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

Meeting Summary
June 4, 2009
Baltimore, Maryland

The Program Advisory and Oversight Committee (PAOC) meeting was held on Thursday, June 4, 2009. The purpose of the meeting was to discuss proposed activities and processes for the rebid of the first round of the Competitive Bidding Program and to solicit the PAOC's advice, feedback and suggestions. Members and others in attendance were informed that they could submit additional comments by e-mail to Ralph.Goldberg@cms.hhs.gov or Gina.Longus@cms.hhs.gov.

The meeting opened with remarks from Jon Blum, Director of the Center for Medicare Management (CMM) at the Centers for Medicare & Medicaid Services (CMS), who thanked the PAOC members for their willingness to share their advice and time. He stressed the importance of the program achieving a balance between determining correct payment amounts for items and services with ensuring beneficiaries' access to those items and services. He informed the members that CMS had engaged in a careful review of the rules in order to ensure that processes and activities met statutory guidelines. In addition, CMS has and will continue to review input from stakeholders. He concluded his remarks by thanking the PAOC for their service and looked forward to hearing their input and constructive suggestions during the meeting.

Thomas Jeffers, Vice President of Government Affairs at Hill-Rom, Inc., was introduced as the co-chair of the PAOC. Mr. Jeffers stated that he hoped that we could learn from the first round and avoid any anomalies in the rebid. He stressed a need for all to employ a broader perspective and when making decisions to err on the side of the beneficiary. However, he continued that we must be cognizant that we are stewards of public resources and must blend the two. He acknowledged that there will be risks for all but we must work to create an effective program that mitigates those risks.

Laurence Wilson, Director, CMS Chronic Care Policy Group, CMM, stated that the legislation required bidding to open in 2009. Therefore, this meeting would focus on the early stages of the program including registration and bidding. Future meetings will focus on implementation. Mr. Wilson briefly reviewed the agenda topics and acknowledged the value of the PAOC in the past and CMS' reliance on their expertise and advice. He looked forward to working with this PAOC and specifically hearing their ideas on the bidding phase of the program. He emphasized the importance of education, stating that it must be at the right time and targeted appropriately. At the conclusion of Mr. Wilson's remarks, the PAOC members introduced themselves.

Background on the Program

Joel Kaiser, Director, CMS Division of DMEPOS Policy, provided a brief background on the program including legislative requirements and payment rules. He presented an overview of the results of the demonstration projects and the first round of the Competitive Bidding Program and reviewed MIPPA (Medicare Improvements for Patients and Providers Act) requirements.

PAOC Discussion

One member questioned why large suppliers were not the dominant winners during the first round and whether CMS was confident that small suppliers could meet beneficiary demand. Mr. Kaiser responded that 98 percent of DMEPOS suppliers are small as defined by the final rule; therefore, the majority of winning suppliers would be small suppliers. He explained that each supplier determines his/her capacity and bid amounts for each item. During the bid evaluation process, CMS ensures that there are a sufficient number of suppliers to meet demand. Mr. Wilson encouraged the PAOC members to provide suggestions on how to achieve a balanced selection that meets rule requirements and beneficiary demand.

Another member questioned whether accreditation and quality standards reduced a small suppliers' ability to compete. Mr. Kaiser responded that the costs were the same for all suppliers and does not favor one supplier over another. Mr. Wilson stated that the process provides a level playing field and sets the floor. One member reminded the committee that safeguards must be in place to insure beneficiary protection. Mr. Wilson assured the PAOC that this topic would be discussed in greater detail at future PAOC meetings. Another member questioned why there was such a small number of suppliers that submitted a bid and how that number could be increased. PAOC members also questions supplier feedback on financial documentation. Mr. Kaiser provided data on the number of small and large suppliers selected and also indicated that he would provide an unduplicated count and overall market capacity. One member commented that the program's purpose should not be to have a large number of participants, but rather the right mix of participants. Members were reminded that MIPPA does not provide the details, on how the program should be administered. That was the purpose of today's PAOC meeting.

On-Line Bidding System

Rich Cuchna, Deputy Director, Provider Communications Group, CMM, provided highlights, improvements and changes in the on-line registration and bidding systems. He stressed the importance of suppliers maintaining current records with the National Supplier Clearinghouse (NSC) as data will be verified with these records and with the Social Security Administration's records. He also encouraged suppliers to have more than one authorized official listed on the enrollment form (CMS-855S) to serve as a back-up authorized official during the bidding process.

PAOC Discussion

One member stressed the importance that the system be adequately tested and the help desk satisfactorily trained. It was also suggested that an Excel template be provided that could be uploaded by the supplier into the DBidS system. CMS responded that bidding suppliers will only be required to provide the model information for the top HCPCS codes so this should not be an issue. A second level associate will be available to also assist suppliers. A PAOC member asked if we had any conception of how long it would take to complete an application now versus how long we did in the past? CMS response was that it depends on how many areas you are bidding on and how many Form B's will be completed. CMS stated that it will do a lot of up-front education. Mr. Blum said that the timeline allowed for sufficient testing of the system and that the system has been continuously refined since the PAOC meeting in October of 2007. One member said that she understood paper copies of Form A and B had been published. Mr. Wilson said that they were part of the Paperwork Reduction Act (PRA) that has been posted to the Federal Register for public comment. He later clarified that they were not included in the PRA but members would be provided with copies of Form A and Form B.

Education on Program Requirements and Bidder Responsibilities

Cindy Dreher, Policy and Content Lead, Competitive Bidding Implementation Contractor (CBIC), provided a summary of activities and resources provided during the first round and a proposed plan for the rebid. She outlined lessons learned, initiatives to address these issues, and the key messages that will be continuously communicated to suppliers. The bona fide bid amount was identified as one issue during the first round. Mr. Kaiser explained that CMS uses a statistical threshold to identify anomalies in submitted bid amounts. For the rebid, CMS intends to evaluate bid amounts across all CBAs versus a single CBA to determine if a bid amount is bona fide. This will address the issue in Round 1 where suppliers' bid amounts were bona fide in one CBA but not in another. Additionally, Mr. Kaiser emphasized that upon request suppliers must submit supporting documentation for a bid amount within the specified time frame. Ms. Dreher concluded by soliciting ideas and suggestions for education and outreach activities.

PAOC Discussion

No suggestions were offered for education and outreach activities. However, several members commented on the methodology to determine suppliers' capacity to meet beneficiary demand. Another member suggested that suppliers who provide an item must also be required to service that item. One member asked how CMS could verify that new suppliers' bid amounts were bona fide; to evaluate a supplier's ability to provide a service requires more than statistical anomalies. Mr. Kaiser stated that the contract supplier would be expected to adhere to the terms of the contract. Members asked if CMS performed criminal background checks in the past and if so, will they continue in the Re-bid round? Another member asked if competitive bidding has higher standards for today, answered yes and suggested that audited tax returns should be done. CMS stated that financial documentation was reduced from 3 years to 1 year which was suggested by our previous POAC members because of the high cost involved. A PAOC member suggested this was a big mistake. Another member asked about the service component, that invoices can be sent but how do we know that they have the ability to service the product?

Financial Documentation

Martha Kuespert, Senior Technical Advisor, Chronic Care Policy Group, CMM, described the new MIPPA requirements to submit financial documents by the covered document review date (CDRD). She also explained the new requirement for one year of financial documents, which should reduce supplier burden while providing an adequate assessment.

PAOC Discussion

PAOC members questioned the rationale for not divulging the financial threshold scoring. One member suggested that releasing the thresholds may discourage some unqualified suppliers from participating. Members also discussed the merits and disadvantages of only one year of financial documents. One member suggested requiring one year of financial statements and three years of tax extracts. Mr. Blum remarked that the goal was to lessen the burden on the bidding suppliers while providing confidence that the suppliers can meet beneficiaries' needs. Several members expressed their concern that suppliers would not be able to ramp up in time to meet beneficiary demand. CMS asked that members send additional specific suggestions in writing on how to ensure enough qualified suppliers were awarded contracts to meet demand.

Licensure, Accreditation, and Subcontracting Requirements

Kim Brandt, Director, Program Integrity Group, CMS Office of Financial Management, provided an overview on the quality standards requirements mandated by the Medicare Modernization Act (MMA). She reminded suppliers of the accreditation deadline and consequences of not obtaining

accreditation. She also explained the surety bond requirements and implementation dates. Ms. Brandt reviewed the licensure and subcontracting requirements as specified in the supplier standards.

Lorrie Ballantine, Technical Advisor, CMS Division of DMEPOS Payment Policy, outlined general licensure requirements and stressed that copies of the applicable licenses must be on file with the NSC at the time of bid submission. During bid evaluation, licenses will be verified with the NSC files. A tool will be provided on the Competitive Bidding Program website to assist suppliers with licensure requirements. She explained the licensure rules for suppliers located in CBAs crossing multiple states. She also stressed that all locations must be accredited at the time of bid submission and that MIPPA requires subcontractors to be accredited.

PAOC Discussion

A PAOC member asked for clarification on the fees for surety bonds. Ms. Brandt explained that the fees were based on market prices, not on the relative risks. One member questioned how a subcontractor could be accredited that was not a supplier and for clarification on subcontracting for inventory. Ms. Brandt indicated that CMS was still working on those issues and expected to provide guidance soon. A discussion occurred on requirements for suppliers located in CBAs that cross state lines. Mr. Wilson confirmed that MSAs (Metropolitan Statistical Areas) may cross state lines. One member suggested that we also require Better Business Bureau (BBB) accreditation. Another member suggested that we should require suppliers to provide names of subcontractors at time of bid submission so that they may be validated before contract awards. It was also suggested that only retail diabetic suppliers be required to be accredited, not mail order suppliers. One member suggested providing a template on the CMS website for suppliers or any stakeholder to complete that would provide specifics of suspected fraudulent activities. One member suggested that subcontractors in certain areas must be bilingual.

New Supplier Issues

Mike Keane, Acting Deputy Director, CMS Division of DMEPOS Payment Policy, described how the financial ratios and credit scores were used to evaluate a suppliers' financial strength during Round 1. He provided the ratios used but reiterated that the thresholds and scores could not be revealed to protect the integrity of the process. Mr. Keane explained a proposed methodology to evaluate new suppliers by increasing the threshold by 75 percent, which would result in awarding more contracts to experienced suppliers.

PAOC Discussion

A PAOC member suggested that if a supplier scores zero (0), that supplier should not be included in determining capacity. Suppliers with no historical capacity but with good financial scores should be given a zero (0) score. Mr. Kaiser explained that demand was projected high and then was positively trended forward to the end of the contract period. Two trending factors were: 1) beneficiary enrollment in the fee-for-service benefit and 2) projected percentage growth in DMEPOS utilization based on the data in the Medicare Trustees Report. Double trending results in padding of the demand figures and further ensures access to items and services. One member suggested that a supplier must be required to demonstrate capacity as indicated in claims history. Another member stated that it was bad policy to give new suppliers a contract and should only be allowed to participate if the supplier had transferable experience. A supplier pointed out that it was up to the new supplier to prove itself before getting customers. Another member suggested that new suppliers should serve only as subcontractors.

A member recommended that the single payment amount (SPA) should be greater than the medium bid amount. Suppliers with no history of providing the item should not influence the SPA. Another member expressed concern that non-contract suppliers were not willing to accept the SPA for repair parts, which would require the beneficiary to obtain the parts from a contract supplier. CMS asked members to submit specifics on this occurrence so that it may be researched further.

One member stressed that the capacity and demand factors were the most important issues. A discussion ensued and CMS pointed out that percentage growth by itself was not key in the calculation but rather the number of items a supplier indicated he could provide annually throughout the duration of the contract. It was determined that because of the complexity of the issue, the discussion would continue at a later meeting.

Mail Order Diabetic Testing Supplies

Joel Kaiser explained the MIPPA provisions and rationale for a national mail order program after 2010. He presented alternatives for a competition and solicited feedback.

PAOC Discussion

A PAOC member asked how this process would be developed and Mr. Kaiser explained that it would be addressed through rule making next year. One member cautioned the PAOC about counterfeit strips. Another member suggested there be a separate CBA during the rebid for mail order. Mr. Kaiser clarified that for the round 1 rebid the statue requires bidding in the same CBAs; a separate CBA could not be added for the rebid. A member expressed concern that there were not enough winning providers with adequate capacity and would submit suggestions in writing. He also suggested that the 50 percent rule for diabetic test supplies stipulated in MIPPA be applied to the rebid. A member suggested that if a mail order pharmacy helps with a monitor they do not get paid the $5.00 difference. Another member suggested that we needed more conversation about capacity and service component.

Tentative Timeline

Martha Kuespert described the draft timeline for the rebid. She noted that additional time was included prior to implementation to adequately educate beneficiaries and referral agents.

PAOC Discussion

A PAOC member cautioned that contract suppliers needed ample time to ramp up their businesses, which may require capital expenditures. Another member reminded the group that the repair and service issue must be resolved prior to implementation. CMS acknowledged there was additional work to do and encouraged members to submit further comments in writing. Members were also asked to contact CMS with questions, concerns and suggestions for future meetings.

Public Comments

- CMS should demonstrate compliance with the Data Quality Act. This would mean the agency would be required to disclose the algorithm for determining capacity. Suppliers should submit comments to the Center for Regulatory Effectiveness website. Comments will be summarized and a paper submitted to CMS.
- Suppliers should be provided education during the bidding phase that contracts are not transferrable and may not be sold. Some suppliers chose not to bid in the first round with the intent of buying winning suppliers' contracts.

- Jon Blum's and Thomas Jeffers' opening comments should be posted to the CMS website. The PAOC should be used more often and other ways for members to communicate should be explored. Suppliers' costs are different dependent upon a supplier's location. Capacity is the most important issue. Contract suppliers should be held accountable from day one of implementation.
- Companies that are not experienced are unable to meet customers' needs on day one. Many new suppliers may bid low not realizing the extent of the service component.
- It is important that beneficiary access and quality of items and services be protected. The 50 percent rule for diabetic testing supplies should be included in the rebid. Beneficiaries should be educated that any retail pharmacy can continue to provide testing supplies. CMS should ensure that winners are qualified and experienced and provide a wide range of diabetic testing products.
- The pharmacy industry (pharmacist, diabetes educator, beneficiary) is not represented on the PAOC. Small suppliers, such as community pharmacies, are not afforded the same opportunities and impediments should be eliminated. Pharmacies should not be required to be accredited as DMEPOS items are a small part of their services and revenue.
- The rules and details outlined in the RFB should be released soon to allow suppliers an opportunity to determine whether they want to participate in the program. Bidders need a 90-day educational period before registration begins, and it appears that there is still not adequate time allowed prior to bidding. Clarification should be provided as to how new suppliers will be handled during bid evaluation. Capacity is the critical topic.
- The commenter expressed appreciation for the slow and deliberate approach taken by CMS. The commenter also questioned what the OIG audit will include that is required in MIPPA? [CMS has not yet received information on this requirement.]
- CMS should carefully review rules for new suppliers being awarded a contract
- Most suppliers, large and small, are not capable of growing their businesses by 20 percent as stated by a former PAOC and documented in the final rule. The new timeline is appreciated. There should be tougher standards for suppliers with no experience with the product category.
- Key areas of concern are 1) experience of bidding suppliers, 2) access to wide range of products; bind suppliers to product offerings, 3) develop patient outcome measures to ensure that beneficiaries are not negatively impacted, 4) transparency in the bid evaluation, 5) beneficiary access to diabetic testing products using the 50 percent rule, and 6) do not apply bid rates from one area to another. There should be new proposed regulations to address the SPA methodology.
- Contract suppliers should be required to repair and service their equipment. CMS should review Group 2 PMDs with multiple seat functions and remove them from the product category. Suppliers have an incentive to provide this item when a Group 3 PMD would be more appropriate for the beneficiary.
- The minimum threshold for demonstrated capacity should be similar to the small supplier target or threshold.

Jon Blum thanked the PAOC members for participating in the meeting, stressed the value and importance of their feedback, and that he looked forward to continued discussions.