

**Before the
Centers for Medicare and Medicaid Services**

**Petition to Compel CMS to Publish
the Secretary’s “Financial Standards” for the
Medicare DMEPOS Competitive Bidding Program**

In the Matter of)
)
Medicare Program; Changes to the)
Competitive Acquisition of Certain)
Durable Medical Equipment,)
Prosthetics, Orthotics and Supplies)
(DMEPOS) by Certain Provisions of the)
Medicare Improvements for Patients) 42 CFR Part 414
and Providers Act of 2008 (MIPPA))

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FILING NOTICES

1. Pursuant to 42 CFR § 401.128(a)(1), this petition is being filed with:

Director/Chief Financial Officer
Office of Financial Management
7500 Security Boulevard
C3-01-24
Baltimore, MD 21244

2. Pursuant to the Administrative Procedure Act, this petition is being filed with:

Associate General Counsel
Medicare and Medicaid Services
7500 Security Boulevard
C2-04-17
Baltimore, MD 21244

3. Pursuant to CMS' commitment to ensuring that the agency's process for evaluating bids is fair and transparent, this petition is being filed for public review and comment with:

The Competitive Bidding Interactive Public Docket
<http://www.thecre.com/blog/>

**Petition before the Centers for Medicare and Medicaid Services
to Compel CMS to Publish the Secretary’s “Financial Standards” for the
Medicare DMEPOS Competitive Bidding Program**

ISSUE: The Social Security Act (“Act”) states that DMEPOS competitive bidding contracts may not be awarded unless “The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.”¹ CMS has not published the Department’s “financial standards” for determining whether a bidder in their DMEPOS competitive bidding program is financially qualified. Failure to publish this policy violates the Social Security Act, the Administrative Procedure Act (“APA”), and CMS regulations.

RELIEF: CMS must suspend initiation of the DMEPOS Competitive Bidding program until after the agency publishes their financial qualification policy.

Legal Infirmities

The DMEPOS Competitive Bidding Interim Final Rule (“IFR”) suffers from critical legal infirmities that prevent its lawful implementation.

▶ ***Social Security Act***

The Act prevents CMS from awarding competitive bidding contracts to any entity unless they meet the agency’s specified financial standards. Because no such standards have been specified, no contracts may be awarded.

It is important to recognize, as discussed below, that the statutory requirement for the Secretary to specify financial standards was enacted following CMS testimony that the agency had not disclosed their financial scoring system in the original Round 1 competitive bid, *i.e.*, Congress found the agency’s lack of transparency on this issue to be unacceptable and prohibited any DMEPOS competitive bid contract from being awarded unless the entity met the financial standards “specified by the Secretary.”

▶ ***Administrative Procedure Act***

CMS has not published any specific financials standards for determining whether or not a bidder is financially qualified. Consequently, any agency contracting decisions based on the undisclosed standards would be inherently arbitrary and capricious.

¹ Social Security Act, Section 1847(b)(2)(A)(ii); 42 USC § 1395w–3(b)(2)(A)(ii). (Emphasis added.)

The APA requires that CMS publish their policy for determining whether or not DMEPOS suppliers are financially qualified to participate in the competitive bidding program. Specifically, 5 USC § 552 (a)(2) states,

- “Each agency, in accordance with published rules, shall make available for public inspection and copying— ... (B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register;”

CMS’ process for evaluating the financial information received from bidding entities to determine whether or not they are financially qualified constitutes an agency policy, or an interpretation of agency policy. This policy/interpretation has not been published in the Federal Register or otherwise made public. Agency refusal to make public the financial standards is potentially actionable under the APA. 5 USC § 706 authorizes a reviewing court to “compel agency action unlawfully withheld or unreasonably delayed....”

- If CMS were to conduct the competitive bidding program without publishing the Secretary’s specified financial standards that entities are required to meet as a condition of receiving a contract, then those standards would be “unlawfully withheld or unreasonably delayed” by the agency.

► ***CMS Regulations***

CMS’ regulations implementing the above section of the APA make clear that CMS is obligated to publish their policy, or interpretation of policy, for determining whether or not entities are financially qualified to participate in the DMEPOS competitive bidding program. Specifically, the CMS’ rules state that,

- “a statement of policy or interpretation that has not been published in the Federal Register as a part of a regulation or of a notice implementing regulations, but which has been adopted by CMS as having precedent, may be published in the Federal Register as a CMS Ruling and will be made available in the publication entitled CMS Rulings.”²

CMS’ process and standards for determining financial qualification of bidding entities constitute an agency policy or an interpretation of policy. In that the standards will be applied to all entities submitting data pursuant to a CMS rule, the standards have “been adopted by CMS as having precedent....” Because CMS did not publish their specific financial standards in the Federal Register, they are obligated by the APA and CMS regulation to publish them in “CMS Rulings.”

² 42 CFR § 401.108(a).

CMS Has Not Disclosed the Secretary’s Financial Standards

In their Final Rule establishing the agency’s Medicare competitive bidding program for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (“DMEPOS”),³ the Centers for Medicare and Medicaid Services (“CMS”) correctly noted that:

- ▶ “Section 1847(b)(2)(A)(ii) of the Act specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.”⁴

As Merriam-Webster explains, the word “specified” means “to name or state explicitly or in detail.”⁵ CMS has not, in the Final Rule, subsequent IFR, or other public document, specified the “applicable financial standards” that DMEPOS suppliers are required to comply with in order to avoid disqualification from the bidding program.

There are currently no publicly available objective financials standards or algorithm which a qualified person, such as a company CFO or accountant, could use to determine whether or not the entity met CMS’ financial qualification requirements. Companies that want to participate in the competitive bidding system are required to meet the unstated financial standards. If they don’t meet the standards their bid will not be considered as “bona fide” and, as CMS explained,

- ▶ “If we conclude that a bid is not bona fide, we will eliminate the bid from consideration.”⁶

While the agency has not specified the financial standards that DMEPOS suppliers are required to meet, they have specified the detailed financial data that DMEPOS suppliers are required to provide to the agency as part of the bidding evaluation process. Moreover, as part of its Information Collection Request (“ICR”) to the Office of Management and Budget (“OMB”) under the Paperwork Reduction Act (“PRA”), CMS formally certified that it “planned and allocated resources for the efficient and effective management and use of the information to be collected.”⁷

Instead of making public their financial standards and related policies, *i.e.*, their plan for efficiently and effectively using the data, the agency has only published vague generalities as to what financial standards have been decided upon by CMS. For example, the Final Rule stated that the data collected,

³ 72 Fed. Reg. 17992. Et. Seq., Tuesday, April 10, 2007

⁴ Ibid., p. 18037.

⁵ <http://www.merriam-webster.com/dictionary/specified>.

⁶ Ibid., p. 18047.

⁷ http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200906-0938-011.

*“will allow us to determine financial ratios, such as a supplier’s debt-to-equity ratio, and credit worthiness, which will allow us to assess a supplier’s financial viability.”*⁸

What specific ratio values are considered acceptable and what are considered unacceptable by CMS remains unstated as do any possible tradeoffs between, for example, an otherwise unacceptable debt-to-equity ratio and an above acceptable credit score.

Similarly, CMS stated,

*“We will use appropriate financial ratios to evaluate suppliers. If suppliers do not meet certain ratios, they could be disqualified from the competition. Examples of ratios we might consider include a supplier’s debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company.”*⁹

Words such as “appropriate” and “might” and “could” do not indicate an objective, specified standard nor a policy but rather an arbitrary and capricious decision-making process by CMS.

CMS explains that,

*“We will be reviewing all financial information in the aggregate and will not be basing our decision on one ratio but rather overall financial soundness.”*¹⁰

Thus, CMS has explained the financial information that they will use (all), what they will not do (use a single financial ratio) and what they are trying to determine (overall financial soundness). What the agency has not done is enunciate a financial standard or methodology against which the financial data of all firms considering submitting bids can be objectively measured – both by CMS and by each submitting entity.

Legislative History Makes Clear that CMS is to Enunciate Specific Financial Standards

As was explained above, CMS did not make publish their specific financial standards during the original Round 1 DEMPOS bidding exercise that was subsequently vacated by Congress. Following the competitive bidding in the first ten areas, the House Ways and Means Subcommittee on Health held oversight hearings on the process.

The hearing transcript includes a statement from then Acting CMS Administrator Weems explaining that the agency had never released their methodology for determining whether or not bidders were financially qualified and that this process was the only non-transparent part of the competitive bidding system.

⁸ Ibid., p. 18037.

⁹ Ibid., p. 18038.

¹⁰ Ibid.

Following the hearing, Congress amended to portions of the Act governing the DMEPOS competitive bidding program. The amendments included the addition to the statute of the provision regarding the “applicable financial standards specified by the Secretary.”¹¹ After enactment of the Medicare Improvements for Patients and Providers Act of 2008, CMS addressed many of the changes required by Congress but has not yet acted with respect to the new provision regarding the financial standards specified by the Secretary.

The following question and response between Rep. Tiberi and CMS Acting Administrator Weems reveals concern over CMS’ lack of transparency and CMS’ assurance that transparency was only lacking with respect to the financial standards bidders were required to meet.

“-- *Mr. TIBERI. ...*

-- Some would say that the entire process in which the implementation of this program has not met transparency levels that we would all be proud of in the Federal Government and that there has been a lack of information provided to both beneficiaries and suppliers and policymakers throughout the implementation of this process.

-- What would you say to that criticism?

*-- *Mr. Weems. I would strongly disagree. I think that we have done a very good job of educating our suppliers. We have an advisory Committee with them that has met six times over the course of this. We have taken considerable input from them. We have been very transparent. About the requirements, the only thing that I would say that we have not disclosed as a matter of the bid process is exactly how we use the financial ratios in judging the financial viability of each bidder. We have told them what financial documentation we need. We have told them the ratios that we would use, but we have not told them how that would be scored.*

-- That, I would say, is the one piece sort of "our audit plan," we have not disclosed.”¹²

If Congress were satisfied with CMS’ undisclosed process for judging financial viability, they would not have added into law the explicit provision regarding financial standards specified by the Secretary that take into account the needs of small providers.

¹¹ Public Law 110-275.

¹² Hearing Before the Subcommittee on Health of the Committee on Ways and Means, U.S. House of Representatives, One Hundred Tenth Congress, Second Session, May 6, 2008 found at <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=7569>. (Emphasis added.)

There is no plausible interpretation of Congress' decision to add § 1395w-3(b)(2)(A)(ii) to Title 42 of the US Code other than insistence that CMS disclose their standards for judging whether or not a bidder was financial qualified to participate in the program. This interpretation is further reinforced by subsection's use of the phrase "taking into account the needs of small providers." How could Congress or any other stakeholder know whether or not CMS' financial standards took the needs of small providers into account unless those specified standards were public? Modification of the financial disclosure burden on small entities is not the same as ensuring that the standards that are applied to the disclosed data takes small business needs into account.

CMS' Lack of Specific Financial Standards Was Raised by Stakeholders During the Public Comment Periods

There have been two public comment periods on the DMEPOS competitive bidding program, the first associated with the 2006 DEMPOS Competitive Bidding Proposed Rule,¹³ and the second was the 2009 Interim Final Rule with Comment Period.¹⁴ In both instances, stakeholders objected to the lack of specific financial standards to no avail. CMS responded to the comments received on the 2006 Notice of Proposed Rulemaking without providing the specific financial standards they intended to use and the agency has yet to the comments received on the IFR.

With respect to the first comment period, CMS noted that,

*"One commenter suggested that CMS also publish the criteria it will use to assess supplier's financial stability and how it will rank suppliers based on these criteria."*¹⁵

Similarly, CMS also recognized in response to the NPRM that,

*"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."*¹⁶

With respect to the IFR under which CMS intends to conduct the Round 1 Rebid, commenters expressed substantial concern that the lack of objective financials standards harmed bidders and left the bid evaluation process open to discrimination and other abuse.

For example, one stakeholder notified the agency that,

¹³ 71 Fed. Reg. 25654. Et. Seq., Monday, May 1, 2006.

¹⁴ 74 Fed. Reg. 2873. Et. Seq., Friday, January 16, 2009.

¹⁵ Final Rule, p. 18037.

¹⁶ Ibid.

“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.”¹⁷

Another commentor, this one 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 assess their current financials in relation to the standards in order to submit informed bids to CMS.”¹⁸

The above comments make clear that CMS’ refusal to engage in their non-discretionary duty under the Act of specifying financial standards results in harm to suppliers, harm to the quality of bids received by CMS, and harm to the integrity of the competitive bidding program.

CMS’ Lack of Specific Financial Standards Harm DMEPOS Suppliers and the Public

CMS’ refusal to publish their specific financial standards for the competitive bidding program causes direct harm to DMEPOS suppliers. For example, if companies that do not meet the standards could determine so prior to bidding, they could save themselves the expense of developing and submitting bids. Virtually every bid that is rejected by CMS because it does not meet the agency’s financial standards represents wasted resources by the bidder that could have been avoided had CMS published their specific financial qualification policy.

- ▶ CMS’s refusal to publish their financial qualification standards is directly counter to the Act’s requirement that the financial standards specified by the Secretary, take “into account the needs of small providers.” Many small businesses seeking to participate in the program will forced to

¹⁷ <http://www.thecre.com/blog/wp-content/uploads/2009/05/cms-reimbursement-advmed.pdf>. (Emphasis added.)

¹⁸ <http://www.thecre.com/blog/wp-content/uploads/2009/05/cms-reimbursement-coalition.pdf>. (emphasis added.)

squander scarce resources in preparing and submitting bids and becoming otherwise qualified without being allowed to know whether or not they meet the agencies financial standards prior to the start of bidding process.

Moreover, had companies known CMS' criteria for determining financial eligibility, those companies may have made different business decisions. For example, a company may have expanded their capabilities to take advantage of perceived competitive bidding opportunities or for other reasons without realizing that the debt taken to finance the expansion would make them ineligible for the CMS program.

As the commentor cited above explained, CMS' lack of clear public financial qualification standards opens the door to the potential for unfair discrimination. As long as the public does not know on what specific financial basis CMS is able to eliminate entities from the competitive bidding process, bidders are potentially subject to various forms of discrimination, bias, favoritism, cronyism, and other abuse of agency discretion – all of which will go undetected since there are no publicly available standards against which the agency's financial qualification decisions can be measured.

- ▶ Medicare patients may find it difficult to have confidence in the quality and integrity of agency services when critical care-related decisions are made via secret protocol.

In short, because CMS is able to disqualify any bidding entity on the basis of undisclosed financial standards, there is no competitive bidding system; there is only an elaborate procedural apparatus that allows CMS to pick and choose whichever DMEPOS providers they prefer.

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 transparency in the rulemaking process, we pioneered the Interactive Public Docket (“IPD”).¹⁹ 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 the CMS Competitive Bidding Interactive Public Docket available at <http://www.thecre.com/blog/>. Extensive public discussion of DME competitive bidding issues is found on the IPD's Discussion Forum available at <http://www.thecre.com/Forum/>.

CRE's Competitive Bidding IPD will be accepting and displaying public comments on this petition, <http://www.thecre.com/blog/>.

¹⁹ http://en.wikipedia.org/wiki/Interactive_Public_Docket.

Conclusion

- ▶ Unless CMS publishes their specific objective financial qualification standards, agency decisions made in the Round 1 Rebid will be arbitrary, capricious, and otherwise unlawful.

Relief

- ▶ CMS must suspend initiation of the DMEPOS Competitive Bidding program until after the agency publishes their specific financial qualification policy.