Before the
Office of Management and Budget

SMALL BUSINESS ENHANCED COMPETITIVE BIDDING: Paperwork Reduction Act Comments on CMS' DMEPOS Competitive Bidding ICR

In the Matter of	)	
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Round 1 Rebid	)	
and Disclosure of Subcontracting	)	
Relationships for the Durable Medical	)	
Equipment, Prosthetics, Orthotics,	)	
and Supplies (DMEPOS)	)	CMS–10169
Competitive Bidding Program	)	
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The Center for Regulatory Effectiveness
Suite 500
1601 Connecticut Avenue, NW
Washington, DC 20009
202.265.2383
www.TheCRE.com

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Center for Regulatory Effectiveness

SMALL BUSINESS ENHANCED COMPETITIVE BIDDING:
Paperwork Reduction Act Comments on CMS' DMEPOS Competitive Bidding ICR

The Center for Regulatory Effectiveness (CRE) recognizes that this ICR is an opportunity to substantially expand competition, and opportunities for small businesses, in the Round 1 Rebid. Specifically, any qualified small business DMEPOS provider (as defined by SBA, not CMS) in a Competitive Bidding Area (CBA) should be able to supply equipment at the "single payment amount" determined through the competitive bidding process. It is important to note that all suppliers would receive the single payment amount; no price for covered DMEPOS in CBAs would be based on the old fee schedule. Moreover, CMS should require that competitive bidding contracts be non-transferrable for a period of no less than one calendar year. Such a provision will uphold program integrity and ensure that larger providers submit bids that are reflective of their operational capabilities by creating a pure competitive acquisition program.

Providing qualified small providers with the option to participate at the competitively-determined price would do much to ameliorate the critical PRA deficiencies detailed below in these comments without compromising the program's cost-cutting imperatives. Moreover, reducing the small business impact of the program would save countless jobs in these small business and prevent yet another industry from becoming dominated by a relative handful of "too big to fail" providers.

Since many of the small DMEPOS providers that would be put of out of business if the program is not expanded may be minority, women-owned, or veteran-owned, HHS' Office of Small and Disadvantaged Business Utilization (OSDBU) should be formally consulted. OSDBU is "fully dedicated to supporting every small business entity...in their pursuit of health-related contracts."

The DMEPOS competitive bidding program is a data-driven exercise. OMB oversight of the program's paperwork is an essential prerequisite for ensuring CMS is able to achieve much needed cost containment in the Medicare program while maintaining quality care. The program's success requires that the data collected, the plan for its use, and all information disseminated meets the standards set by the Paperwork Reduction Act (PRA), and the OMB and CMS guidelines implementing the Data Quality Act (DQA). For the competitive bidding program, ICR review is more important than regulatory review.

CRE explained the need for the agency to demonstrate adherence to information quality standards in a Data Quality Alert that was sent to key CMS officials. Subsequently, CRE discussed the data quality issue in a presentation to CMS' Program Advisory Oversight Committee (PAOC) at a public meeting held on June 4, 2009. CMS officials are being provided with copies of these ICR comments as part of CRE's ongoing dialog with federal officials and other stakeholders aimed at protecting the nation's fiscal and medical health. CRE's PAOC testimony, Data Quality Alert and other key documents are publicly available in the Competitive Bidding Interactive Public Docket found at http://www.thecre.com/blog/.

In these comments CRE will address small business concerns, the proposed bidding forms, burden estimates, and PRA certification issues. Reflecting, however, the supreme importance of Data Quality to the success of the competitive bidding program, the comments will begin with a discussion of these issues within the context of the PRA. As discussed below, the ICR will need to be revised to bring it into DQA and PRA compliance.

The ICR revisions will also provide CMS the opportunity to ensure it allows for far more SBA-defined small businesses. It is only by expanding this ICR to allow all qualified small providers to participate in the program that cost-cutting objectives can be achieved while maintaining health care quality and preserving jobs.

CMS' ICR and the Data Quality Act

The PRA requires that for each ICR the agency have "a plan for the efficient and effective management and use of the information to be collected...."[1] CMS must also adhere to the PRA's other substantive and procedural requirements, including ensuring that the data collected would have practical utility. Thus, the PRA sets quality standards governing the agency's collection and use of information. As CMS has recognized, the DQA's information dissemination standards also apply to the collection and use of data since these are prerequisites for developing quality information products.

Specifically, CMS' "Guidelines for Ensuring the Quality of Information Disseminated to the Public" recognize that PRA compliance is the foundation for compliance with the DQA. As the CMS Guidelines explain,

> "*Through the PRA process CMS ensures that information that will be collected, maintained, and used in a way that is consistent with OMB, HHS and CMS information quality guidelines.*"[2]

In our Data Quality Alert to CMS, CRE identified five specific Data Quality competitive bidding responsibilities; Level II HCPCS Codes, Beneficiary Demand, Supplier Capacity, Composite Bids, and Pivotal Bids. For each of these issues, CMS needs to document compliance with Data Quality standards through their pre-dissemination review process and provide that record for public review and comment during the ICR process.

CRE recognizes that it would be difficult for CMS to provide records for all five responsibility areas during this ICR review. Thus, we are focusing on Supplier Capacity as this issue is the keystone of the competitive bidding process. Our comments will also discuss the HCPCS Codes since CMS presented them for approval as part of their ICR package.

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[1] 44 USC § 3506(c)(1)(A)(vi).

[2] http://www.thecre.com/pdf/20021026_hhs-cmms-dqfinal.pdf.

Supplier Capacity: The Crucial Determination

CMS' planned determinations of Supplier Capacity is the least transparent part of the competitive bidding system. The agency's Supplier Capacity calculations are based on the information that would be submitted under this ICR. These calculations affect; 1) the business opportunities available to bidders, 2) DMEPOS costs, and potentially 3) the health of Medicare participants.

If CMS underestimates the capacities of some suppliers in one or more product categories, the agency may have to accept higher-cost bids to meet estimated demand, thus needlessly increasing program costs by raising the median winning bid price. If, however, CMS overestimates the ability of a winning bidder to supply specified products within a CBA, there could be shortages of products, threatening the quality of patient care. Overestimating the capacity of certain suppliers could also result in other suppliers, particularly smaller ones, being unfairly excluded from winning a bid. The Supplier Capacity determinations are, without a doubt, "influential" information as defined by the OMB and CMS Guidelines.

It needs to be recognized that the problems associated with underestimating and/or overestimating the capacity of any given supplier could be prevented by allowing qualified small suppliers to provide equipment at the single payment amount. Allowing these small qualified businesses to participate creates a robust system that avoids the fragility inherent in creating dependence on a few larger companies. Thus, **many of the Data Quality problems described below could be effectively resolved by allowing all small qualified companies to participate in the program**.

Despite the centrality of Supplier Capacity determinations to the success of the competitive bidding program, the algorithm CMS would use for making these determinations remains opaque. Stakeholder concerns regarding the lack of transparency go back to the program's inception and continue to this day. Since the capacity determinations are largely based on the information contained in this ICR, review of this ICR is the appropriate forum for ensuring that CMS has a plan for using the data that adheres to the quality standards set forth by the agency and thus that the data to be collected has "actual, not merely the theoretical or potential, usefulness of information...taking into account...the agency's ability to process the information it collects...in a useful...fashion."[3]

The information CMS proposes to collect under this ICR that would be used in Supplier Capacity calculations include the data on Form B as well as the supporting financial documentation. Form B, "Bidding Form," requires submission to CMS of capacity-related data including; revenue by product category within a CBA (Question 1), number of customers to which the bidder provided items in the product category in the CBA (Question 2), information about current and planned staff, funding levels, inventory control methods, facility size, distribution methods and other information for instances in which a potential supplier expects to expand their sales, (Question 5a), and the "Total Estimated Capacity" data to be provided in Column E of the Form B Bidding Sheet.

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[3] 5 CFR § 1320.3(l).

In addition to the Form B data, bidders are also required to provide to CMS, in hardcopy, the financial documentation detailed in the Request for Bids Instructions (pp. 15-19) and Appendix B, "Financial Documentation Toolkit." Generally, the required documentation includes an income statement, balance sheet, cash flow statement, specified portions of tax returns, and credit report and numerical score. CMS has stated that they will use this data in making their supplier capacity determinations.

While CMS is admirably clear about the financial and certain other information required by the ICR, the agency resorts to vague generalities in describing just how the data will be used to determine supplier capacity. As will be discussed in more detail further below, the supplier capacity determination methodology was supposedly set in a 2007 Final Rule.[4] The text of the regulation, however, merely states that CMS will be "Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category."[5]

In the preamble to the final rule, CMS recognized that,

> "*Several commenters argued that there was insufficient information given as to how CMS will determine a supplier's capacity. ... The commenters also noted that CMS did not describe what criteria it will use to compare bidders (aside from bid price) and how these criteria will be applied.*"

In the final rule's preamble, in response to the above-cited concerns, CMS indicated that they had not yet decided on the specific calculation methodology.

After explaining that CMS will "look at" documentation provided "to determine the ability of that supplier to furnish its projected capacity" the agency stated that "We might, however, make two types of adjustments to a supplier's projected capacity for purposes of finalizing the pivotal bid." The first type of potential adjustment suggested was that "if a supplier estimates that it can furnish more than 20 percent of what we determine to be the expected beneficiary demand for the product category in the CBA, we will lower that supplier's capacity estimate to 20 percent" to ensure that there are at least five bidders are awarded contracts. Furthermore, CMS "might further adjust a supplier's capacity if, after making the initial adjustment discussed above, we conclude that the supplier's financial and business expansion documentation do not support the projected capacity stated in its bid."[6]

Thus, CMS stated that, based on the information collected, they might make unspecified further adjustments to a non-specific methodology. This is not the transparency required by the DQA.

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[4] 72 Fed. Reg. 17992, April 10, 2007.

[5] 42 CFR § 414.414(e)(2).

[6] 72 FR 18039-40, April 10, 2007.

Stakeholders continued to express concerns regarding CMS' opaque process for calculating supplier capacity in response to their 2009 Interim Final Rule (IFR) which initiated this ICR process even though the agency did not request comments on this issue. For example,

> "*Increased transparency is also needed in the bid evaluation process, supplier capacity calculations, and in providing information about selected suppliers and the specific services they offer. For example, CMS should more clearly state its decision criteria for evaluating bids the weights assigned to different factors, such as a supplier's financial viability, ability to serve a particular geographic area, current and proposed product offerings, and experience in serving Medicare beneficiaries.*
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> ***
>
> *Transparency in the criteria CMS will use for evaluating financial capacity is especially critical today, given the challenges suppliers will face in expanding their existing credit limits for growing their businesses at a time of great turmoil and uncertainty in the nation's credit markets. Understanding the criteria that will be used is also crucial, since CMS believes that it can determine whether a supplier demonstrates financial soundness by reviewing only one year of documentation rather than three as required in the original Round 1.*"[7]

In the above example, the commenter is expressing concern over the lack of a public plan for how the agency is going to use the data collected and also discusses the relationship between the data use plan and the appropriateness of the amount of information that bidders will need to submit to the agency – a pure PRA issue. It is only after CMS demonstrates that they have a data use plan consistent with the PRA and the agency's information quality guidelines that they would be able to determine how many years of financial information are required by that plan.

Other commenters raised additional concerns regarding how CMS's lack of transparency in their methodology for using the ICR data harms the practical utility of the data collected. For example, a commenter representing a coalition of suppliers explained that

> "*The Coalition continues to believe that the absence of any transparency with respect to the financial standards used by CMS to evaluate bidding suppliers is inappropriate in view of the centrality of the standards in the bid process, and leaves open the possibility that such standards could be used to unfairly discriminate against and eliminate many willing and respectable businesses from participation in the Competitive Bidding Program. If the standards are too restrictive, fewer suppliers will be able to participate in the bid process...potentially adversely affecting the single payment amount. If the standards are not restrictive enough, unsound suppliers may be awarded contracts. ... CMS must make these standards public, so that suppliers can*

[7] http://www.thecre.com/blog/wp-content/uploads/2009/05/cms-reimbursement-advmed.pdf.

> *assess their current financials in relation to the standards in order to submit informed bids to CMS.*"[8]

Although CMS did not request comment on the supplier capacity issue in the IFR, they did request comment on the IFR's information collection requirements. Public comments on the information that would be submitted to CMS under this ICR should be considered as PRA comments – and responded to as such by CMS as part of the record as required by 5 CFR § 1320.5 (F). Even though the supplier capacity-related comments may not have been specifically labeled as concerning the ICR, they should be considered as such since, as was explained above, capacity calculations are fundamentally a PRA issue and the commenters are clear addressing PRA issues. OMB should also recognize that some of the stakeholders providing comments are small businesses that may not have the administrative law expertise to recognize the difference between rulemaking comments and PRA comments.

It is important to note that multiple stakeholders at the PAOC meeting also expressed concerns about CMS' lack of transparency about how they would calculate supplier capacity.

With respect to information quality, CMS's Guidelines explains that their "quality assurance process begins at the inception of the information development process."[9] For the DMEPOS competitive bidding program, that means that DQA quality assurance begins with their ICR to collect data that the agency plans to use that data in the competitive bidding program. CMS further explains that the agency "reviews the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance and dissemination." The process by which CMS assures compliance with the information quality guidelines is called "pre-dissemination review."

CRE will not reiterate all of CMS' relevant pre-dissemination requirements that are detailed in their Guidelines. Instead, we will highlight a few examples of the standards that the agency must meet in collecting and processing Supplier Capacity-related data that are of particular concern and relevance in this ICR.

Utility, one of the statutorily-defined components of information quality, refers to "the usefulness of the information to its intended users" and "is achieved by staying informed of information needs and developing new data, models, and information products where appropriate."[10] Unless there is a specific algorithm (or algorithms) the agency intends to use for processing the information received through the ICR and performing the Supplier Capacity calculations, the determination process would be arbitrary, capricious and lack utility; also the information collected for those calculations would lack practical utility.

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[8] http://www.thecre.com/blog/wp-content/uploads/2009/05/cms-reimbursement-coaltion.pdf. (emphasis added.)

[9] CMS, "Guidelines for Ensuring the Quality of Information Disseminated to the Public," found at http://thecre.com/pdf/20021026_hhs-cmms-dqfinal.pdf.

[10] Ibid. (Emphasis added.)

Objectivity, arguably the most crucial component of Data Quality for the agency's Supplier Capacity calculations, "involves a focus on ensuring that information is accurate, reliable and unbiased...." One the agency's mechanisms for achieving objectivity is use of "sound analytic techniques. ... Analytical techniques are reviewed for their appropriateness to the data and the analysis being conducted and are clearly identified in reports." Thus, the agency's Supplier Capacity algorithm(s) need to be reviewed to ensure that they constitute sound analytic techniques and are appropriate for their intended purpose.

Integrity refers to, among other requirements, CMS ensuring "that the information is not compromised through corruption or falsification." Commenters expressed concern regarding the possibility that some bidders might falsify financial information. For example, in discussing paperwork-related issues, one commenter stated,

> "*Some providers might hold the view that it is easy to falsify one year's worth of financial statements when compared to three, while others might welcome streamlining the paperwork burden imposed on small bidders. Obviously these viewpoints represent important competing interests since fraud of this type places the program at risk, whereas small providers are legitimately concerned about their ability to compete effectively.*"[11]

Any falsification of financial information provided to CMS, or of the data submitted on the Bidding Form, would threaten the integrity of the program. Thus, CMS' pre-dissemination review record needs to include: 1) a discussion of the specific steps the agency will take to ensure the integrity of the data submitted; and 2) their pre-dissemination review record demonstrating that these steps are appropriate and effective for achieving the agency's integrity objectives.

CMS applies additional quality standards for "influential" information which the agency defines as "information will have a substantial impact on important public policies or important private sector decisions or will have important consequences for specific health practices, technologies, substances, produces, or firms." CMS' Supplier Capacity determinations will substantially impact DMEPOS equipment suppliers, and potentially, the equipment recipients. The capacity calculations are at the heart of the a major Medicare reform initiative and directly concern each bidder's business opportunities and the price CMS pays for the equipment. The capacity determinations are influential information.

With respect to influential information, CMS' "guidelines call for identification and documentation of data sets used in producing estimates and projections, and for clear descriptions of the methods used."[12] CMS does explain that "Many estimates and projections included in CMS information products are not directly reproducible by the public because the underlying data sets used to produce them are confidential" a situation that exists with the competitive bidding program. There is no need, however, to release confidential bid data. Instead, what is needed is for CMS to release their algorithm(s) for processing the

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[11] CMS-2009-0008-0749.1.

[12] CMS Guidelines.

data and their pre-dissemination review record demonstrating that those algorithms comply with CMS and OMB DQA standards.

The CMS Guidelines also provide an additional mechanism for ensuring the quality of complex influential data by explaining that "Where estimates and projections may not be easily reproduced by third parties due to the complexity and detail of the methods and data, greater emphasis is placed on periodic review by outside panels of technical experts." In accordance with a Congressional directive, CMS recently extended the term of an outside panel of technical experts, the PAOC. CMS could and should ensure that their methodology for calculating Supplier Capacity meets Data Quality standards, without any disclosure of confidential data, by also providing their methodology to the PAOC for review and comment.

Once CMS has made clear their DQA-compliant process for using the information collected in this ICR for determining supplier capacity, and the associated issue of determining the agency's specific requirements for determining "qualified" suppliers, CMS should leverage this utility of this process by allowing all qualified suppliers who are small businesses, as defined by SBA, to supply DMEPOS equipment at the single payment amount. Expanding small business opportunities would reduce the burdens placed on small businesses without compromising the competitive bidding program's crucial cost containment objectives. To the contrary, by announcing a DQA-compliant plan for using the data to be collected in this ICR, CMS will obtain more informed and qualified bids, lowering DMEPOS costs.

Practical Utility of HCPSC Codes Needs to be Evaluated as Part of the ICR Process

The Healthcare Common Procedure Coding System (HCPCS) Level II codes are "used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and" DMEPOS "when used outside a physician's office." The codes are used for submitting claims for these items.[13] CMS maintains and distributes the codes under delegated authority as provided under HIPAA. Bidders submit these codes to CMS as part of the bidding process.

Stakeholders provided CMS with comments expressing serious concerns that at least some of the codes lack practical utility for the competitive bidding program. CMS should respond to these comments as part of the ICR process since they address paperwork issues.

The primary concern expressed by commenters is that the HCPCS are insufficiently specific, meaning that the data submitted by bidders will lack practical utility. For example, one stakeholder explained that,

> "*In order for DMEPOS suppliers to submit bids for individual HCPCS codes, there must be a narrow range of technology defined by each HCPCS code. That specificity simply does not exist with the majority of HCPCS codes. We therefore recommend that CMS refine the HCPCS codes for each product category it intends to include in a competitive bidding program. ... If CMS fails to refine the HCPCS code system for*

[13] http://www.cms.hhs.gov/MedHCPCSGeninfo/.

> *product categories it intends to include in competitive bidding, suppliers will not be able to provide intelligent bid information for each code....*"[14]

Another stakeholder provided two specific examples of why at least some of the HCPSC codes as currently constituted lack practical utility for DMEPOS competitive bidding. The commenter explained,

> "*The enteral formulas within particular billing codes are not interchangeable. One of the basic tenets of the competitive acquisition program appears to be an assumption that the program can generate additional savings by limiting coverage to particular products within the HCPCS billing codes that may be cheaper than other products within those codes. For this approach to work, the products within a billing code must be interchangeable. That is not the case for several of the enteral formula billing codes.*
>
> *B4153 contains enteral formulas that are described as 'nutritionally complete, hydrolyzed proteins.' This category contains enteral formulas that meet this definition but which are not used for the same purposes. For example, Crucial Complete Elemental Diet is an enteral formula that is used for advanced wound healing, while Peptamen, is used for patients suffering from malabsorption. No clinician would consider the two products to be clinically interchangeable.*
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> *B4154 contains enteral formulas that are designed for patients with special metabolic needs, where formulas in this category are used to treat particular disease states. Thus, Novasource Pulmonary is intended for patients with respiratory disease, while Diabetisource AC is a product engineered for patients with diabetes. It should be obvious that these products cannot be substituted clinically for each other.*"[15]

As the situation now stands, the record before OMB and the public is incomplete. CMS needs to respond to the PRA-related comments on HSPCS codes, including modifying the codes as necessary, demonstrate that they meet PRA and DQA standards, and then resubmit them to the public and OMB for review and comment.

Lack of Required PRA Certifications

In their ICR *Federal Register* notice, CMS directed the public to their excellent PRA website, http://www.cms.hhs.gov/PaperworkReductionActof1995/ for copies of the supporting statement and related materials. The package of information on the competitive bidding ICR available at the website includes a variety of useful documents including the agency's Supporting Statement, copies of the forms,

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[14] CMS-2009-0008-0743.1. (Emphasis added.)

[15] CMS-2009-0008-0787.1.

instructions, worksheets, and a thoughtful flow chart illustrating the competitive bidding process.[16] What is missing from the package is the set of 10 certifications CMS is required to make by the PRA.

CRE recognizes that agencies often treat the PRA certification process as a mere *pro forma* technicality rather than, as intended by Congress, a process in which a senior government official takes personal responsibility on behalf of their agency by ensuring and attesting to the accuracy of the information contained in the certifications. In its role as regulatory watchdog, CRE has long advocated measures to ensure that agencies take their PRA certification duties seriously.[17]

Irrespective, however, of the seriousness with which an agency views their legal obligations under the PRA, the certification process is non-discretionary. Because the statutorily required documentation has not been provided to the public and OMB for review and comment, the record is critically deficient and the PRA's minimum requirements have not yet been met. Thus, aside from the other deficiencies in the ICR, OMB needs to return the ICR to CMS without approval. CMS will need to then revise their ICR package and provide it to OMB and the public for review and comment.

Form B, The Bidding Form, Is Incomplete and Ambiguous

Questions 4a and 4c on the Form B do not clearly state what information bidders will need to provide nor is it clear how much information they will need to provide to the agency. For example, Question 4a states, in part,

> "*The HCPCS codes listed below represent the top codes that account for approximately 80% of the allowed charges for this product category. Indicate the number of units that your business organization has furnished to all customers, both Medicare and non-Medicare, in this CBA during the past calendar year.*"

The codes, however, are not listed below. Below the question is a three row, three column table. The boxes in the first column are each labeled "HCPCS Code." These boxes are blank. Based on the question, it appears that CMS would provide the codes that account for "approximately 80% of the allowed charges for this product category." The codes are not provided, however, either on the form or in an attachment. The sample form is thus incomplete and needs to be revised. A similar lack of HSPCS code information that Form B claims is present but is missing occurs with respect to Question 4c.

CMS needs to provide for public review and comment the HCPCS codes that the agency believes account for "approximately 80% of the allowed charges for this product category" for each relevant category. CMS is not clear as to whether the 80% of charges determination is based on national data or is specific to each CBA. If the agency's 80% determination vary by CBA, they need to provide, as part of the ICR process, their list of top codes by product category for each CBA. If is not feasible to provide the data on a single

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[16] http://www.cms.hhs.gov/PaperworkReductionActof1995/downloads/CMS-10169.zip.

[17] http://www.thecre.com/quality/2005/20051002_quality.html.

sample form that is relevant to all bidders, they could provide an attachment that lists the code data by product category by CBA.

Question 4a shows that bidders would need to provide total sales data and Medicare sales data for three HSPCS codes for each Form B. Thus, the agency is stating in their ICR package that three HSPCS codes account for "approximately 80% of the allowed charges " in each product category. If more than three codes account for about 80% of charges in any product category, than CMS needs to clearly indicate this by providing the specific data and informing bidders just how much data they need to provide.

If bidders would need to provide Medicare and non-Medicare sales data for more than three HCPSC codes for any product category, the burden would be higher, perhaps much higher depending on just how many additional HSPCS codes for which bidders will need to provide sales data. It seems unlikely that three HCPSC codes account for about 80% of allowed charges for every DMEPOS product category, but that is what Form B states. If a higher number of codes are needed for some categories and/or some CBAs, CMS needs to clearly indicate such along with the associated burden.

Even if three HSPCS codes do account for 80% of allowed charges in each product category, CMS still needs to provide the specific codes for which bidders are to provide sales data for public review and comment under the PRA.

Similarly, CMS needs to revise Question 4c to include for public review and comment, "the top HCPCS codes for the product category in this CBA in terms of allowed charges" for which bidders need to provide manufacturer name, model name and model number information.

Missing information also occurs on the Form B Bidding Sheet with respect to columns A-D and F.

Also with respect to Form B, CRE also does not understand why the top of the form states "Form Approved" with an OMB Control Number. A previous version of the form was approved [Form CMS-10169B (04/07) EF (04/2007)], but not the subject document.

CMS' Burden Estimates Are Incomplete

No Burden Estimate for Submitting Financial Data

CMS' Supporting Statement provides burden estimates for each form. There is, however, no burden estimate for the extensive financial information that must be submitted along with the forms. It cannot be assumed that there is no burden to providing this data, particularly for small businesses. For example, some of the small bidders may need to purchase the credit report and numerical score that has to be provided to CMS. Some small business, particularly those that are privately held, may need to have an accountant prepare some of the required financial statements, such as the cash flow statement. Since CMS has not estimated the burden associated with providing the required financial documentation, they need to revise their burden estimates and resubmit them for public comment.

No Recordkeeping Burdens Provided

CMS is asking for the submission of specific data but provides no burden estimate for maintaining the records that need to be submitted. This is particularly significant for Form C, which is a quarterly report detailing, for each CBA, the number of units of equipment provided by HCPCS code, Manufacturer, Make, and Model number. Suppliers will not be able to provide this information unless they maintain records of the data in an appropriate form. This could entail firms changing their recordkeeping system to accommodate CBA-specific data. Despite this recordkeeping burden, CMS, on their "Part II: Information Collection Detail" worksheet for Form C, does not estimate any recordkeeping burden whatsoever. The only burden on the worksheet for this form is for reporting and that is the only burden included in the Supporting Statement. CMS needs to revise their ICR to include an objectively supported estimate of the recordkeeping burdens associated with all of the information submissions.

Low Estimate of Per-Hour Paperwork Costs

CMS uses an hour rate of only "$31.25 (in wages and overhead)" for the costs associated with submitting the bid. According to the Supporting Statement, the only basis for this estimate is agency's 2007 assumptions. Thus, CMS is assuming that the bidders, including many small businesses, will be able to complete the bidding process paperwork without the assistance of accountants, lawyers and other highly skilled professionals. This is not credible. CMS needs to revise their burden estimates so that they can provide for public comments, a "specific, objectively supported estimate of burden."

Small Business Paperwork Reduction Deficiencies

CMS' regulations implementing the DMEPOS paperwork-intensive competitive bidding program were promulgated through an Interim Final Rule (IFR) with a comment period rather than through a Notice of Proposed Rulemaking (NPRM.) In waiving the NPRM, CMS stated they did "do not believe that we need to delay publication of this rule until a notice and comment period is completed. We are conforming the competitive bidding regulations to specific statutory requirements contained in section 154 of MIPPA [Medicare Improvements for Patients and Providers Act of 2008] and informing the public of the procedures and practices the agency will follow to ensure compliance with those statutory provisions."[18]

It should be noted that prior to passage of the MIPPA, CMS had completed a notice-and-comment rulemaking for a DMEPOS competitive bidding program.[19] The agency's planned collection and use of information specified in the 2007 Final Rule forms the basis for the IFR's competitive bidding program. As CMS explained in the IFR, "To the extent this interim final rule with comment period does not specifically modify regulatory language, the current regulations, as set forth in the April 10, 2007 final rule, remain unchanged and will govern the Round 1 rebid."

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[18] 74 Fed. Reg. 2873, January 16, 2009.

[19] NPRM: 71 Fed. Reg. 25654, May 1, 2006; Final Rule: 72 Fed. Reg. 17992, April 10, 2007.

SBA Excluded From the ICR Comment Process

CMS' decision to waive notice-and-comment, which was hotly contested by numerous stakeholders, has direct implications for this ICR. By not publishing an NPRM, CMS avoided fulfilling their various duties under the Regulatory Flexibility Act (RFA) including: 1) preparing an Initial Regulatory Flexibility Analysis (IRFA); 2) accepting comment on the preliminary small business impact analysis; and 3) preparing a Final Regulatory Flexibility Analysis including a response to comments on the IRFA.

These small business impact analyses, and responses to comments, are directly relevant to the subject ICR since one of the mandatory certifications that agencies are requires to make under the PRA is that the agency "shall certify (and provide a record supporting such certification) that the proposed collection of information— ... Reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities...."[20]

The paperwork burden in the ICR falls overwhelmingly on small businesses. CMS stated in the IFR, "we estimate that 85 percent of suppliers of the items and services affected by this rule would be defined as small entities...."[21]

Normally, the Office of Advocacy in the US Small Business Administration (Advocacy) would play a major role in defending small businesses on paperwork burdens contained in the ICR. CMS, however, has essentially cut SBA out of the process. Independent SBA review of small business burden is generally triggered by the Chief Council for Advocacy receiving from the agency either: 1) an IRFA; or 2) a formal certification under § 605(b) of the RFA, "along with a statement providing the factual basis for such certification," demonstrating that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." Since Advocacy received neither notification from CMS, they have not had an appropriate opportunity to review and comment on the small business burdens.

CMS should formally notify Advocacy of the ICR proceeding on DMEPOS competitive bidding and either; request their recommendation on reducing the small business paperwork burdens, or certify, and provide a supporting record, that the ICR would not have a significant impact on a substantial number of small entities.

As noted earlier, CMS should also notify and consult with HHS' Office of Small and Disadvantaged Business Utilization. The competitive bidding program as currently envisaged threatens to close many small businesses, potentially including minority owned and other disadvantaged businesses. Particularly since commenters have explicitly expressed concern that CMS' opaque methodology could open to door to unfair discrimination, it is essential that OSDBU and SBA both be consulted.

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[20] 5 CFR § 1320.9.

[21] 74 Fed. Reg. 2879, January 16, 2009.

Inaccurate Statements Concerning Small Business Impact

CMS has made conflicting and inaccurate statements regarding the burden on small suppliers. First CMS states; that 85% of the businesses affected by the rule and associated paperwork are small entities, and that "This regulation merely codifies the MIPPA provisions, so there are no options for regulatory relief for small suppliers. The RFA therefore does not require that we analyze regulatory options for small businesses."[22] Then, the agency goes on to assert that, "We have determined that this rule will not have a significant impact on a substantial number of small entities and on small rural hospitals."

If CMS has not analyzed the regulatory impact of the competitive bidding system on small businesses, how can they claim that they have determined it would not have a significant economic impact?

If CMS has determined that the rule would not have a significant economic impact on a substantial number of small entities, why have they not provided certification of the determination, along with their supporting documentation, to SBA?

If CMS had recognized the serious economic consequences of their competitive bidding system to small businesses, would they have made a more intensive effort to reduce the paperwork burden on these entities?

CMS' position appears to be that their hands are tied, they are simply implementing statute without discretion. While certain limited aspects of the program, such as excluding Puerto Rico as a CBA, are non-discretionary, the fundamental competitive bidding process, and the associated collection and use of information, remain under CMS' discretion. §154 of MIPPA only required that Round 1 Rebid be conducted "in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provide for in...." Nothing is the law restricted CMS' options for reducing small business burdens, including paperwork burdens.

The agency's apparent misinterpretation of MIPPA is included in part 7 of their "PAPERWORK REDUCTION ACT SUBMISSION WORKSHEET, Part I: Information Collection Request" form submitted as part of the ICR package. This abstract section incorrectly states that "Section 154 of" MIPPA "requires that CMS conduct the Round 1 Rebid of the Medicare DMEPOS Competitive Bidding Program in the same manner as the 2007 round 1 competition except that...." No, as the quote from MIPPA clearly demonstrated, MIPPA only requires that the rebid be conducted "in a manner," so that it occurs this year with respect to the same items and services, other than specified exceptions, as previously occurred. The law does not require that the competition be conducted in the "same manner" as 2007. Since the Worksheet is inaccurate and misleading, it needs to be returned to CMS for correction.

CMS' basic premise regarding their lack of discretion is not accurate. Since CMS wrongly considers that they have no discretion, questions are raised as to whether the agency actually minimized "to the extent practicable and appropriate" the paperwork burden on small entities as required by the PRA.

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[22] Ibid.

One key opportunity CMS has to reduce the burden of the competitive bidding rule on small businesses is to allow all qualified small suppliers to provide DMEPOS items at the competitively bid-determined single payment amount. CMS should include discussion of allowing these additional firms to participate in their Supporting Statement's discussion of measures to mitigate burdens on small entities.

Inaccurate Small Business Relief Information Statement in Supporting Statement/RFB Instructions

With respect to the treatment of small businesses under the PRA, CMS enumerates four actions taken to minimize "the burden of collecting this information...."[23] The fourth action that CMS states they have taken with regard to small suppliers is that "the option of submitting manual bids is allowed for small suppliers without access to a computer."[24] Similarly, Item B.2.a in the Supporting Statement states, "Hardcopy RFB forms will be available upon request for those suppliers that are unable to access the electronic system."[25]

CMS' statements are, however, directly contradicted by the agency's "Request for Bids (RFB) Instructions" which state,

> "*Suppliers will be required to complete these forms online using the CMS DMEPOS Bidding System (DBidS).*"[26]

The RFB Instructions make no mention of any alternative options for small suppliers. To the contrary, the document explicitly states that there are no alternatives to filling out the forms electronically. Nowhere does CMS indicate how they would notify small suppliers of a manual submission option. Thus, there is an error in either CMS' Instructions or in their Supporting Statement (or both.) In either case, CMS needs to revise their ICR package to correct their small business relief statements and/or RFB Instructions and resubmit them for public review and comment. As the situation currently stands, based on the RFB Instructions, CMS has made a false assertion to OMB regarding measures taken to alleviate burden on small businesses.

About CRE

CRE is a regulatory watchdog formed by former senior career officials from the Office of Management and Budget. As a watchdog, CRE is committed to ensuring federal compliance with the "good government" laws that regulate the regulatory process, including the Paperwork Reduction Act, Data Quality Act and Regulatory Flexibility Act. As part of CRE's ongoing work to promote increased

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[23] CMS, CMS–10169, Supporting Statement – Part A, 4/24/09, pp 4-5.

[24] Ibid., p. 5.

[25] Ibid., p. 3.

[26] CMS, "Request for Bids (RFB) Instructions for the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program," p. 8. (Emphasis added.)

transparency in the rulemaking process, we pioneered the Interactive Public Docket which was discussed on National Public Radio.[27] In response to rulemakings which are particularly data-intensive, such as the CMS DMEPOS competitive bidding program, CMS created an enhanced IPD. The first example of which is Competitive Bidding Interactive Public Docket available at http://www.thecre.com/blog/.

Recommendations

- The ICR needs to be expanded to allow all qualified small business DMEPOS providers (as defined by SBA, not CMS) to supply equipment at the single payment amount with the provision that competitive bidding contracts be non-transferrable for a period of no less than one calendar year.

- The ICR needs to be returned to CMS so that the following corrections and additions can be made before being resubmitted to OMB and the public for review and comment:

  - The mandatory PRA certifications need to be made, after a senior agency official has ensured that such certifications would be complete and accurate;

  - CMS needs to respond to the paperwork collection-related comments in the IFR docket;

  - CMS needs to provide their pre-dissemination review record demonstrating the Supplier Capacity calculations and bidder qualification determinations comply with OMB and CMS information quality guidelines including the requirements for influential information, *e.g.*, "clear descriptions of the methods used;"

  - The agency needs to provide their pre-dissemination review record for the HSPCS codes, including any necessary modification to some or all of the codes to ensure they have practical utility for the competitive bidding program;

  - The agency needs to provide their pre-dissemination review record for ensuring the integrity of all information to be submitted under the ICR;

  - Revisions need to be made to Questions 4a and 4c on Form B to provide the specific HSPCS codes for which bidders will need to supply data;

  - An objectively supported burden estimate for bidders to provide the required financial documentation needs to be provided;

  - An objectively supported burden estimate for the recordkeeping requirements necessitated by Form C and other information submissions needs to be provided;

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[27] http://www.npr.org/templates/story/story.php?storyId=4599065.

- An objectively supported estimate of the hourly rates for the various categories of skilled persons who would be needed to perform the recordkeeping and other paperwork functions needs to be provided;

- A correction needs to be made to the Paperwork Reduction Act Worksheet, Part I: Information Collection Request to accurately state MIPPA's requirements for the Round 1 Rebid;

- A correction needs to be made to the RFB Instructions to describe the process cited in the Supporting Statement by which manual bids could be submitted by small companies including a description of how these companies would be notified by non-computerized means of this option; and

- An addition needs to be made to the small business section of the Supporting Statement to explain the CMS is allowing SBA-defined small businesses who are qualified to supply DMEPOS at the competitively bid single payment amount.

Copies sent to:

– Michelle Shortt, Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs, CMS

– Jonathan Blum, Director, Center for Medicare Management, CMS

– Joel Kaiser, Director, Division of DMEPOS Policy