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Office of Information and Regulatory Affairs
Office of Management and Budget

Attention: CMS Desk Officer
Fax Number: (202) 395–6974
Email: OIRA_submission@omb.eop.gov

Re: PRA Comments on Document CMS–10169 (OCN: 0938–1016)

Dear OIRA CMS Desk Officer:

This letter and the documents incorporated by reference constitute the Center for Regulatory Effectiveness' (CRE's) written comments on CMS' proposed revised collection of information, "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program" in response to the agency's Request for Comments published in the *Federal Register* on July 27, 2012, pp. 44241-42.

These comments consist of three sections:

1. Analysis of CMS' Response to Comments;
2. Substantive Paperwork Reduction Act (PRA) and Data Quality Act (DQA) Violations; and
3. Conclusions and Recommendation

ANALYSIS OF CMS' RESPONSE TO CRE COMMENTS

CMS made several perplexing assertions in their Response to CRE's comments, all in response to issues which they termed "out of scope" of the information collection requirements.

- ***CMS Is Required to Comply with <u>All</u> Relevant Statues***. The agency stated that the "DMEPOS Competitive Bidding Program is required by statute," a statement that the agency makes twice in responding to different issues raised in comments to the agency.

  CMS' repeated statement is odd since CRE has never questioned the agency's duty to conduct competitive bidding for DMEPOS. CRE has explained, however, that certain specific aspects of

how the agency has chosen to use data from the bidding forms, an issue which is well within the agency's discretion, clearly violate CMS' statutory duties under the PRA. Moreover, as explained in the Substantive PRA Violations section of these comments, CMS is using the information in a manner that fails to meet to meet one of the bidding program's statutory objectives – obtaining DME equipment and services at competitive prices.

The agency's duty to adhere to the Medicare statute in no way diminishes its obligation to also adhere to all other relevant laws, including the PRA. CMS declined to address the substance of CRE's comments – that their use of the data they propose to collect would not comply with the requirements of the PRA or the Data (Information) Quality Act.

- ***The Medicare Statute's Allowance of Binding Bids Is An Issue Within the Scope of the PRA***. CMS' Response asserts that its "procedures" for awarding contracts are "beyond the scope of this PRA package," and cites their 2006-07 notice-and-comment process as well as a 2009 Interim Final Rule with comment opportunity.

  CMS' assertion is wrong; how the agency uses collected data is at the heart of the PRA, not an issue beyond its scope. One of the Purposes specified by Congress for the PRA is to "improve the quality and use of Federal information to strengthen decisionmaking, accountability, and openness in Government and society...." [44 USC 3501(4)]

  Moreover, OMB's regulations implementing the PRA specifically require review of the planned use of the information the agency's proposes to collect:

  > *The office established under §1320.7 shall review each collection of information before submission to OMB for review under this part.*
  >
  > *(a) This review shall include: . . .*
  >
  > *(7) A plan for the efficient and effective management and use of the information to be collected, including necessary resources.*
  >
  > 5 CFR 1320.8 [Emphasis added]

  It is not clear why CMS cited their notice-and-comment rulemaking events as part of their response since one the purposes of the PRA – and a reason for the statutory three year maximum time period for which ICRs are authorized – is to ensure that agencies and OMB review, at regular intervals, how collected information is being used and whether changes should be made.

- ***ICRs Are Required to Comply with the DQA***. CMS incorrectly asserted that the "provisions of the Data Quality Act go beyond the scope of the PRA for the submission of bids under the competitive bidding program." OMB has explicitly informed agencies that,

> *OMB will approve only those information collections that are likely to obtain data that will comply with the OMB and agency information quality guidelines.*[1]

Given OMB's crystal clear directive on the need for ICRs to comply with data quality standards, the source of CMS' contention that DQA provisions somehow "go beyond the scope of the PRA" is a mystery.

CRE is even more perplexed by CMS' assertion since the Centers for Medicare & Medicaid Services own agency-specific *Guidelines for Ensuring the Quality of Information Disseminated to the Public* state:

> *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]

- ***CMS Considers 5 CFR 1320.5(d)(1) to be "Out of Scope" of the PRA***. CMS' Response, under the heading "Issues Raised by the Commenter that are Out of Scope of the Information Collection Requirements" included the statement that the "commenter believed that the competitive bidding program would shift costs to the public."

  CRE's comments cited 5 CFR 1320(d)(1) as the source for our view that disproportionate cost shifting is prohibited by the PRA. The section states:

  > *(d)(1) To obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information:*
  >
  > *(iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public.*

  CRE has no idea why CMS considers part of OMB's regulations implementing the PRA to be "out of scope" of the PRA. Moreover, the agency's "response" asserting savings and projected savings from the bidding program, do not address the inevitable and substantial cost shifting analyzed by Dr. Cramton that was discussed in our ICR comments to CMS.

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[1] Memorandum for President's Management Council, June 10, 2002, available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/iqg_comments.pdf.

[2] HHS Information Quality Website, Centers for Medicare & Medicaid Services available at http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml. [Emphasis added]

CRE reiterates here the cost-shifting problem created by how CMS has chosen to use the information collected from the bidding forms that are the subject of this ICR and expands on our comments. In a September 2010 letter signed by 167 auction experts from universities across the country,[3] which is hereby incorporated by reference as an integral part of these comments, the co-signatories warned about cost-shifting:

> *What is odd is that rather than paying winners the clearing price (the last-accepted bid), the auction pays winners the unweighted median among the winning bids. This is unique in our collective experience. The result is that fifty percent of the winning bidders are offered a contract price less than their bids. This median pricing rule further encourages low-ball bids, since a low bid guarantees winning, has a negligible effect on the price and gives the supplier a free option to sign a supply contract. Even if suppliers bid their true costs, up to one-half of the winning suppliers would reject the supply contract and the government would be left with insufficient supply. Others may accept the contract and cross-subsidize public patients with the revenue from private patients, or just take a loss. This pricing rule does not develop a sustainable competitive bidding process or healthy supplier pool.*

- ***Protecting Jobs and Small Businesses IS a Function of the PRA***. CMS' Response to comments noted that CRE believes that the competitive bidding program "is promoting consolidation in the home medical supply industry" and states that the comment "is beyond the scope of the PRA...."

  To the contrary, protection of jobs is a core function of the PRA. The statute states that the law's Purpose is to

  > *ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government;* 44 USC 3501(2) [Emphasis added]

  Protecting jobs – including those generated by small businesses – is unquestionably an essential part of securing "the greatest possible public benefit" from the use of the bid form data. As the White House stated less than a month ago:

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[3] Available at http://www.cramton.umd.edu/papers2010-2014/comments-of-concerned-auction-experts-on-medicare-bidding.pdf [Emphasis added]

> *The President believes that entrepreneurs and small businesses are engines of innovation and economic growth and are at the forefront of the nation's economic recovery.*[4]

Thus, as a matter of law and Obama Administration policy, preventing the devastation of small businesses from agency misuse of collected data IS within the scope the PRA.

CRE will further explicate in these comments the CMS-documented decimation[5] of small businesses occurring because of the agency's discretionary decisions on how to use data collected from the bidding forms – a decision that is contrary to the requirements of the PRA.

Moreover, these ICR comments will demonstrate, based on CMS data, that the bidding program has inflicted radically greater harm on small businesses than the agency projected in their 2007 final rule – strong proof that the agency's understanding of the impacts of their program, and their assertions that current that the program is running well, are deficient and that the use of the bidding form data needs to be reformed.

- ***The Unsustainable Competitive Bidding Program – CMS' Lack of Response Speaks Volumes***

CMS declined to respond at all to one of the key points CRE made repeatedly throughout our comments, that the way in which CMS has chosen to use the data collected from the bidding forms results in an unsustainable program.[6] If the information collected from the bid forms is used in a way that results in the program not being sustainable, then the data is being used in a manner inconsistent with the program's statutory objectives and thus lacks practical utility.

CRE submitted to the docket, reaffirms here and discusses in greater detail below, comments which demonstrate a broad consensus among virtually all outside experts which have examined the bidding program that the agency's methodology for using the bid form data results in a program that is not sustainable and is contrary to the Medicare statute:

1. **A June 2011 letter to President Obama signed by 244 auction experts**. The letter states:

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[4] White House Press Release, "Obama Administration Takes Immediate Actions to Help Small Businesses," July 11, 2012.

[5] Definition of decimate: "drastically reduce the strength or effectiveness of (something): *public transport has been decimated*." Oxford Dictionaries available at http://oxforddictionaries.com/definition/english/decimate.

[6] *What we cannot speak about we must pass over in silence.* – Ludwig Wittgenstein, *Tractatus*.

> *The use of non-binding bids together with setting the price equal to the median of the winning bids provides a strong incentive for low-ball bids—submitting bids dramatically below actual cost. This leads to complete market failure in theory and partial market failure in the lab.*

The letter was a follow-up to the September 2010 letter from 167 auction experts. The September 2010 letter stated:

> *This pricing rule does not develop a sustainable competitive bidding process or healthy supplier pool.*

The letter signed by 167 auction experts, including several Nobel laureates, concluded:

> *We recommend that the government fix the flaws in the current auction program and develop a new design that emphasizes the key features of successful designs. Implementation of the current design will result in a failed government program.* [Emphasis added]

The 2011 letter to the President concluded:

> *Given that nine months have passed and given the disregard by CMS of the market design recommendations received from recognized experts, we call upon the executive branch to direct CMS to proceed otherwise.*

2. **Statements by a Senior Congressional Budget Office Official.**

CRE's comments discussed statements made by the Chief of the Congressional Budget Office's (CBO's) Health Systems and Medicare Cost Estimates Unit while speaking at the Medicare Auction Conference co-sponsored by the University of Maryland and the National Science Foundation.[7] The CBO official stated:

> *One of the things we learned is that the purpose of an auction that's intended to be repeated -- and I think that's an important part of what we've been discussing today -- is that it reveals the sustainable marking -- market clearing price; that is, the price at which the seller and the buyer are willing to contract to exchange something and then are expecting to be willing to come back to the auction on the next round.*
>
> *The auction mechanism that CMS used in the first round was poorly suited to the task of revealing that sustainable market price.*
>
> ***

[7] Medicare Auction Conference, 1 April 2011, Agenda *available at* http://www.cramton.umd.edu/papers2010-2014/medicare-auction-conference-program.pdf.

> *I think there's also a very high probability that CMS is going to make moves in the direction of structuring an auction that actually reveals sustainable market prices. They may do that in time to avoid any of those failures. They may have to get whacked up side the head by having an auction failure.* [Emphasis added]

CRE notes that it is Medicare beneficiaries and taxpayers who will be getting "whacked upside the head" by CMS' failure to correct the lack of practical utility in the agency's plan for using the bid form information.

CMS' decision not to respond to the discussion in our comments concerning the CBO official's statement (which was under the bold section heading on p. 4 "CBO Warns of 'Near Certainty' of Auction Failure" discussing the bidding program's "high probability of failure in the near future" and "near certainty of failure sometime down the road" or the letter from 244 auction experts does make the issue disappear. To the contrary, not responding to key points made by CRE can only be construed as an effort to "kick the can down the road," an approach this Administration has made clear is unacceptable.[8]

In Section 8, "Federal Register/Outside Consultation" of CMS' Supporting Statement, the agency asserted, "Comments were received from one regulatory clearinghouse. The comments have been addressed." CRE's comments, as explained above, have not been addressed.

SUBSTANTIVE PRA AND DQA VIOLATIONS

CRE is supplementing our previous comments with discussion of the following PRA and DQA compliance issues:

1. Lack of practical utility;

2. Non-compliance with DQA standards – including with the requirements for influential information; and

3. Decimation of the home medical equipment industry.

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[8] http://www.whitehouse.gov/the-press-office/2011/07/05/remarks-president-status-efforts-find-balanced-approach-deficit-reductio

- ***The ICR's Use of the Collected Information Lacks Practical Utility***

The PRA defines "practical utility" as referring to "the ability of an agency to use information, particularly the capability to process such information in a timely and useful fashion." [44 USC 3502(11)]

OMB provided additional guidance on the term in their implementing regulations, explaining that practical utility "means the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability...." [5 CFR 1320.3(l)]

OMB also provided additional guidance on the practical utility requirement in 5 CFR 1320.1 which stated that the Purpose of the statute is to "maximize the practical utility and public benefit of the information...."

Thus, in determining whether the ICR meets the practical utility requirement, there are two questions which need to be answered:

- Is the information useful as used by the agency, considering its accuracy, validity, adequacy and reliability? and

- Does the ICR "maximize" the practical utility and public benefit of the information?

Each of these questions will be analyzed.

Usefulness of the Information: Prices Must be Competitive:

The meaning of the term "usefulness" regarding the information CMS seeks to collect and process can best be understood in context of the purpose of the statute which authorizes the DME competitive bidding program, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Sec 302(b)(1) of MMA states, in part:

> *The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services....* [Emphasis added]

Thus, the "usefulness" of the information CMS seeks to collect and use needs to be understood in terms of achieving acquisition of the specified DME products and services at competitive prices. If the prices CMS obtains are not competitive, the purpose of the statute has not been achieved and the ICR would not meet the practical utility requirement.

It is important to note that, under MMA, its not sufficient that the prices be determined through a competition. Rather, the equipment and services obtained through the competition must be "competitively priced." The Conference Report accompanying the MMA provided additional insight into this issue when it noted (p. 575) that the Secretary is,

> *able to exempt rural areas and areas with low population density within urban areas that are not competitive....*

Clearly, based on the MMA, it's not enough for there to be a competition among suppliers but also the prices obtained though the process must themselves be competitive.

Based on the views on virtually all non-CMS Medicare experts and auction experts which have analyzed the CMS program, both in academia and in the federal government, the prices from the agency's specific methodology for conducting the bidding exercise are NOT competitive.

The most rigorous analysis of the CMS program is found in the peer reviewed study published in the Quarterly Journal of Economics and included in the formal record of this ICR proceeding in CRE's June 26, 2012 comments. The study, which was financed by the Gordon and Betty Moore Foundation with additional support from the National Science Foundation, stated unambiguously in the Abstract:

> ***The CMS auction fails to generate competitive prices of goods and fails to satisfy demand.***

Thus, the ICR lacks practical utility.

The Congressional Budget Office's Chief of Medicare Cost Estimates made a similar point about the non-competitive outcome of the CMS bidding process at the conference co-sponsored by the University of Maryland and the National Science Foundation. The relatively extensive quote below is included without redaction since it provides an expert, independent, non-technical summary of how CMS uses the information collected from the forms in the subject ICR.

> *The auction mechanism that CMS used in the first round was poorly suited to the task of revealing that sustainable market price. That auction mechanism creates very strong incentives for bidders to submit bids that are below the amount at which they're willing and able to commit to deliver, and CMS's price setting mechanism, once they got those bids in, was -- I'll describe it as an interesting method of attempting to compensate for that incentive to bid low.*
>
> *Why did it create an incentive to bid low? Because the bidders were not actually bidding for the price at which transactions would occur; they were bidding for an invitation to the next round. They were bidding to the*

> *invitation to the "any willing supplier" round or "any willing vendor" round.*
>
> *And once they got there, then we have to deal with the mechanism that CMS used to set the price. CMS had this median price mechanism. I think the median -- the focus on the median price is actually kind of misleading. I think they selected the median price because they realized that they had all these crazy low bids, and they needed to get them out of the calculation.*
>
> *What they did was they selected bidders up to the quantity well over the amount needed to clear -- to serve the given market, and then from that vastly expanded pool, they selected the median.*
>
> *Fundamentally, that's an arbitrary number. It's a number that bears no relationship to the market clearing price other -- otherwise -- other perhaps than when they went up the scale of all the bidders, they were, in their judgment, going high enough so that the median of that distribution was what, in their judgment, was a reasonable approximation of that market clearing price.*[9]

Thus, the ICR lacks practical utility.

The 244 auction experts who wrote to President Obama succinctly stated:

> *bidder quantities are chosen arbitrarily by CMS, enabling a wide range of prices to emerge that have no relation to competitive market prices.*

Thus, the ICR lacks practical utility.

In short, virtually every economist outside of CMS who has examined the program has determined that it does NOT generate competitive prices. Because CMS uses the information collected from the bidding forms in a manner inconsistent with the MMA's stated goal, the ICR lacks practical utility.

Usefulness of the Information: An Unsustainable Program is Not Maximizing Utility

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[9] Timestamps omitted, emphasis added. The transcript, which is incorporated by reference as an integral part of these comments, is available at http://www.cramton.umd.edu/papers2010-2014/medicare-auction-conference-final-panel-562.rtf.

Since CMS' planned use of the data from the bid forms, an integral aspect of the ICR, fails to achieve the MMA's key goal – procuring DME goods and services at competitive prices, the ICR lacks practical utility that could be maximized.

The agency has made much of their asserted and projected savings from the bidding program and used them as a justification for not reforming their use of the bid form data. It is important to recognize, however, that the agency's savings assertions are consistent with the analyses by three groups of highly credentialed experts who all made the same basic point: CMS' use of the bid form results in below-competitive prices, an unsustainable situation. In quick summary:

- ***Quarterly Journal of Economics***: "RESULT 5. Prices generated in the CMS auction do not approximate the competitive price. They are significantly and consistently lower than the competitive price." (p. 811)

- ***244 Concerned Auction Experts***: "use of non-binding bids together with setting the price equal to the median of the winning bids provides a strong incentive for low-ball bids..."

Of particular relevance to OIRA are words of the CBO's Chief of Medicare Cost Estimates. The federal official explained that the data manipulations that CMS used for the first round to produce acceptable results will almost certainly fail in subsequent rounds, the subject of this ICR now before OMB:

> *And that makes it far more difficult in the next round to do a similar compensation that will substitute somebody's judgment of the sustainable market clearing price for -- to calculate that price out of the bids they got because the incentive for the vendors to bid low exists. And more and more of them are going to bid low because they realize that this is only bidding for an invitation to the next round.*
>
> *So at this stage of the process, CMS is looking back on its first round, and it is, in their terms, largely a success.*
>
> . . .
>
> *And the next point is, I think, the probability of failure in a subsequent round of bidding is very high because mechanisms they use aren't actually designed to reveal those prices.*[10]

The conclusion is that the ICR does not maximize practical utility.

- ***The ICR's Planned Use of the Information Requested Does NOT Comply with DQA Standards***

[10] Medicare Conference Transcript, p. 6, p. 7. [Emphasis added]

Consistent with OMB's government-wide guidelines, HHS established both Department-wide guidelines and operating agency specific information quality guidelines. The HHS-wide Departmental guidelines made clear the relevance of the Guidelines to the ICR currently before OIRA in the Department's discussion of HHS Information Quality Goals:

> *when HHS agencies prepare a Paperwork Reduction Act (PRA) clearance submission, they strive to engage in a data development effort that will result in information that will be collected maintained, and used in a way that is consistent with OMB, HHS, and agency-specific information quality guidelines.*[11]

As was already noted, CMS' Guidelines also state the agency's commitment to adhering to data quality standards in ICRs.

The OMB, HHS and CMS Guidelines all set quality standards based on the importance of the data with all data required to meet basic standards and the most important "Influential" data required to meet the most rigorous standards.

The data the agency disseminates as a result of their use of the bid form data includes the Single Payment Amount, the amount Medicare pays for the various types of DME goods and services.

There is no question that the Single Payment Amount, which determines the revenues and viability of an entire industry, is influential information. CMS defines influential scientific, financial and statistical information in Section VII of their Guidelines to mean that the agency "can reasonably determine that dissemination of the 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 uses "annual publication of provider payment rates," as an example of Influential information.

CMS' Single Payment Amounts, derived from the information the agency collects in the bidding forms, do not meet even minimal quality standards let alone the far more rigorous requirements for influential information.

CMS Guidelines, applicable to all information, state:

> *Information released by CMS is developed from reliable data sources using accepted methods for data collection and analysis, and is based on thoroughly reviewed analyses and models.*

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[11] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, *available at* http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml#d4 [Emphasis added]

As has been documented above, CMS data analysis methodology and model is not accepted by anyone outside the agency who has analyzed the program. To briefly highlight some of the key points made in material already in this ICR's docket:

From the peer-reviewed Merlob, *et. al* study published in the Quarterly Journal of Economics:

- "The CMS auction fails to provide a sufficient disincentive for perverse bidding behavior that leads to low efficiency and poor performance." (p. 811)

- "RESULT 5. Prices generated in the CMS auction do not approximate the competitive price. They are significantly and consistently lower than the competitive price." (p. 811)

- "RESULT 6. Outcomes in the CMS auction are not consistent with policy objectives: the auction fails to obtain adequate procurement and has poor efficiency levels relative to the excluded-bid auction." (p. 813, emphasis added)

- "The policy of nonbinding bids can independently make an otherwise well-functioning auction perform poorly. Similarly, the median-bid pricing rule has the independent ability to disrupt well-functioning auctions." (pp. 815-16)

- "the CMS auction performs poorly as a procurement auction." (p. 821)

From the transcript of the Congressional Budget Office's Chief of Medicare Cost Estimates speaking at a University of Maryland/National Science Foundation Conference:

- "The auction mechanism that CMS used in the first round was poorly suited to the task of revealing that sustainable market price." (p. 4)

- "CMS's price setting mechanism, once they got those bids in, was -- I'll describe it as an interesting method of attempting to compensate for that incentive to bid low." (pp. 4-5)

- "If they don't change the mechanism they use, I think there is a high probability of failure in the near future. There is near certainty of failure sometime down the road." (p. 8)

From the letter to President Obama signed by 244 (!) economists and other auction experts:

- "The flaws in the auctions administered by the Centers for Medicare and Medicaid Services (CMS) are numerous. The use of non-binding bids together with setting the price equal to the median of the winning bids provides a strong incentive for low-ball bids—submitting bids dramatically below actual cost."

- "On 1 April 2011, a Medicare auction conference was conducted at the University of Maryland to show how the modern auction methods work and to conduct a nearly

full-scale demonstration of an efficient auction. Over 100 leaders in government and the DME industry attended the event. The results are documented at www.cramton.umd.edu/health-care, including a complete video and transcript of the event. The mock auction achieved an auction efficiency of 97%. In sharp contrast, the CMS auction exhibited efficiencies well below 50% in the laboratory, even in simplified environments. Despite these sharp results, CMS continues to assert that all is well and that no significant changes are required." [Emphasis added]

- "**it is now clear that the CMS design is not an auction at all but an arbitrary pricing process**." [Emphasis added]

Since CMS' data use plan for the information the agency is requesting permission collect does not meet basic quality standards, it of course cannot meet CMS' own standards for influential information. The CMS Guidelines state:

> *CMS is committed to applying rigorous scientific standards to ensure the accuracy and reliability of program evaluation results. The scientific/research, financial, and statistical community recognizes peer review as the primary means of quality control. CMS routinely seeks input from qualified peer reviewers, inside and outside the Federal government prior to dissemination of this type of information.*

As was discussed above, the only peer reviewed analysis of CMS's data use methodology has harshly criticized it, explaining that the agency's "auction fails to generate competitive prices of goods and fails to satisfy demand."

The CMS Guidelines, based on OMB and HHS requirements, set "Transparency and Reproducibility" standards for influential information. As Section V. D. of the CMS Guidelines explain:

> *If an agency is responsible for disseminating "influential" information, guidelines for dissemination should include a high degree of transparency about data and methods to facilitate its reproducibility by qualified third parties. Information is considered influential if it will have a substantial impact on important public policies or important private sector decisions.*
>
> *CMS's guidelines call for identification and documentation of data sets used in producing estimates and projections, and for clear descriptions of the methods used.*

OMB's government-wide Guidelines further explain:

> *If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.*[12]

Aside from its other flaws, the CMS data use plan is not sufficiently transparent as to allow qualified third parties to reproduce the agency's results if they had access to the confidential bid data. The CBO official described the Single Payment Amount as "Fundamentally . . . an arbitrary number" while the 244 economists who strongly support federal use of procurement auctions explained that:

> *Another problem is the lack of transparency. For example, bidder quantities are chosen arbitrarily by CMS, enabling a wide range of prices to emerge that have no relation to competitive market prices.*

The 244 "concerned auction experts" further explained:

> *The problems with the CMS auction grow worse upon closer inspection. The complete lack of transparency is inappropriate for a government auction. For example, we now know that CMS has almost complete discretion with respect to setting prices in a nontransparent way. CMS can and did manipulate the quantities reported by bidders during qualification.*

The letter writers from dozens of universities concluded that:

> *The CMS competitive bidding program violates all of the principles, especially the principles of transparency and of basing regulations on the best available science. Indeed, the current program is the antithesis of science and contradicts all that is known about proper market design.*

Clearly, the ICR will not result in information that complies with OMB, HHS and CMS data quality standards.

The Decimation of the Home Medical Equipment Industry:
The Bidding Program Has Not Lived Up to the Small Business Protection Assertions Made in the CMS 2007 Final Rule

CRE, in our analysis above of CMS' Response to Comments, explained that protecting jobs and small business is absolutely within the purview of the PRA. CMS' discretionary decision to use information

[12] 67 Fed. Reg. 8460, Friday, February 22, 2002, col. 1.

collected from the bidding forms, approved previously by OIRA, in a way that needlessly devastates the DME industry – with the associated loss of jobs – is contrary to the very purpose of the PRA, ensuring that the public obtain "maximum" benefit from agency collection and use of information from the bid forms.

CMS' Response to comments cited their 2007 final rule as a reason for not changing their use of the data from the bid forms. To the contrary, a comparison of the results of the Round 1 Rebid with the agency's Regulatory Flexibility Analysis in the final rule demonstrates a great need to revise CMS' use of data from the bidding forms since the agency's expectations of the impacts from their program on small businesses were woefully inadequate.

In the Definitions section (§ 414.402) of the CMS 2007 final rule for competitive bidding,[13] the agency defines "small supplier" to mean "a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue" and that is the definition used in the following analysis.

As part of their Regulatory Flexibility Analysis in the final rule, CMS provided projections of: 1) the number of small suppliers; and 2) the number of all suppliers who would be affected by the rule, year-by-year from 2007-2012. Moreover, CMS included a column in their chart which provided projections, year-by-year, of share of all affected suppliers who would be small suppliers. Although the estimate of affected suppliers is not identical to an agency estimate of how many suppliers would win contracts, it is the best available proxy since suppliers who don't win contracts will no longer be Medicare suppliers.

The table on the next page illustrates: 1) CMS' estimate in their 2006 NPRM of the percentage of DMEPOS suppliers who were considered small businesses by SBA in 2003; 2) CMS' 2007 projection of the share of DMEPOS suppliers affected by the bidding program who would be small suppliers (CMS definition) in 2012; and 3) the share of Round 1 Rebid contracts which actually went to small suppliers.

It is important to note that CMS had the opportunity to revise their Regulatory Impact Analysis in their 2009 Interim Final Rule but declined to do, a decision they discussed in IFR's Regulatory Impact Statement.

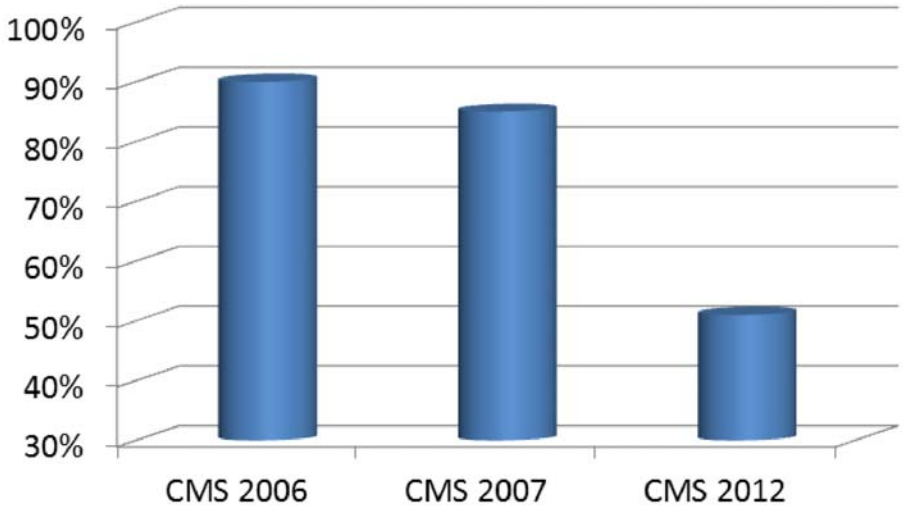
As the chart on the next page makes evident, the share of Medicare HME suppliers has plunged from 90% of all companies reported in CMS' 2006 Notice of Proposed Rulemaking and an 85% projected share of affected Medicare HME supplies who would be small businesses in 2012 to the 51% of suppliers actually receiving contracts in the Round 1 Rebid who were small businesses.

[13] 72 Fed. Reg. Tuesday, April 10, 2007, 18085 col. 2.

The Decimation of Small Home Medical Equipment Suppliers

CMS Expectations versus Reality

% of Medicare HME Suppliers Classified as Small



Sources: *CMS 2006* – Estimate of registered DMEPOS suppliers considered small business by SBA *from* CMS NPRM, 71 Fed Reg 25691, col. 3 (May 1, 2006*)*.
CMS 2007 – CMS estimate for 2012 Percent "of the number of affected small suppliers [of] total affected suppliers" *from* CMS Final Rule, 72 Fed Reg 18082, Table 17 (April 10, 2007).
CMS 2012 – CMS estimate of winning suppliers that are small businesses *from* CMS Competitive Bidding Update – One Year Implementation Update (April 17, 2012).

CRE has used the term "decimate" within these comments in the modern sense of the term, "to drastically reduce the strength or effectiveness of (something)." The modern definition is certainly applicable to the DME industry, as was noted in Footnote 5. The Oxford Dictionaries, however, also includes the historical meaning of the term, to "kill one in every ten of (a group of people, originally a mutinous Roman legion) as a punishment for the whole group."[14]

Although an industry which provides life-sustaining equipment and services to Medicare beneficiaries cannot be considered as akin to a mutinous legion, CMS' punishment of them is far harsher, instead of one of every ten mutineers being killed, perhaps one in ten Medicare DME supplies, irrespective of size, is being allowed to survive.

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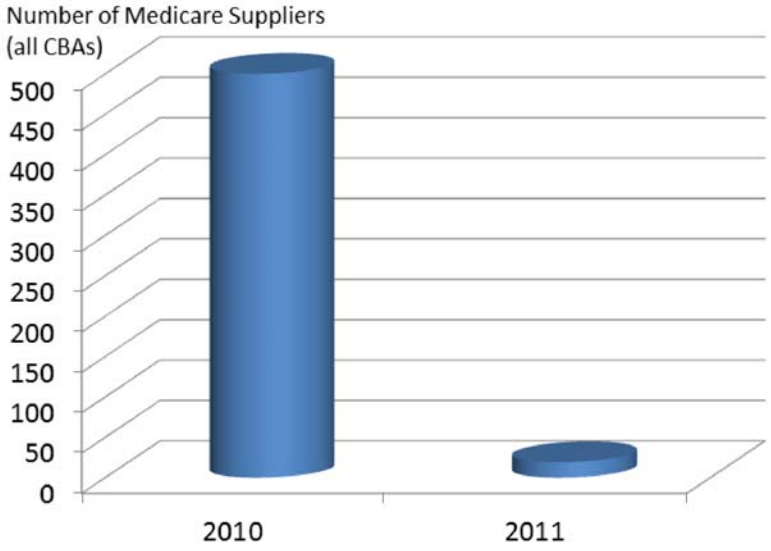
[14] Oxford Dictionaries, *available at* http://oxforddictionaries.com/definition/english/decimate.

The following three charts illustrate the devastation wrought on home medical equipment suppliers from CMS decisions on how to use the data from the bidding forms. All of the data in the following charts is CMS data analyzed by Dr. Cramton and submitted to the ICR docket in CRE's comments.[15]

Each of the following charts illustrate two data points, the number of DME suppliers submitting claims in any competitive bidding area (CBA) in 2010 and the number of contract supplies who have submitted claims in any CBA in 2011. The charts, therefore, include data from all CBAs. The number of non-contract suppliers submitting claims in a CBA were not included since these reflect either a transitory grandfathering of suppliers or misfiled/non-allowed claims.

The charts below are for three types of home medical equipment, mail order Diabetic Supplies, Oxygen Supplies, and Enteral Nutrients, nutritional supplies for people who need to be fed through a tube.

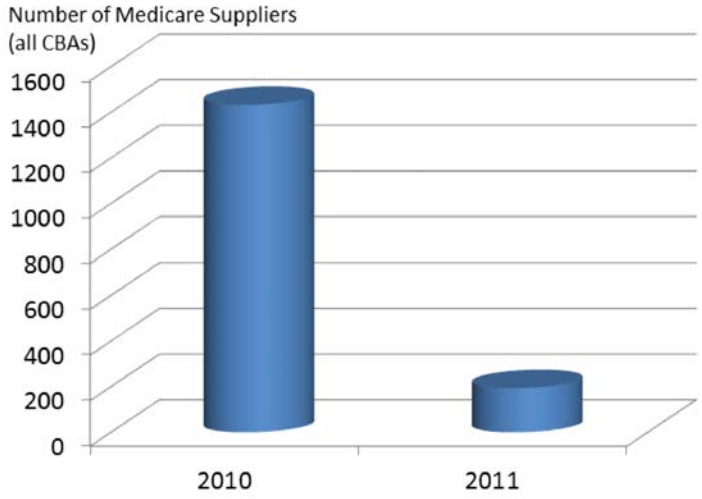
Competitive Bidding Slashes Mail Order Diabetic Supplies Providers Submitting Claims by 96%



Source: Cramton, "The Hidden Costs of a Flawed Medicare Auction," p. 7, based on CMS data.

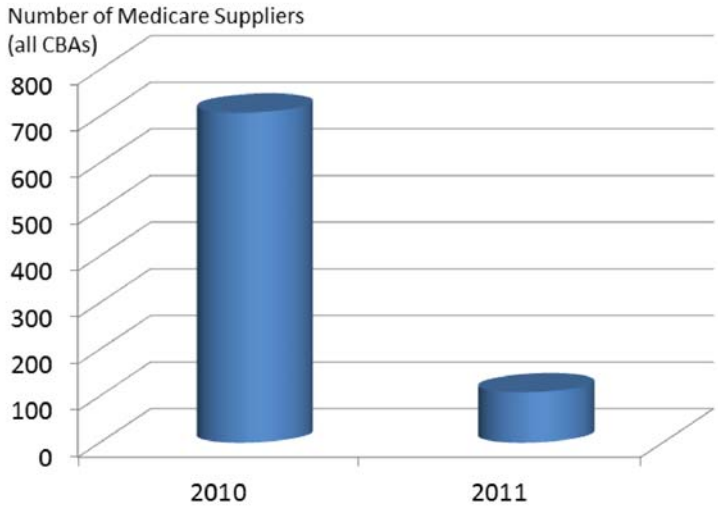
[15] Peter Cramton, "The Hidden Costs of a Flawed Medicare Auction," 20 January 2012 *available at* http://www.cramton.umd.edu/papers2010-2014/cramton-hidden-cost-of-flawed-medicare-auction.pdf.

Competitive Bidding Slashes Oxygen Supplies
Providers Submitting Claims by 86%



Source: Cramton, "The Hidden Costs of a Flawed Medicare Auction," p. 10, based on CMS data.

Competitive Bidding Slashes Enteral Nutrients
Providers Submitting Claims by 85%



Source: Cramton, "The Hidden Costs of a Flawed Medicare Auction," p. 8, based on CMS data.

CONCLUSIONS

- **Practical Utility**. The ICR does meet the Paperwork Reduction Act's practical utility requirements since it does not meet the MMA's goal of obtaining home medical equipment and services at competitive prices.

- **Utility and Transparency**. The ICR does not meet the Data (Information) Quality Act's utility and influential information requirements because it does not use accepted models and a transparent methodology.

- **Small Business and Job Loss**. CMS' use of the data from the ICR has been demonstrated to reduce the small business share of the Medicare home medical equipment market by almost half from CMS projections for 2012 and radically reduces the number of Medicare supplies by 85-95%.

OPTIONS

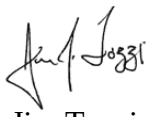
- **Option 1**. Approve the ICR for the DME bidding program despite the overwhelming consensus by academic and federal experts that CMS' use of the bid information results in the "high probability of failure in the near future" and "near certainty of failure sometime down the road."

- **Option 2**. Not approve the ICR prior to CMS reforming their data use plan to conform the requirements of the PRA and DQA.

RECOMMENDATION

- Option 2.

Sincerely,



Jim Tozzi
Member, Board of Advisors