to drop their customers just before the end of a rental term to force other suppliers to accept them and face a loss. Members suggested either not conducting bidding on capped rental items, not employing grandfathering provisions, or setting a limit after which capped rental agreements with non-contract suppliers may not be ended. Another issue of significant discourse was the stipulation that contract suppliers would be required to perform maintenance and repair for items that they did not supply. Several committee members stated that this would lead to bad service or that this stipulation was simply impossible for suppliers to perform. One noted that significant manufacturer training is required before servicing certain items and the large number of manufacturers would make it impossible for all suppliers to have personnel trained for all items. Several comments concerned or addressed new stipulations of the DRA that cap oxygen rentals or capped item duration. CMS noted that as the DRA was released in the final stages of regulation development, the rule sections relating to the DRA were developed quickly and may be readdressed in the final rule.

SUBMISSION OF BIDS UNDER COMPETITIVE BIDDING PROGRAM,

DMEPOS COMPETITIVE BIDDING PROGRAM SUBMISSION OF BIDS – PROPOSED PROCESS

The final presentations of the first day were conducted by Lorrie Ballantine and Alexis Meholic on Submission of Bids Under Competitive Bidding and the bidding process and draft RFB forms.

PAOC DISCUSSION

PAOC members commented and discussed several issues raised by the presentations, focusing largely on the burden of some of the reporting requirements, the proposals to allow networks and subcontractors, and the requirement for physicians and SNF to bid and win a contract to continue serving their beneficiaries. The introduction of the concept of networks and subcontractors caused some confusion, with some members wanting a clarification on what the difference was. Others warned that some suppliers could try to use these mechanisms to game the system or avoid meeting eligibility criteria. Similarly, some members were concerned that suppliers not included in a market would be allowed to submit bids, thinking that this could lead suppliers to bid frivolously hoping to get lucky in a certain market. Other comments focused on the proposed information and attachments that would be required on bids and on quarterly reports. Some members stated that it was not possible for most suppliers to provide the reviewed or audited financial

statements that would be required. Several members noted that suppliers would face a very high burden and cost to report the manufacturer, model and model number of every product they sold. A member offered his opinion that the cost for CMS and its contract suppliers to build such a reporting system may wipe-out any savings generated. Several members suggested that this should not be required, while other said this requirement could be better satisfied if it were integrated into claims and was only required for the top items. Some members took this discussion further to suggest that if the intention was to ensure that quality products were being supplied, CMS would be better served by introducing quality standards into the HCPCS codes. Some members cited the reporting burden, as well as the costs of accreditation and accepting late cap-rental transfers, to suggest that suppliers' costs would increase to the point where they may be above the fee schedule. Some members suggested that the requirement to bid below the fee schedule for each HCPCS was unfair and was not using market forces to obtain the true cost of an item and the additional program costs supplier will face. There was also some discussion on the risk to patients by requiring physicians and Skilled Nursing Facilities to bid and win contracts in order to continue providing to their patients.

PUBLIC COMMENTS -PLEASE CONFIRM NAMES AND ORGANIZATION FROM SIGN-IN SHEET

1. Ted Mannin ????

Criteria for selecting products should explicitly consider access to care. For diabetes products, many beneficiaries will be inconvenienced by not being able to obtain them in their pharmacy or nearby. He said that by reducing access, they will reduce compliance and this will result in poor health and higher overall costs.

2. Madeline Smith, Advamed ?????

Said Advamed cannot comment on the proposed rule until quality standards have been released. She said that the quality standards will effect the competitive bidding process, and requested a suspension of the comment period.

3. Colin Cooke – United Ostemy Association of America

Asked if ostomy and urological supplies will be included in competitive bidding.

4. Virginia Prasson? Abbot?

Said she wants to make sure competitive bidding does not harm access to care. She said that quality standards were important, but that she cannot comment on them until the final standards have been released. She said CMS should delay bidding for items not included in the demonstration. She stated that the HCPCS system should be revisited. Finally, she said that they felt physician authorization was very important.

5. Tom Jeffers ? Hillrom?
He said that the entire industry was under significant pressure with the BBA, a 3 year freeze and now the DRA and that CMS needs to be careful with the bidding program and with the future market adjustments. He said the CMS must ensure there is a safe margin for supplier capacity in bidding areas.

6. Peter Clendenon? National Association in Support of LTC
He noted that nursing home providers are absent from the PAOC discussion. He wanted CMS to release the quality standards and comments. He said that nursing homes outsource many services, and that nursing home patients are very different than home care, including disabilities and cognitive limitations. For this reason nursing home prices should not be compared to home care prices. He also cautioned about forcing nursing homes to lose control over the care they provide.

7. Dave Mclauslen ? Roho group
He said he was concerned about the proposal to combine products from different policy groups into a single product category, and felt the policy groups should be kept separate. He said that the methodology for selecting MSAs was well developed, and they need a similar formula for selecting products.

10. SEMA
Said that bidding should not take place in Puerto Rico, because 50% were enrolled in Medicare Advantage, and that Puerto Rico was too rural, too small, had too many storms, and that the importing costs were high.

11. Susan Morris - Advamed
She had concerns about linkage between codes and competitive bidding. She said that they need to redefine codes for better products, and not group very simple with very complex items. She was also concerned about bidding items that were not in the demonstrations.

12. Mary Ellen Conway? Capital Consulting Co.?
She said she heard there were 150,000 suppliers, and that this is too many to accredit. She said she was concerned about the validity of beneficiary focus groups. She also said that unannounced surveys should not be done because they were unfair. She also said that these concerns should be included in the Hopson-Tanner bill.

13. Don Clayback? MedGroup
He said there remained too many things that were unknown to offer comments on. He wanted an updated implementation timeline and wanted to extend the comment period. He also felt that they should have another PAOC meeting within 30 days to discuss in detail some of the problematic issues. Finally he said that you could not get results from a survey of 44 individuals.

15. Eric Soefel?? Power Mobility Corporation?
He wanted to know if a beneficiary could purchase a covered item from a non-contract supplier if they did not seek reimbursement.

16. Seth Lundy?
He said that he challenged the assumption that bids would be reasonable prices because suppliers will not know the new costs. He said that the composite bid price increases uncertainty. He also said they will get many “one dollar” bids by people just trying to keep in the market and this will skew the entire process. He said that using the median price is unreasonable because half of all bidders will receive prices below their bids, and that the others will be the low bidders. He said that significant cost savings should be defined, and guidelines should determine what percentage of suppliers will be selected. Finally he said that mail order suppliers should not be carved out.

17. Mayer Afasksus?
He said that he thought that this program had the potential to destroy this industry. He said the real issue was fraud and abuse and that is what they should concentrate on. He said they need to stop this process.

TUESDAY, MAY 23, 2006

SMALL SUPPLIER IMPACTS

The second day of the PAOC meeting began with a presentation by Linda Smith on Small Supplier Impacts.

PAOC DISCUSSION

Much of the PAOC discussion concerned clarifying how the definition of a small supplier would be applied and what consideration would be given for small suppliers. Several members requested clarification of how revenue for suppliers would be measured. Several members discussed the importance of distinguishing between overall revenue and DMEPOS sales, noting that some very large firms such as pharmacies could have very limited DMEPOS revenue, or that a firm's DMEPOS business could be performing better or worse than the overall firm. CMS clarified that for the purposes of background analysis, DMEPOS claims were used to identify that the large majority of suppliers exhibited less than $1 million in revenue for eligible DMEPOS items and services. However, for the purposes of supplying financial standards under competitive bidding, firms will be required to report information for the entire company. A PAOC member noted that CMS must consider that some large firms may report information for individual locations, but that the overall company's financials should be considered. Once the PAOC had discussed how a small supplier should be defined, consideration was given to the proposals and alternatives for ensuring small suppliers had an opportunity to participate. Some members were under the impression that the law specified that small suppliers would be permitted into the program without needing to bid or that a certain percentage of the market would be set-aside for small businesses. CMS clarified that the law only required CMS to provide small suppliers with an opportunity to participate in the competitive bidding program, and did not require any special consideration for small suppliers. CMS proposed to hold small suppliers to lower financial standards and not required them to provide audited financial statements. The proposal to allow small suppliers to bid as a network would permit them to meet the requirement that they agree to serve the entire competitive bidding area. Finally, bidding by product category would allow them to specialize. It was noted that most suppliers would be considered small, and that supplier capacity will have no role in assessing their eligibility.

CONDITIONS FOR AWARDING CONTRACTS,

SINGLE PAYMENT AMOUNT,

REBATE PROGRAM

The next three presentations concerned some of the mechanics of bid evaluation, supplier selection, and payment calculation. A presentation was also given on a proposed voluntary program to allow low-bidding suppliers to provide rebates to their customers. The first presentation on Conditions for Awarding Contracts was given by Michael Keane. The presentation discussed the four conditions that must be met, 1) Quality Standards and Accreditation, 2) Supplier Eligibility, 3) Financial Standards, and 4) Evaluation of Bids. The next two presentations were given by Lorrie Ballantine. Determining the Single Payment Amount walked through an example of the process outlined in the previous presentation on how eligible bidders will be evaluated and selected. The next presentation focused on a proposal to create a program where winning suppliers who provided a bid below the median price for an item could elect to offer the difference as a rebate to their customers.

PAOC DISCUSSION

These three presentations lead to the most heated discussion of the PAOC meeting, and the committee appeared to reach consensus on several issues. The two primary concerns raised by the PAOC were the proposed rebate program and the use of the median of the accepted bids to set the payment amount. Every PAOC member who spoke on the subject advised strongly against the rebate program, with four claiming it to be illegal, and one member said his organization was preparing to sue CMS over this proposal. The overriding concern of the rebate proposal was that it would be uncontrollable and may lead to rampant fraud and abuse. Several members representing suppliers said it would be completely unworkable to track and issue rebates, one noting that it costs his company $10 to cut a check and that they certainly wouldn't do this to pay rebates likely worth only a few cents. Some found the stipulation that they would be barred from advertising their rebates to be unrealistic, illogical and would also lead to flouting of the law. One member representing a government competitive bidding program noted that he did not believe it was possible for CMS to monitor, control and administer such a program. While the rebate proposal consumed most of discussion, many members also keyed in on the proposal to base payment amounts on the median accepted bid for each HCPCS, claiming that this would result in unreasonably low payment rates. Some members discussed their belief that the program will see a large volume of small DMEPOS suppliers bidding extremely low just to ensure they could stay in the market, and others envisioned out-of-market suppliers submitting low bids in most or every market as a gamble hoping to get a contract at a high price and then subcontracting with non-winning suppliers in that market. The PAOC members noted that these low or zero quantity suppliers would be weighted equally with suppliers with high volume, and are likely to outnumber them as well.

In this case the median bid would be reflective of these “low-bidders” and the real suppliers would be unable and unwilling to service the market at this price. Several members said that CMS should continue to use the process in the demonstration where composite prices were set to the pivotal bid, saying that this was a sensible and successful approach and this was what Congress intended when the legislation was drafted. Other suggestions made by PAOC members were to use the demonstration payment method in the first rounds and then see what prices would have been under different scenarios, to eliminate outlier or unreasonable bids, and to set parameters for a reasonable final bid price. Several members also aired their concern that the final price be based only on reasonable bids by qualified suppliers, saying that disqualifications for quality standards, eligibility or financial measure occur before price calculation. Others noted that this should also apply when determining capacity, and at least in the initial round CMS should ensure there is a large cushion of capacity to meet demand based on demographic changes and the realization that the bidding, reporting, and accreditation requirements will cause substantial business closures.

TERMS OF CONTRACTS,

SELECTION OF NEW SUPPLIERS AFTER BIDDING

The final two CMS presentations from Karen Jacobs and Ralph Goldberg centered on proposed rules and processes that would govern the operation of the program after winning bidders were selected.

PAOC DISCUSSION

During the PAOC discussion, comments centered on complications of the service, repair and maintenance requirements arising from competitive bidding and the Deficit Reduction Act. Several members noted that the requirement that only contract suppliers will do service and repair and that contract supplier cannot refuse to do this work was impossible and infeasible. Members noted that not all suppliers do repair work and most try to avoid it because it incurs significant losses. They also said that it is impossible for a supplier to repair products that they themselves do not provide, noting that repair and service requires supplier staff to receive manufacturer training and experience and this was impossible to gain for every product from every manufacturer. One member said that CMS must consider the future of the repair and service requirement and payment outside of the context of competitive bidding, that a new solution is necessary for all of Medicare. Another issue concerned how CMS could monitor compliance with the terms of the contracts and other problems. CMS staff mentioned accreditation, NSC eligibility, representative sample and targeted surveys and complaints. CMS also stated that there will be an extensive education and ombudsmen program conducted by the CBIC and that in practice the ombudsmen on the ground will find out when something goes wrong.

Another issue of discussion concerned restrictions on the sale of contract suppliers. One member said that he envisioned significant consolidation in the industry regardless of competitive bidding, and that these restrictions would harm small business owners whose businesses would become more valuable if they have a contract. He said that it shouldn't make any difference to the government who owns the businesses as long as they meet the quality standards.

OPEN DISCUSSION

The open discussion gave PAOC members an opportunity to air any other questions or comments about any facet of the propose rule. A member asked about a definition for a national accrediting body, and CMS said that a definition will be forthcoming in the Federal Register. The representatives from the VA gave an overview of their competitive bidding program for DMEPOS to the other PAOC members. They noted that the VA can pay for rental of items similar to Medicare, but generally the VA will actually buy specific products and the VA beneficiary will take ownership. The VA will then establish repair and service contracts separately. Contracting is conducted by work-groups consisting of physicians, engineers and contracting personnel. They mentioned that the VA has the benefit of having these items prescribed, fitted and provided by their own physicians and staff. They also said that while the VA has a voluntary minimum small business participation level, about half of their contracts are held by SBA-definition small businesses without the need for any intervention on their behalf. A representative of another bidding program said that in his experience, Medicare needs to have an expectation of what savings will be generated, and use this in a mechanism to eliminate outlier bids. He also strongly advised against the allowance of networks and subcontracts, saying that this would be chaotic, would erode CMS control and dilute the standards of the program. Two members discussed physician authorization, noting that it is good that the provision includes all prescribers and that while it is done now for some product lines such as custom wheelchairs, it will be beneficial for this to be addressed in the supplier contracts. One member discussed the proposed modification to the gap-filling process for setting payment for new items and services. The member noted that it was good that this process was being addressed, but that it should be done independently of competitive bidding and should be a transparent process.