IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEXAS ALLIANCE FOR HOME CARE SERVICES, et al., Plaintiffs, v. KATHLEEN SEBELIUS, Secretary of the Department of Health and Human Services, et al., Defendants.	Civil Action No. 1:10cv747 (HHK)

MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

Dated July 23, 2010

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Table of Contents

Table of Authorities

CASES

STATUTES & REGULATIONS

MISCELLANEOUS

INTRODUCTION

Plaintiffs seek to halt the Secretary of Health and Human Services' ("the Secretary") implementation of a competitive bidding program designed to allow Medicare beneficiaries to obtain high quality durable medical equipment, prosthetics, orthotics and supplies[1] ("DMEPOS") at competitive prices. Plaintiffs, who challenge a program that will not commence for almost six more months, allege only that they have suffered "procedural injury." In particular, Plaintiffs assert that the Secretary has unlawfully failed to specify the financial standards she will use to evaluate whether a supplier is sufficiently financially viable to serve as a Medicare DMEPOS contract supplier. Plaintiffs make this assertion notwithstanding the fact that they are concededly aware of the financial documentation the Secretary has required all suppliers to submit in connection with the bidding process, and notwithstanding the fact that the Secretary has published since 2007 the precise financial information within that documentation that the Secretary will use to make her evaluation.

And although Plaintiffs intimate that the Secretary's design and implementation of the financial evaluation process has been shrouded in secrecy, the reality is demonstrably different. In the years leading up to the nationwide rollout of the DMEPOS competitive bidding initiative, the Secretary has, as Congress contemplated, held numerous public meetings to inform interested members of the public about competitive bidding, and to solicit feedback. The Secretary has also conducted notice and comment rulemaking proceedings on the precise issue of financial

[1] The term "durable medical equipment, prosthetics, orthotics and supplies" generally speaking, "includes iron lungs, oxygen tents, hospital beds, . . . wheelchairs, . . . blood-testing strips and blood glucose monitors . . . [and] seat-lift chair[s] . . . . ," *see* 42 U.S.C. § 1395x(n).

standards, and established websites designed to foster greater public awareness about competitive bidding.

Although the Secretary has disclosed every component on which she will rely in making financial evaluations, Plaintiffs nonetheless press for more, arguing that they have a statutory right to know the precise methodology by which the Secretary will combine suppliers' financial information to arrive at a viability determination as well as the numerical threshold below which a supplier would not be eligible for consideration in the competitive bidding program. Plaintiffs do so despite the fact that Congress expressly precluded challenges to the Secretary's design and implementation of the competitive bidding process, and despite Plaintiffs' failure to identify how they have suffered any legally cognizable harm due to this asserted lack of knowledge, or how the relief they seek would redress their alleged harm. Accordingly, subject matter jurisdiction is lacking.

Plaintiffs' Complaint furthermore fails to state a claim upon which relief can be granted. Where, as here, Congress has not instructed the Secretary to promulgate regulations with a particular level of specificity, judicial deference to the degree of specificity with which an agency has drafted regulations is at its zenith. This Court is constrained to uphold the Secretary's financial evaluation process as long as the regulation at issue is reasonable. Because providing the information Plaintiffs seek would both unduly hamstring the Secretary's ability to modify the competitive bidding process in response to experience, and increase the prospect of the very fraud that the program was designed to eliminate, there can be no doubt that the Secretary has met this unexacting standard. For each of these separate and independent reasons, Plaintiffs' Complaint must be dismissed.

STATUTORY BACKGROUND

A. Overview Of The Medicare Act

Title XVIII of the Social Security Act, commonly known as Medicare, 42 U.S.C. §§ 1395, *et seq.*, establishes a program of health insurance for the elderly and disabled. The program provides payment for covered medical services provided to eligible Medicare beneficiaries. *Id.* at §§ 1395c, 1395k, 1395w-22, 1395w-102. The Secretary is charged with promulgating regulations "necessary to carry out the administration of the insurance programs" established by the Medicare Act. *Id.* at § 1395hh(a)(1). Additionally, the Secretary serves as trustee of the Federal Supplementary Medical Insurance Trust Fund ("Medicare Part B Trust Fund"), *see United States v. Erika, Inc.*, 456 U.S. 201, 202-03 (1982), and as such, has a fiduciary duty to protect the trust fund's assets. Experts expect that "Medicare spending will continue to grow at a rate higher than the rest of the economy for the foreseeable future." *See* Nancy-Ann DeParle, *Medicare at 40: A Mid-Life Crisis?*, 7 J. Health Care L. & Pol'y 70, 85 (2004). Accordingly, "Medicare faces significant long-term financing challenges . . . ." *Id.*

B. Section 302 Of The Medicare Prescription Drug, Improvement And Modernization Act Of 2003

For the past several years, Medicare has paid for "durable medical equipment . . . using a different fee schedule for each class of covered items." H.R. Rep. No. 108-391, at Title III § 302 (2003) (Conf. Rep.). The Centers for Medicare and Medicaid Services ("CMS") developed the fee schedule for each item of DMEPOS by using "a weighted average of either local or regional prices, subject to national limits (both floors and ceilings)" that were updated annually. *Id.* Congress investigated the DMEPOS fee schedule payment system, reviewing numerous studies

conducted by the Department of Health and Human Services ("HHS") and the Government Accountability Office ("GAO"), and concluded that the existing fee schedule amounts were too expensive for both taxpayers and Medicare beneficiaries and that it did not provide adequate value for what Medicare paid.[2] H.R. Rep. No. 108-178, pt. II at Title III, § 302 (2003).

In an effort to "combat [such] waste, fraud, and abuse," Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003). The MMA referenced the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997) ("BBA"), which authorized a demonstration project to test whether a competitive acquisition program would be a more efficient method of paying for DMEPOS.[3] H.R. Rep. No. 108-178, pt. II at Title III, § 302 (2003). The BBA competitive acquisition demonstrations were successful. *Id.* Congress found that both taxpayers and Medicare beneficiaries "saved significantly and quality standards were higher under the demonstration." *Id.*

Accordingly, in 2003 Congress enacted the Medicare DMEPOS Competitive Bidding Program ("the competitive bidding program" or "the DMEPOS program") as part of the MMA. *See* 42 U.S.C. § 1395w-3; 42 C.F.R. § 414.400 *et seq*. The MMA requires the Secretary to "establish and implement programs under which competitive acquisition areas are established

[2] "For example, [HHS] found that Medicare's reasonable payment methodology paid too much for parenteral nutrition . . . [and] that Medicare payments for hospital beds were substantially higher than rates paid by other payors." H.R. Rep. No. 108-178, pt. II at Title III, § 302 (2003).

[3] "Three competitive bidding demonstrations for durable medical equipment, prosthetics, orthotics, and supplies were implemented, two in Polk County, Florida and one in the San Antonio, Texas area." H.R. Rep. No. 108-391, at Title III § 302.

throughout the United States for contract award purposes for the furnishing under this part of competitively priced [DMEPOS] items and services." *Id.* at § 1395w-3(a)(1)(A). Under the program, the Secretary is required to conduct "a competition among entities supplying items and services," *id.* at § 1395w-3(b)(1), wherein suppliers submit bids, offering to furnish items or services (including attendant services) for a set price. *Id.* at § 1395w-3(b)(6)(B).

The competitive bidding program contains safeguards protecting the quality of goods and services provided. Suppliers must meet quality standards developed by CMS, 42 U.S.C. § 1395w-3(b)(2)(A)(i); 42 C.F.R. § 414.414(c), and must be accredited by a CMS-approved accreditation organization before placing a bid or being awarded a contract. 42 U.S.C. § 1395m(a)(20); 42 C.F.R. § 424.58(b)(1); *see also* CMS, Competitive Acquisition for DMEPOS, New Quality Standards, *available at* http://www.cms.gov/MedicareProviderSupEnroll/07_DMEPOSAccreditation.asp#TopOfPage. As a prerequisite for consideration in the competitive bidding program, a supplier must meet "financial standards specified by the Secretary . . . ." 42 U.S.C. § 1395w-3(b)(2)(A)(ii).[4]

"[I]n order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must submit a bid to furnish those items and be awarded a contract . . . ." 42 C.F.R. § 414.412(a). The Secretary began phasing in the DMEPOS

[4] Section 302 of the MMA also provides for the protection of small DMEPOS contract suppliers. The Secretary is required to "tak[e] into account the needs of small providers" in developing financial standards that entities have to meet, 42 U.S.C. at § 1395w-3(b)(2)(A)(ii), and is required to "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation" in the competitive acquisition program when developing bidding and contracting procedures. *Id.* at § 1395w-3(6)(D). Moreover, contracts are awarded "to multiple entities submitting bids in each area for an item or service," *id.* at § 1395w-3(b)(4)(B), which will maintain "access of individuals to a choice of multiple suppliers" in each

competitive bidding program in ten of the largest metropolitan areas[5] in 2007 as part of the initial phase of the program in advance of a nationwide rollout of DMEPOS competitive bidding. 42 U.S.C. § 1395w-3(a)(1)(B); 42 C.F.R. § 414.410. Evidence in the initial round indicates that the Secretary complied with these statutory and regulatory mandates. The successful participation of small suppliers in the competitive bidding program was demonstrated during the program's demonstration programs, when "three-quarters of the DME [contract] winners were small businesses and beneficiary satisfaction remained high." *See* H.R. Rep. No. 108-178, pt. II at Title III, § 302 (2003).

C. Initial Implementation Of The DMEPOS Competitive Bidding Program

One of Congress' purposes in the MMA was to ensure that all contract suppliers would be sufficiently financially viable so as not to jeopardize beneficiaries' access to DMEPOS items. The MMA states in pertinent part that the Secretary "may not award a contract to any entity under the competition conducted in a[] competitive acquisition area . . . to furnish such items or services unless the Secretary finds . . . [that] [t]he entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers." 42 U.S.C. § 1395w-3(b)(2)(ii).

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competitive bidding area. *Id.* at § 1395w-3(b)(2)(A)(iv).

[5] The Act refers to metropolitan areas as Metropolitan Statistical Areas ("MSAs"), which have the same meaning as that given by the Office of Management and Budget. 42 C.F.R. § 414.402. The ten MSAs where the Secretary was required to begin implementing the competitive bidding program are Charlotte-Gastonia-Concord, North Carolina/South Carolina; Cincinnati-Middletown, Ohio/Kentucky/Indiana; Cleveland-Elyria-Mentor, Ohio; Dallas-Fort Worth-Arlington, Texas; Kansas City, Missouri/Kansas; Miami-Fort Lauderdale-Miami Beach, Florida; Orlando, Florida; Pittsburgh, Pennsylvania; Riverside-San Bernardino-Ontario, California; San Juan-Caguas-Guaynabo, Puerto Rico.

1. The DMEPOS Program Advisory and Oversight Committee

In the MMA, Congress directed the Secretary to form an advisory committee to provide input and advice on the design and implementation of the DMEPOS competitive bidding program. Specifically, 42 U.S.C. § 1395w-3 instructs the Secretary to assemble a Program Advisory and Oversight Committee ("PAOC") for the DMEPOS competitive bidding program. 42 U.S.C.A. § 1395w-3(c). The PAOC, whose membership includes representatives from industry and beneficiary groups, "is responsible for providing advice on the development and implementation" of certain provisions of Section 302 of the MMA, including "the establishment of financial standards for suppliers under the program that take into account the needs of small providers." 69 Fed. Reg. 52,723; *accord* 42 U.S.C.§ 1395w-3(c)(3). In an effort to maximize public input and participation, the Secretary published via listserv and on the CMS website the time and place of PAOC meetings, solicited comments, and published registration procedures for members of the public who wished to attend. *See id.* at 52,723-24. CMS publishes information about the PAOC's role and responsibility on its website, which is publicly available.[6]

As contemplated by Congress, the PAOC has since 2004 held public meetings over the course of several years to inform interested persons about the proposed design and implementation of the DMEPOS competitive bidding. Agendas and summaries of many of these meetings (from 2004 to present) are available on CMS' website.[7]

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[6] *See* http://www.cms.gov/DMEPOSCompetitiveBid/09_Program_Advisory_and_Oversight_Committee_PAOC.asp#TopOfPage

[7] *See* http://www.cms.gov/DMEPOSCompetitiveBid/PAOCMI/list.asp#TopOfPage

2. Notice and Comment Rulemaking Proceedings

The Secretary conducted extensive notice and comment proceedings regarding financial standards for the DEMPOS competitive bidding process. By proposed rule dated May 1, 2006, the Secretary specified what information would be relevant to supplier financial evaluations. In a section of the proposed rule titled "Financial Standards," the Secretary stated that:

> [T]he [request for bid] will identify the specific information we will require to evaluate suppliers, which may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency. We welcome comments on the financial standards, in particular the most appropriate documents that will support these standards.
>
> We found that in the demonstration, general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency, were important considerations for evaluating financial stability.
>
> As we develop our methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process.

71 Fed. Reg. 25,654, 25,675. Thereafter, the Secretary accepted comments for 60 days, until June 30, 2006. *Id.* at 25,654.

On April 10, 2007, the Secretary issued the final rule governing DMEPOS competitive bidding. In this rule, the Secretary reiterated that CMS "will be reviewing all financial information in the aggregate, and will not be basing [its] decision on one ratio but rather on overall soundness." 72 Fed. Reg. 17,992, 18,038. Under this totality of the circumstances approach, and based on CMS' experience in the DMEPOS demonstration projects, the Secretary concluded that "general financial condition, adequate financial ratios, positive credit history,

adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency were important considerations for evaluating financial stability." *Id.* at 18,037.

Commenters correctly recognized the necessary balancing between requiring suppliers to provide enough evidence to allow CMS to conduct an accurate and comprehensive financial evaluation without discouraging suppliers from submitting bids with unduly burdensome requirements for the collection of financial documentation. *See id.* at 18,037 ("The commenters stated that if financial standards are too restrictive, qualified suppliers might not be able to participate in the Medicare DMEPOS Competitive Bidding Program. [Commenters] added that, conversely, if financial standards are too lax, suppliers may be financially unable to meet the challenges of a competitive market."). In response to concerns that its proposed financial documentation requirements would place an undue burden on certain suppliers, CMS agreed to reduce the financial documentation it would require suppliers to submit. The final rule states in pertinent part that:

> After further consideration and in response to comments, we believe that the proposed financial documentation discussed in the preamble to the proposed rule (71 FR 25675) would be too burdensome, particularly for small suppliers. Therefore, in order to obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process, we will require that for the initial round of competition, suppliers must submit certain schedules from their tax returns, a copy of the 10K filing report from the immediate 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded) certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid . . . .

72 Fed. Reg. at 18,037.[8] Cognizant of the fact that the competitive bidding process remained in its infancy, CMS stated in the final rule that it might further modify what financial documentation suppliers would have to provide in the future. *See id.* ("We will generally require that suppliers submit the same types of [financial] information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a supplier is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program.").

In the final rule, CMS made clear that it would specify in the Request for Bids what documentation and financial ratios would be central to the Secretary's analysis. The rule stated in pertinent part that:

> We are clarifying in the final rule that the [Request for Bids] will specify what financial documents will be required (§ 414.414(d)) so that we can obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process. This financial information will provide enough information to 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.

72 Fed. Reg. at 18,072. In this way, CMS sought to "balance[] the needs of small suppliers and the needs of the beneficiaries in requesting documentation that will provide us with sufficient information to determine the financial soundness of a supplier." In May 2007, CMS also specified the financial ratios it would use to make financial viability determinations.

[8] *See also id.* ("[W]e recognize that our collection of financial information must be comprehensive enough to allow us to assess a supplier's financial soundness, but not so burdensome as to encumber the bidding process (especially for small suppliers) and the bid evaluation process.").

Approximately one month after the issuance of this final rule, on May 15, 2007, CMS issued a request for bids for the first round of the Medicare DMEPOS competitive bidding program. The bidding deadlines were extended a number of times and the bidding window closed September 25, 2007. *Id.* Round One of the DMEPOS competitive bidding commenced on July 1, 2008.

D. The Medicare Improvements For Patients And Providers Act Of 2008

In response to concerns expressed by the DMEPOS contract supplier community, Congress held a hearing on May 6, 2008 to address the then-approaching nationwide implementation kickoff of the DMEPOS competitive bidding program.[9] Congress' overriding concern was that CMS disqualified what some regarded as an unacceptably high number of suppliers for the first phase of the nationwide rollout. *See* Hearing on Medicare's DMEPOS Competitive Bidding Program: Hearing Before the H. Subcommittee on Health, H. Comm. on Ways and Means, 110th Cong. 6 (2008) at 6 (statement of Rep. Stark that 630 of 1,005 were applications rejected for inadequate data) [hereinafter H.R. Hearing].

By contrast, Congress gave scant indication that any other aspect of the Secretary's financial evaluation process was a source of concern. At this same hearing, Acting CMS Administrator Kerry Weems rebutted criticism that CMS' implementation of the DMEPOS competitive bidding program had lacked transparency. In an exchange with Rep. Pat Tiberi (R-Ohio), Weems explained that CMS had been open and forthright about the bidding process:

[9] A transcript of this hearing is available at http://waysandmeans.house.gov/Hearings/transcript.aspx?NewsID=10346. The transcript of this hearing, attached hereto as Exhibit A, spans 38 pages. References to this hearing transcript are in the form of H.R. Hearing at ___.

> 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 [CMS] [has] done a very good job of educating our suppliers. We have an advisory Committee (the PAOC) 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 ratio[]s 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 [] of "our audit plan" we have not disclosed.

H.R. Hearing at 25. Shortly after the May 2008 hearing, Congress amended the MMA.

On July 15, 2008, two weeks into the competitive bidding regime, Congress passed the Medicare Improvements For Patients and Providers Act ("MIPPA"). Pub. L. No. 110-275, § 154, 122 Stat. 2494 (Jul. 15, 2008). "MIPPA effectively negated DME[POS] competitive bids submitted under the MMA, reinstated temporarily the fee-schedule system in place before the MMA," and required the Secretary to rebid Round 1 of the competitive bidding. Compl., ¶ 17; *accord* 74 Fed. Reg. 2873, 2875. MIPAA "ma[de] certain limited changes to the Medicare DMEPOS Competitive Bidding Program." 74 Fed. Reg. at 2875. MIPAA did not alter the MMA's requirement that the Secretary "may not award a contract to any entity under the

competition conducted in a[] competitive acquisition area . . . to furnish such items or services unless the Secretary finds . . . that "[t]he entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers." 42 U.S.C. § 1395w-3(b)(2)(ii).

With respect to the competitive bidding process, the most significant change Congress made pertained to situations where CMS determined that a supplier had failed to supply the requisite financial documentation. Prior to disqualifying a bid for inadequate documentation, MIPPA requires the Secretary to inform a supplier that its financial documentation is deficient, tell the supplier what documentation is missing, and give the supplier an opportunity to correct this deficiency. *See* 42 U.S.C. § 1395w-3(a)(1)(F); 42 C.F.R. § 414.414(d)(2); 74 Fed. Reg. at 2876-77.[10] Notably, however, Congress did not require the Secretary to publish the threshold below which a supplier would not be eligible to participate in the competitive bidding program, or otherwise modify the financial evaluation process set forth in CMS regulations. *Accord* Compl., ¶ 17 (Congress' amendments to MMA in MIPPA are "not relevant" to this case).

On January 16, 2009, CMS promulgated an interim final rule implementing MIPAA and requesting comments.[11] 74 Fed. Reg. at 2873. In this regulation, CMS articulated how it planned to implement Congress' directive that it give suppliers an opportunity to remedy missing financial documentation, including the timelines by which suppliers must provide the requested

[10] MIPPA makes clear that this review process is limited: It applies only to covered financial documents that were timely submitted; it does not apply to other deficiencies. MIPPA expressly "does not apply to any determination as to the accuracy of or completeness of covered documents submitted or whether such documents meet applicable requirements." 42 U.S.C. § 1395w-3(a)(1)(F)(iii)(II).

[11] The regulation required comments to be submitted by March 17, 2009 at 5 p.m. The rule became effective on February 17, 2009.

documentation. *Id.* at 2876-77. Rounds One and Two of the Competitive Bidding Program were delayed from 2007 and 2009 to 2009 and 2011, respectively. *Id.* at 2876.

E. Post-MIPPA Implementation Of The DMEPOS Competitive Bidding Program

Following MIPPA's enactment, the Secretary continued to hold periodic PAOC meetings in advance of the Round One re-bid of the DMEPOS competitive bidding program. As before, CMS continued to make information about each such meeting publicly available on its website.[12] Following MIPAA, CMS also held a multi-part series of "Open Door Forum" ("ODF") meetings for bidders to discuss the Round 1 DMEPOS competitive re-bidding process. The topic at a September 29, 2009 ODF meeting was "How a Bid is Evaluated." Transcripts of this and other ODF meetings remain publicly available on CMS' website. *See* http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/ODF_9-29-09_Transcript.pdf/$FIle/ODF_9-29-09_Transcript.pdf?Open&cat=Suppliers.

CMS also established a public website, http://www.dmecompetitivebid.com/, where Medicare suppliers interested in participating in the DMEPOS competitive bidding program could learn more about the bidding process and the DMEPOS program in general. Among other information, this website explains precisely how the Secretary will evaluate suppliers' financial viability. In a section of the website titled "Financial Measures for the Medicare DMEPOS Competitive Bidding Program," the Secretary specified and defined the ten financial ratios she will employ in making financial evaluations:

The following financial ratios will be used for the Round 1 Rebid:

[12] *See* http://www.cms.gov/DMEPOSCompetitiveBid/PAOCMI/list.asp#TopOfPage.

- Current ratio = current assets/current liabilities
- Collection period = (accounts receivable/sales) x 360
- Accounts payable to sales = accounts payable/net sales
- Quick ratio = (cash + accounts receivable)/current liabilities
- Current liabilities to net worth = current liabilities/net worth
- Return on sales = net income/annual net sales
- Sales to inventory = annual net sales/inventory
- Working capital = current assets – current liabilities
- Quality of earnings = cash flow from operations/(net income + depreciation)
- Operating cash flow to sales = cash flow from operations/(revenue – adjustment to revenue)

The website concludes by stating that "[t]hese ratios and the credit report and score are used to determine bidder compliance with financial standards."[13] This information was initially published in May 2007, and has been publicly available at this link continuously since September 2009.

On October 21, 2009, CMS opened the bidding window for DEMPOS Round One re-bidding. The window to submit bids closed 60 days later, on December 21, 2009. To date, CMS has not completed the contract award process. *Accord* Compl., ¶ 22 ("At this time, no DMEPOS supplier contracts have been awarded by Defendants under the DME re-bid provisions of MIPPA."). Round One rebid contracts and prices are scheduled to go into effect on January 1, 2011.

[13] *See* http://www.dmecompetitivebid.com/palmetto/CBIC.nsf/DocsCat/852573EE00644C008525763B0073EAB3

FACTUAL BACKGROUND

Plaintiff Texas Alliance for Home Care Services ("TACHS") is a corporation whose purpose is to advocate for the Texas durable medical equipment industry. It claims to represent an unspecified number of DME suppliers who have submitted bids in conjunction with the Round One DMEPOS re-bidding process. Compl., ¶ 8. Plaintiff Dallas Oxygen Corporation ("DOC") is a supplier of durable medical equipment and a member of TACHS. DOC, which claims to qualify as a small business provider under applicable CMS regulations, has applied to be a DMEPOS Medicare supplier. *Id.* at ¶ 9.

Plaintiffs' Complaint challenges the manner in which the Secretary has implemented a subsection of the Part B supplementary medical insurance program[14], specifically, Section 302 of the MMA. *See* Compl., ¶ 12, *citing* 42 U.S.C. § 1395w-3 (directing the Secretary to establish a competitive bidding program by which suppliers compete for contracts to supply DMEPOS to Medicare beneficiaries in designated areas). Specifically, Plaintiffs allege that Defendants "have not specified financial standards, even internally and without public notice and comment, and are making decisions regarding the financial soundness of prospective DME suppliers on an *ad hoc* basis without the applications of specified financial standards." Compl., ¶ 1. According to Plaintiffs, this failure violates a scattershot of federal laws, including various provisions of the Medicare Act[15], the Administrative Procedure Act[16], and the Freedom of Information Act.[17]

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[14] Medicare Part B covers health care services such as physician visits, outpatient diagnostic tests, and durable medical equipment. *See* 42 U.S.C. § 1395k(a)(1).

[15] 42 U.S.C. § 1395w-3(b)(2)(A)(ii); 42 U.S.C. § 1395hh(b).
[16] 5 U.S.C. § 553(b)-(c); 5 U.S.C. § 701.
[17] 5 U.S.C. § 552(a)(1)(D); 5 U.S.C. § 552(a)(4)(B).

Plaintiffs' "procedural injury" challenge is extremely narrow: they do not contest the Secretary's authority to establish financial standards, nor do they allege that the Secretary lacked the authority to request from potential suppliers financial documentation in order to determine whether a supplier meets the Secretary's financial standards. *Cf.* Compl., ¶ 18 (conceding that Secretary has identified "covered documents" suppliers must submit in connection with DME bid).[18] Rather, they argue that the Secretary has unlawfully failed to "specify" financial standards the Secretary will use in her evaluation of 'covered documents.'" *Id.*; *accord* Compl., ¶ 28 ("Rather than specifying financial standards, Defendants have only required submission of certain financial documents, and have not specified what financial standards they will use to evaluate such documents."). In other words, Plaintiffs argue that the Secretary has improperly failed to inform suppliers how their bids will be evaluated.

STANDARD OF REVIEW

Defendants first seek dismissal of Plaintiffs' Complaint on the grounds that the Court lacks subject matter jurisdiction over it. "Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." *Steel Co. v. Citizens for a Better Env't.*, 523 U.S. 83, 94 (1998) (internal quotations and citation omitted). Where, as here, subject matter jurisdiction is challenged, "a court may look beyond the pleadings to resolve disputed jurisdictional facts when considering a

[18] Plaintiffs correctly do not allege that the Secretary has failed to define what financial documents are "covered documents" for purposes of DMEPOS competitive bidding. *See* 42 C.F.R. § 414.402 (defining "covered documents"); 42 C.F.R. § 414.414(d)(1) ("General rule. Each supplier must submit along with its bid the applicable covered documents (as defined in

motion to dismiss under Fed. R. Civ. P. 12(b)(1)." *Tootle v. Secretary of Navy*, 446 F.3d 167, 174 (D.C. Cir. 2006). A plaintiff bears the burden of demonstrating that his case meets the requirements of subject matter jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Courts should "presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991) (internal quotation marks and citations omitted).

Defendants also seek dismissal of Plaintiffs' Complaint because it fails to state a claim upon which relief can be granted. In order to survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). A complaint made up of "labels and conclusions" does not satisfy this standard because "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 1965.

ARGUMENT

I. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS BECAUSE CONGRESS HAS PRECLUDED JUDICIAL REVIEW OF DEFENDANTS' IMPLEMENTATION OF THE COMPETITIVE BIDDING PROGRAM

By establishing and implementing the DMEPOS competitive bidding program, the Secretary is acting pursuant to the explicit directive from Congress that she "shall establish and implement" competitive bidding programs "throughout the United States for contract award purposes" to furnish DMEPOS to Medicare beneficiaries. 42 U.S.C. § 1395w-3(a)(1)(A). In

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§ 414.402) specified in the request for bids.").

furtherance of this objective, Congress explicitly barred judicial review of the key aspects involved in establishing and implementing the program. The MMA states in pertinent part that:

> [t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of --
> (A) the establishment of payment amounts under paragraph (5);
> (B) the awarding of contracts under this section;
> (C) the designation of competitive acquisition areas under subsection (a)(1)(A) of this section;
> (D) the phased-in implementation under subsection (a)(1)(B) of this section;
> (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section; or
> (F) the bidding structure and number of contractors selected under this section.

Id. at § 1395w-3(b)(11).

Although Plaintiffs bring this lawsuit under the guise of a challenge to the adequacy of the Secretary's APA notice and comment rulemaking proceeding, it is in reality an attack on the substance of the Secretary's financial standards. There can be no question that Plaintiffs, like every other interested party, had ample opportunity to voice their opinions to CMS about the design and implementation of DMEPOS competitive bidding, including the Secretary's financial evaluation process, during notice and comment rulemaking proceedings. *See supra*, at 8-11. Evidently dissatisfied with the substantive outcome of that rulemaking proceeding, Plaintiffs allege that CMS' regulations are deficient because they do not include (i) the precise formula by which the Secretary will combine certain publicly-specified financial ratios to arrive at a financial viability score; or (ii) the score threshold below which a supplier would not be eligible to participate in the DMEPOS competitive bidding program.[19] Accordingly, subsections (B) and (F)

[19] In evaluating suppliers, the Secretary also applies a second threshold not at issue here. This

above preclude Plaintiffs' challenge. As explained below, the absence of subject matter jurisdiction here is consistent with other instances in which Congress has foreclosed judicial review, both in the Medicare context generally and in the competitive bidding context in particular.

Although there is generally a presumption of review of agency action, that presumption "may be overcome by, *inter alia*, 'specific language or specific legislative history that is a reliable indicator of congressional intent,' or a specific congressional intent to preclude judicial review that is 'fairly discernible' in the detail of the legislative scheme." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 673 (1986) (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349-50 (1984)); *see also Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (rejecting presumption of reviewability where Congress's intent to preclude judicial review is "clear and convincing" from the statutory text); *Am. Soc'y of Cataract and Refractive Surgery v. Thompson*, 279 F.3d 447, 452-53 (7th Cir. 2002) (same). The statute could not be more plain: There "shall be no administrative or judicial review" under 42 U.S.C. § 1395ff "or otherwise," 42 U.S.C. § 1395w-3(b)(11), of the "awarding of contracts," *id.* § 1395w-3(b)(11)(B), just as there shall be no administrative or judicial review of the "bidding structure and number of contractors selected," id. § 1395w-3(b)(11)(F), nor of various other determinations. Indeed, courts in this jurisdiction

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second relates to a supplier's capacity. Unlike the financial evaluation threshold, the capacity threshold is never dispositive of a supplier's eligibility to participate in the competitive bidding program. Suppliers who fall below the Secretary's capacity threshold are not disqualified from the program; rather, this threshold is used only to guide the Secretary's determination of how many additional suppliers are needed to ensure that beneficiary demand can be met. *See generally* 72 Fed. Reg. at 18,039; http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/Fact_Sheet_Capacity_and_Expansion_Plan.pdf/$FIle/Fact_Sheet_Capacity_and_Expansion_Plan.pdf (fact sheet explaining how

and elsewhere have previously determined that the MMA's jurisdiction-stripping provision bars challenges to the Secretary's design and implementation of the DMEPOS competitive bidding program. *See, e.g.*, *Carolina Med. Sales v. Leavitt*, 1:07cv1298 (D.D.C.) (Dkt. #30) (June 19, 2008) (Mem. Op.); *All Florida Network Corp. v. U.S.*, 82 Fed. Cl. 468, 473 (Fed. Cl. 2008).[20]

The plaintiffs in *Carolina Medical Sales* argued that the Secretary exceeded his statutory authority by distinguishing between mail-order and storefront providers of diabetic supplies pursuant to the very same DME regulations Plaintiffs challenge here. Because the Secretary had implemented the competitive bidding program based on a distinction the MMA does not countenance, plaintiffs there argued, the statutory provision foreclosing judicial review did not bar plaintiffs' claim. As relevant here, the plaintiffs there also argued that the Secretary had failed to give the requisite notice of his intent to treat mail-order and storefront providers differently, thereby unlawfully denying plaintiffs the opportunity to be heard on that issue. The Court rejected all of these challenges, correctly recognizing that Plaintiffs' challenge was an impermissible attack on the Secretary's substantive design and implementation of DMEPOS competitive bidding. Noting the "broad, general" language Congress used in § 1395w-3(b)(11), the Court concluded that "[t]he scope of the other areas of preclusion indicate a scheme to insulate the entire program from review." Mem. Op. at 13.

No different result can or should obtain here. Plaintiffs here allege that CMS regulations

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CMS evaluates supplier expansion plans).

[20] This is true even as to assertions of procedural injury. Like the Plaintiffs here, the plaintiffs in *Carolina Medical Sales* also alleged "procedural injury," claiming that the Secretary had unlawfully failed to follow required notice and comment procedures and failed to provide an adequate explanation for the design of the DMEPOS competitive bidding program. *Compare Carolina Medical Sales v. Leavitt*, 1:07cv1298 (D.D.C.) (Dkt. #1 at ¶¶ 7, 32-39) (Complaint);

unlawfully failed to include (i) the precise formula by which she will combine certain publicly-specified financial ratios to arrive at a financial viability "score"; or (ii) the score threshold below which a supplier would not be eligible to participate in the DMEPOS competitive bidding program. However, Congress has expressly precluded administrative or judicial review of, *inter alia*, any challenge to "the awarding of contracts" or "the bidding structure" related to competitive bidding under the MMA. 42 U.S.C. § 1395w-3(b)(11)(B), (F). The Secretary's promulgation and application of financial standards is inextricably intertwined with "the awarding of contracts," just as the Secretary's requirement that suppliers must provide certain financial documentation as a prerequisite for consideration is part of "the bidding structure." Consequently, § 1395w-3(b)(11)(B) and (F), taken together, operate to bar Plaintiffs' challenge. *See All Florida Network Corp.*, 82 Fed. Cl. at 473 (holding that "eligibility determinations are part of the overall award scheme" for DMEPOS competitive bidding, and explicitly rejecting "distinction between 'eligibility determinations' and 'the awarding of contracts' in this competitive acquisition program").

That Plaintiffs have characterized Defendants' conduct as *ultra vires* does not alter the operability of the MMA's statutory provision precluding judicial review. *See* Compl., ¶ 41 (alleging that Secretary has "failed to specify financial standards that DME suppliers must meet" "as mandated by the MMA"). To begin with, Plaintiffs' *ultra* vires allegation "is a conclusory legal assertion that this court is not required to accept." *Benson v. Arizona State Bd. of Dental Examiners*, 673 F.2d 272, 275-76 (9th Cir. 1982); *accord Mountain States Legal Foundation v. Bush*, 306 F.3d 1132, 1137 (D.C. Cir. 2002) (rejecting "bald assertion" that defendant exceeded

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with Compl., ¶¶ 26-34, 41 (procedural injury allegations).

authority, and dismissing complaint). More fundamentally, courts have consistently given effect to "no review" clauses in other Medicare Part B provisions notwithstanding assertions of illegality. *See Palisades Gen. Hosp. v. Leavitt*, 426 F.3d 400, 403-05 (D.C. Cir. 2005); *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004); *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 452 (7th Cir. 2002); *Painter v. Shalala*, 97 F.3d 1351, 1356-57 (10th Cir. 1996); *Skagit County Pub. Hosp. v. Shalala*, 80 F.3d 379, 385 (9th Cir. 1996); *Santa Cruz County v. Leavitt*, No. 07-02888, 2008 WL 686831 at *3-6 (N.D. Cal. Mar. 11, 2008); *AMA v. Thompson*, 2001 WL 619510 at *3-7 (N.D. Ill. May 29, 2001); *Am. Soc'y of Anesthesiologists v. Shalala*, 90 F. Supp. 2d 973, 974-76 (N.D. Ill. 2000); *Am. Soc'y of Dermatology v. Shalala*, 962 F. Supp. 141, 146 (D.D.C. 1996), aff'd, 116 F.3d 941 (D.C. Cir. 1997).

The issue in *Amgen*, for instance, was whether courts had subject matter jurisdiction to entertain a challenge to an equitable adjustment to the Medicare Part B rate at which the federal government pays hospitals for using a product manufactured by the plaintiff. The plaintiff, Amgen, contended that the Secretary exceeded his statutory authority by making such adjustments to reimbursement rates. In support of this argument, Amgen noted that a provision of the statute set forth the means for calculating pass-through payments, provided "that the Secretary 'shall' make pass-through payments, . . . and describe[d] the manner of their calculation." *Amgen*, 357 F.3d at 114. Given the mandatory nature of this language, Amgen argued that the Secretary lacked the discretion to make the challenged equitable adjustments. *Id.* at 114-15.

The *Amgen* Court rejected this argument. Observing that the statute expressly permitted the Secretary to make "other adjustments" to hospital payments beyond those already allowed by

the statute, "as determined to be necessary to ensure equitable payments," the Court concluded that "[i]t is difficult to see how a decision by the Secretary to adjust pass-through payments for a specific treatment downward, based on the Secretary's conclusion that the treatment is too costly relative to its benefits, would not lie at the heart of such authority." *Id.* at 114 (internal quotations omitted). Because the challenged adjustments were within the Secretary's discretion, and because Congress precluded judicial review of the Secretary's exercise of that discretion, the Court held that Amgen's challenge was foreclosed. *Id.* at 114, 118.

The plaintiffs in *American Society of Cataract & Refractive Surgery* sought to challenge a component of the formula by which physicians are reimbursed for their provision of services covered by Medicare. The District Court there dismissed plaintiffs' claims, holding that they were expressly precluded by 42 U.S.C. § 1395w-4(i)(1), which states that "there shall be no administrative or judicial review under section 1395ff of this title or otherwise of — . . . (B) the determination of relative values and relative value units under subsection (c) of this section. . . ." *American Society*, 279 F.3d at 452. On appeal, plaintiffs argued that their claims were not barred, claiming that they were not challenging the formula components, but rather mounting a "systemic challenge to the Secretary's interpretation of Congress's nondiscretionary instructions for establishing components of the physician fee schedule." *Id.* The Court rejected plaintiffs' attempt to end run the statutory provision foreclosing judicial review, noting that "[i]t would be difficult for Congress to have written paragraph (B) in clearer terms prohibiting such a challenge." *Id.* at 453. As this voluminous case law makes clear, Plaintiffs' attack on the Secretary's financial standards process is but the latest in a long line of impermissible challenges that courts have rightly declined to entertain.

II. BECAUSE PLAINTIFFS HAVE SUFFERED NO ACTUAL INJURY CAUSED BY DEFENDANTS, THEY LACK ARTICLE III STANDING

Quite apart from the fact that Plaintiffs' claims are foreclosed by statute, this Court also lacks jurisdiction because Plaintiffs' alleged injuries are insufficient to confer Article III standing. "Article III of the Constitution confines the federal courts to adjudicating actual 'cases' and 'controversies.'" *Allen v. Wright*, 468 U.S. 737, 750 (1984). This requirement is "founded in concern about the proper — and properly limited — role of the courts in a democratic society," *Warth v. Seldin*, 422 U.S. 490, 498 (1975), and "is built on a single basic idea — the idea of separation of powers." *Allen*, 468 U.S. at 752. Without this requirement and related limitations, "the courts would be called upon to decide abstract questions of wide public significance even though other governmental institutions may be more competent to address the questions and even though judicial intervention may be unnecessary to protect individual rights." *Warth*, 422 U.S. at 500.

As the party seeking federal jurisdiction, Plaintiffs bear the burden "clearly to allege facts demonstrating that" subject matter jurisdiction is proper. *Spencer v. Kemna*, 523 U.S. 1, 11 (1998). To meet the "irreducible constitutional minimum of standing," a plaintiff must demonstrate that he has suffered an "injury in fact" that is "fairly traceable" to the conduct of the defendant and which is "redress[able] by a favorable decision" of the court. *Lujan v. Defenders of Wildlife*, 504 U.S. at 560-61. In this case, the injuries Plaintiffs allege are purely procedural in nature; they do not allege that they have suffered any actual or imminent injury as a result of the DMEPOS competitive bidding process. *Accord* Compl., ¶ 22 ("At this time, no DMEPOS supplier contracts have been awarded by Defendants under the DME re-bid provisions of

MIPPA.").

With respect to "procedural injury" allegations, standing is lacking unless Plaintiffs can demonstrate that the procedural requirement at issue was "'designed to protect some threatened concrete interest' of the litigant." *County of Delaware, Pennsylvania v. Dep't. of Transp.*, 554 F.3d 143, 147 (D.C. Cir. 2009) (quoting *Lujan*, 504 U.S. at 573, n.8). In order to establish causation sufficient for standing purposes, "it is not enough to show that the agency omitted some procedural requirement"; Plaintiffs "must also show that it is substantially probable that the procedural breach will cause the essential injury to [Plaintiffs'] own interest." *County of Delaware*, 554 F.3d at 147 (internal quotations omitted). Put differently, Plaintiffs "must show that the government act performed without the procedure in question will cause a distinct risk to a particularized interest of the plaintiff[s]." *Center for Law and Educ. v. Dep't. of Educ.*, 396 F.3d 1152, 1167 (D.C. Cir. 2005).

Plaintiffs do not and cannot meet their burden to show that subject matter jurisdiction is proper. Plaintiffs concede, as they must, that the Secretary has identified what financial documents would-be suppliers must submit to be considered for the DMEPOS competitive bidding program. Compl., ¶¶ 16, 18-19 (discussing "applicable financial documentation" and "covered documents" and citing regulations). Plaintiffs nonetheless complain that they "had to formulate their bids while being in the dark about the financial standards" that the Secretary would apply, owing to the Secretary's purported failure to abide by notice and comment rulemaking procedures. Had they known what financial standards the Secretary would apply in evaluating the documentation suppliers provided, Plaintiffs speculate that this knowledge "would

affect what bids they would be willing to submit." *Id.* at ¶ 19.[21]

For Article III standing purposes, Plaintiffs' professed ignorance regarding how the Secretary would evaluate financial documentation falls woefully short of establishing any concrete injury. Again, there is no dispute that the Secretary has publicly specified what financial documents will be relevant to her supplier evaluations, as well as the precise financial information within those documents that the Secretary deems relevant. The Secretary will make her financial viability determination based on these objective documents, and the information contained therein. To the extent any supplier fails to meet the Secretary's financial viability standards, that denial will not have anything to do with the specificity of the Secretary's standards. Rather, it will be because of the substance of that supplier's financial documentation: in every case, the documentation bears out that a supplier is viable under these standards or that it is not.

Plaintiffs have either submitted the requisite financial documentation or they have not. To the extent that Plaintiffs have not provided the Secretary with this documentation, their injury (namely, their eventual, inevitable non-selection to be a participating DMEPOS contract supplier) would be a self-inflicted wound not attributable to the Secretary.[22] *Nat'l. Family Planning and Reproductive Health Ass'n, Inc. v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006). ("We have

[21] Plaintiffs' allegation that the Secretary's alleged procedural failures "cause a distinct risk of harm to Plaintiffs' concrete Medicare DME supplier interests," Compl., ¶ 7, "is a conclusory legal assertion that the Court need not accept as true in resolving a motion to dismiss." *King & King, Chartered v. Harbert Intern., Inc.*, 436 F.Supp.2d 3, 16 n.24 (D.D.C. 2006). At no point do Plaintiffs explain what, precisely, this "distinct risk" is, or how it threatens their interests.
[22] As Plaintiffs correctly note, however, "no DMEPOS supplier contracts have been awarded by Defendants under the DME re-bid provisions of MIPPA." Compl., ¶ 22.

consistently held that self-inflicted harm doesn't satisfy the basic requirements for standing. Such harm does not amount to an 'injury' cognizable under Article III.") (internal citations omitted). Furthermore, such an injury (even if it were legally cognizable, which it would not be), would not be redressed by the injunctive relief Plaintiffs seek. Plaintiffs ask this Court to order the Secretary to specify with greater precision the standards by which she makes financial evaluations of DEMPOS applicants. Compl., Prayer for Relief, ¶ 4. But if Plaintiffs have failed to submit the financial documentation — specified pursuant to notice and comment rulemaking proceedings the adequacy of which Plaintiffs do not challenge — no procedural improvement could remedy their non-selection, and redressability therefore would be lacking. *See Nat'l. Family Planning*, 468 F.3d at 831 ("[E]ven if self-inflicted harm qualified as an injury it would not be fairly traceable to the defendant's challenged conduct."); *County of Delaware*, 554 F.3d at 149 (redressability absent unless "the relief sought . . . will likely alleviate the *particularized* injury alleged") (emphasis added).

Alternatively, if Plaintiffs have submitted the requisite financial documentation as they claim, *see* Compl., ¶ 19, the Secretary will either accept or reject their bids to participate in the DMEPOS competitive bidding program based on, *inter alia*, her analysis of this documentation. No application will be turned down because of because of the Secretary's failure to articulate financial standards with a greater degree of specificity. And more specificity about the Secretary's evaluation process plainly cannot change a supplier's financial condition. Either way, Plaintiffs' knowledge and understanding (or lack thereof) of how the Secretary would evaluate their financial submissions would be immaterial to the outcome of the bidding process. Even if the notice and comment procedures pertaining to financial standards were somehow deficient,

then, Plaintiffs cannot show that it is "substantially probable" that these alleged deficiencies would cause Plaintiffs *any* injury, let alone "the essential injury to [Plaintiffs'] own interest." *County of Delaware*, 554 F.3d at 147 (internal quotations omitted).

In the final analysis, even Plaintiffs concede that the effect of the Secretary's alleged procedural failures is "uncertain[]." Compl., ¶ 7. What is certain, however, is that Plaintiffs do not and cannot show that the "procedural step" they allege to be defective (the absence in the regulation of a specific financial methodology and viability cutoff score) "was connected to the substantive result" (the eventual outcome of their DMEPOS bids). *County of Delaware*, 554 F.3d at 147. Accordingly, Plaintiffs' have failed to carry their burden to demonstrate that Article III jurisdiction is proper, and their Complaint must be dismissed.

III. PLAINTIFFS' CHALLENGE FAILS TO STATE A CLAIM ON WHICH RELIEF CAN BE GRANTED

Even if Plaintiffs had carried their burden to demonstrate that subject matter jurisdiction is proper (which they have not), they have nonetheless failed to state a cognizable claim on which relief could be granted. The Secretary has properly specified what "covered financial documents" a putative supplier must provide to be considered under the DMEPOS competitive bidding program. *See* 42 C.F.R. § 414.414(d)(1). And notwithstanding Plaintiffs' assertion that the Secretary "ha[s] declined to provide" the financial standards by which she will make eligibility determinations, the Secretary has — since 2007 — publicly specified the precise financial ratios derived from these covered financial documents that she will employ in making financial soundness determinations. *See supra*, 10, 14-15. Plaintiff's assertion that they "had to

formulate their bids while being in the dark about the financial standards" is thus belied by judicially noticeable facts. Compl., ¶ 19.

To the extent that Plaintiffs are arguing that the Secretary's regulation regarding financial standards is invalid because it fails to specify the precise methodology the Secretary will employ in making financial soundness determinations, or the financial viability threshold, the short answer to this is that no such specificity is required. There is no basis for imposing a requirement that the Secretary specify financial standards in that particular manner rather than — as she did here — provide the general rubric within which financial soundness would be evaluated. Where, as here, "Congress has not specified the level of specificity expected of the agency," "the agency is entitled to broad deference in picking the suitable level." *Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 217 (D.C. Cir. 2007).[23] "[J]udicial deference is at its highest in reviewing an agency's choice among competing policy considerations, including the choice here of the level of generality at which it will promulgate norms implementing a legislative mandate." *Metro. Washington Airports Auth. Prof'l Fire Fighters Ass'n v. United States*, 959 F.2d 297, 300 (D.C. Cir. 1992) (citation omitted). Consequently, the Secretary's regulation regarding financial standards must be upheld as long as this Court concludes that the level of detail the Secretary has required is reasonable. *State of New Mexico v. EPA*, 114 F.3d 290, 293 (D.C. Cir. 1997).

Consistent with these principles, the D.C. Circuit has repeatedly rebuffed challenges attacking agency regulations as insufficiently specific. *See, e.g.*, *Cement Kiln Recycling*

[23] *See also Shays v. Federal Election Com'n*, 528 F.3d 914, 930 (D.C. Cir. 2008) (same) (citing *Cement Kiln Recycling*); *Animal Legal Defense Fund, Inc. v. Glickman*, 204 F.3d 229, 235 (D.C. Cir. 2000) (Courts must "accord agencies broad deference in choosing the level of generality at which to articulate rules.").

Coalition v. EPA, 493 F.3d 207, 223 (D.C. Cir. 2007) (rejecting argument that agency must quantify precise risk level below which permit approval would be unconditional); *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 191-92 (D.C. Cir. 1993) (statutory mandate to set "minimum staffing levels" did not require specification of precise numbers of personnel); *State of New Mexico v. EPA*, 114 F.3d 290, 293 (D.C. Cir. 1997) (statutory mandate to set "criteria" regarding radioactive waste disposal "says nothing to suggest that the criteria must be detailed or quantitative.").

In *Cement Kiln Recycling Coalition v. EPA*, for example, a trade association challenged an EPA regulation governing the permitting process for facilities that burn hazardous waste as fuel. Relevant here, the trade association argued that the EPA impermissibly failed to specify, in numerical terms, the precise risk threshold above which further risk analysis would be required, but below which a permit would be categorically approved. 493 F.3d at 223. The D.C. Circuit rejected this claim out of hand, observing that "there is nothing in the statutory language that compels such a numerical definition." *Id.* The Court refused to disturb the challenged regulation, holding that the Court "must uphold the challenged regulation so long as it establishes an identifiable standard governing the information that permitting authorities may request." A regulation cannot be set aside under these circumstances "only if it creates no standard at all, instead delegating the decision regarding what information is required of permit applicants to permitting authorities." *Id.* at 220.

The Secretary's financial standards easily meet this "identifiable standard" threshold. Like the statute at issue in *Cement Kiln Recycling Coalition*, there is nothing in the MMA or MIPPA that compels the Secretary to articulate financial standards with the numerical precision

Plaintiffs mistakenly argue she must. Not can there be any suggestion that the Secretary has "delegated" to anyone what financial information suppliers must provide. To the contrary, it is undisputed that the Secretary has herself detailed, pursuant to notice and comment procedures and in the request for bid, the financial information a would-be supplier "is required" to produce. *See* Compl., ¶¶ 18, 29; 42 C.F.R. § 414.414(d)(1). Accordingly, Plaintiffs' assertion that the Secretary's financial standards are unlawfully devoid of specificity fails to state a valid cause of action.[24]

The Secretary's determination not to publish the precise methodology (as distinguished from the publicly available financial ratios) by which she will make financial viability determinations is sensible for at least two reasons. First, the Secretary must be free to modify the competitive bidding program to account for the teachings of experience. Based on the DMEPOS initial rounds, the Secretary has required potential suppliers to provide certain financial documentation which in the aggregate contains financial information she believes are predictive of overall financial soundness. *See* 71 Fed. Reg. at 25,675 ("We found that in the demonstration, general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity, and line of credit, net worth, and solvency, were important considerations for evaluating financial stability."). However, the nationwide rollout of the DMEPOS competitive bidding program has not yet even begun. Once it does, the Secretary

[24] Plaintiffs allege that Defendants "have not specified financial standards [] even internally . . . and are making decisions regarding the financial soundness of prospective DME suppliers on an ad hoc basis." Compl., ¶ 1. As explained previously, *see supra* at 6-15, this assertion is conclusively belied by judicially noticeable facts. Furthermore, Plaintiffs have pled no facts in support of this bald assertion, let alone facts that would warrant overturning the "strong presumption of agency regularity." *Louisiana Ass'n of Indep. Producers v. FERC*, 958 F.2d

may refine what documents she believes are needed to provide the most accurate and comprehensive financial picture. Recognizing that there was a balance between obtaining the complete financial information on the one hand and the burden on suppliers to gather that information on the other, the Secretary expressly contemplated refining her methodology so as to find the best balance between these two competing goals. *See id.* ("As we develop our methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process."); 72 Fed. Reg. at 18,037 ("We will generally require that suppliers submit the same types of [financial] information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a supplier is financially stable enough to participate in the Medicare DMEPOS Competitive Bidding Program."). Requiring the Secretary to publish the precise methodology by which she will evaluate the inputs gleaned from supplier documentation and then faithfully adhere to that methodology (at least absent further rounds of notice and comment rulemaking) would wrongly deprive the Secretary of the flexibility the statute makes clear that she has to tailor the competitive bidding process on an ongoing basis. S*ee New Mexico*, 114 F.3d at 293 (flexible standard "seems quite reasonable" "[i]n light of the complexity and uncertainty of planning for contingencies" in the future).

Second, the Secretary's decision not to publish her specific methodology or financial viability cutoff is consistent with the MMA's purpose of "combat[ing] waste, fraud, and abuse,"

1101, 1111 (D.C. Cir. 1992).

in the Medicare procurement and reimbursement process. H.R. Rep. No. 108-178, pt. II at Title III, § 302. Faced with the potential exclusion from participation as a Medicare-reimbursement eligible provider — with the attendant financial hardship that might entail — suppliers that were so inclined would be able to determine with numerical precision what accounting manipulations would be needed to give the false impression of financial viability for competitive bidding purposes. If the Secretary were required to publish the precise formula spelling out in detail what weight she gives to particular financial data, would-be suppliers would have a roadmap telling them exactly what they would need to do to qualify, thus making the Secretary's job to select winning bidders that much more difficult. Armed with the knowledge of CMS' minimum financial qualification standards, firms in danger of falling below CMS' cutoff could conceivably manipulate their financial information until they edged just over the threshold. Such fraud would be all the more difficult to detect if Plaintiffs knew precisely what information the Secretary deemed most important. In the absence of knowing exactly what information the Secretary might deem most important, a supplier willing to manipulate its financial data would need to alter a considerable amount of information in the hopes of shading their financial data to attempt to meet CMS' standards.[25] But if the Secretary's methodology and eligibility threshold were required to be public, there would be no need for accounting fraud on a wide scale. A firm could target its fraud in a much more concentrated and effective way — a tweak here and a nudge there would be all a firm conceivably need do. Indeed, with the Secretary's methodology and cutoff score in hand, a firm could manipulate its data repeatedly in advance of submitting its bid,

[25] It goes without saying that Defendants are not in any way suggesting that Plaintiffs themselves have done anything untoward with respect to the DMEPOS bidding process.

crafting the illusion of viability through trial and error. Knowing all along what mark it needed to hit, a firm could thus "backtest" various permutations of its financial data until it arrived at the most compelling and subtle presentation of its fraud. It would be both counterproductive and ironic if, in a program designed to remedy waste, fraud, and abuse present in the pre-competitive bidding era, the Secretary were legally bound to make public the very information most helpful to those who might be inclined to commit Medicare fraud or otherwise abuse the procurement process for their own financial gain. *See Animal Legal Defense Fund*, 204 F.3d at 235 ("[B]ecause the Secretary was reasonably concerned that more precise specification might cause harm, it was entirely reasonable under the statute for him to choose a relatively flexible standard."). Compelling the Secretary to release the information Plaintiffs seek therefore would be precisely antithetical to MIPPA's stated objectives of rooting out waste, fraud, and abuse from the Medicare system. For these reasons, the Secretary's design and implementation of the financial evaluation process was reasonable, and Plaintiffs' challenge therefore fails as a matter of law.

The nature and scope of Congress' changes to the MMA in MIPPA further confirm that Congress has ratified the Secretary's design and implementation of the financial evaluation process of the DMEPOS competitive bidding program. The Supreme Court has instructed that "the construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong, especially when Congress has refused to alter the administrative construction." *CBS, Inc. v. FCC.*, 453 U.S. 367, 382 (1981) (citations omitted). "Such deference is particularly appropriate where, as here, an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any

misperception of its statutory objectives."). *Id.* (internal quotations omitted). Plaintiffs have adduced nothing to show that the level of specificity of the challenged regulation is "wrong", let alone anything that "compel[s]" such a conclusion. "Public controversy" was inarguably present here: the DME supplier community voiced its full-throated opposition to competitive bidding, furiously lobbying Congress to scrap the Secretary's proposal. *See* H.R. Hearing at 6 (impetus for hearing was that members of Congress "[were] hearing from the suppliers in their communities"); *id.* at 29 (deriding DMEPOS competitive bidding program as a "train wreck" and as "poorly conceived" and "fundamentally flawed") (statement of Thomas Ryan, American Association for Homecare). Congress acted promptly, although evidently not to Plaintiffs' satisfaction.

In Section 154 of MIPPA, titled "Delay in and Reform of DMEPOS Competitive Bidding," Congress placed a two-year moratorium on DMEPOS competitive bidding, delaying Rounds One and Two from 2007 and 2009 to 2009 and 2011, respectively. *See* Pub. L. No. 110-275, § 154, 122 Stat. 2494 (Jul. 15, 2008) (amending 42 U.S.C. § 1395w-3(a)(1)(B)(i)(II)-(III)). As to the substance and design of the DMEPOS program the Secretary had designed, Congress did not disturb the Secretary's financial evaluation process, save changes not relevant here. *Accord* Compl., ¶ 17 (agreeing that Congress' amendments to MMA are "not relevant" here). Congress' failure to amend the financial evaluation process is significant. If, as Plaintiffs claim, the Secretary's financial evaluation process were insufficiently transparent, or otherwise operated in a manner Congress deemed improper, it stands to reason that Congress would have corrected such ostensible flaws when it amended the MMA via MIPPA. That Congress did not correct the supposed "defects" that Plaintiffs ask this Court to declare unlawful suggests that, in Congress'

view, the Secretary's financial evaluation process was not defective in the first place.

As discussed in detail previously, *see supra* at 6-15, the Secretary's design and implementation of the DMEPOS competitive bidding process — including the financial standards evaluation aspect of this process — could hardly have been more collaborative or transparent. In light of this openness and transparency, it is unsurprising that Congress was unpersuaded by the arguments Plaintiffs again advance here.

Congress' failure to instruct the Secretary to publish the precise threshold at which the Secretary deems a supplier minimally financially viable cannot be because Congress was unaware of how the Secretary had implemented the financial evaluation process. As noted previously, Acting CMS Administrator Weems expressly told Congress that the Secretary had *not* made this threshold public just weeks before Congress reformed the MMA. H.R. Transcript at 25 (financial qualification threshold was "the one piece" of the financial evaluation process that was not publicly available). Nor can Congress' inaction be attributed to the exigencies of time. The two-year delay MIPPA provided gave Congress more than ample opportunity to carefully consider any and all grievances against the DMEPOS program as designed by the Secretary. Having presumably examined the Secretary's financial evaluation process and found no fault material to this case, this Court must decline Plaintiffs' invitation to order changes to the competitive bidding program Congress itself did not see fit to make. *Gross v. FBL Financial Services, Inc.*, 129 S.Ct. 2343, 2349 (2009) ("When Congress amends one statutory provision but not another, it is presumed to have acted intentionally.").[26] For each of the foregoing reasons,

[26] *See also Lamie v. U.S. Trustee*, 540 U.S. 526, 541 (U.S. 2004) ("This alert, followed by the Legislature's nonresponse, should support a presumption of legislative awareness and

Plaintiffs' Complaint fails to state a valid cause of action, and dismissal is therefore appropriate.

CONCLUSION

For the reasons stated above, Defendants' Motion to Dismiss should be granted, and Plaintiffs' Complaint should be dismissed.

Dated: July 23, 2010

Washington, D.C.

Respectfully submitted,

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intention."); *Progressive West Ins. Co. v. Preciado*, 479 F.3d 1014, 1018 (9th Cir. 2007) ("Faced with statutory silence, we presume that Congress is aware of the legal context in which it is legislating.") (citations omitted).