UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEXAS ALLIANCE FOR HOME CARE SERVICES, *et al.*,	)	
Plaintiffs,	)	
v.	)	10-cv-747 (RCL)
KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

In 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) or "MMA," Congress directed the Department of Health and Human Services ("HHS") and the Center for Medicaid and Medicare Services ("CMS") to transition payment for Durable Medical Equipment ("DME")[1] under Medicare Part B from a fee schedule to a competitive bidding process by 2009. As part of this new law, Congress declared that CMS could not issue contracts to DME suppliers unless those entities met financial standards specified by the Secretary of HHS. The Secretary, along with an advisory group created by the MMA, held several public meetings on this new program—which included discussions on appropriate financial standards—and published a proposed rule in the *Federal Register* that, *inter alia*, described the purposes for collecting a supplier's financial information and gave examples of financial metrics that CMS would consider. In 2007, the Secretary

[1] Examples of DME include "iron lungs, oxygen tents, hospital beds, . . . wheelchairs, . . . blood-testing strips and blood glucose monitors . . . [and] seat-lift chair[s]." 42 U.S.C. § 1395x(n).

published a final rule outlining the competitive process (the "DME Bidding Program"). The final rule stated that bidders would need to submit certain financial documentation, and directed interested parties to a website for the Program describing ten financial metrics CMS would use to evaluate potential DME suppliers. Before the initial implementation of the DME Bidding Program, Congress amended the statute via the Medicare Improvements for Patients and Providers Act. Pub. L. No. 110-275, 122 Stat. 2494 (2008) ("MIPPA"). These changes pushed back the target dates for implementation, and the Secretary subsequently promulgated an interim final rule incorporating the statutory changes and proceeded with the revised DME Bidding Program. But before the results of the revised Program could be announced, plaintiffs—a DME supplier and an industry group[2]—filed suit challenging the Secretary's financial standards. The gravamen of plaintiffs' complaint is that the standards lack the specificity required by statute, leaving potential DME suppliers in the dark when bidding for contracts. The DME Bidding Program has not yet been implemented, however, and so plaintiffs' suit focuses on the procedures used by the Secretary in designing the Program. Specifically, plaintiffs allege that the generality with which the Secretary's rulemaking process discussed financial standards renders the notice-and-comment process required by both the MMA and the Administrative Procedure Act ("APA") insufficient, that the absence of any published formula for financial viability violates the Freedom of Information Act ("FOIA"), and that the lack of a defined method for determining a supplier's soundness implies that CMS is acting arbitrarily, and the defendants are acting *ultra vires*. Defendants now move to dismiss plaintiffs' complaint, arguing that judicial review of these questions are precluded by the plain text of the MMA, that plaintiffs lack standing, and that the complaint fails to state a claim upon which relief may be granted.

[2] Specifically, plaintiffs are Texas Alliance for Home Care Services, "a non-profit corporation . . . that represents the Texas durable medical equipment industry," and Dallas Oxygen Corporation, "an accredited and bonded Medicare DME provider and . . . member of [Texas Alliance]." Complaint ¶¶ 8–9, May 10, 2010 [1].

Plaintiffs oppose defendants' request, and have sought several times to amend their original complaint. For the reasons set forth below, the Court finds that it lacks subject-matter jurisdiction over this matter and that, in any event, the Secretary's rulemaking process was legally sufficient. The Court will therefore dismiss this action in its entirety.

II. BACKGROUND

A. Statutory and Regulatory Background

Medicare is an "insurance program" that "provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care." 42 U.S.C. § 1395c. Those eligible for the program include individuals over the age of 65, qualified individuals who have less than two years until they reach age-based eligibility, and certain other individuals afflicted with particular medical conditions. *Id*. Most drugs, medical equipment, and medical services are covered by Medicare, which pays for a significant proportion of the cost in accordance with fee schedules that are published and revised by HHS and CMS—a process that has traditionally applied to the purchase of DME for Medicare beneficiaries.

In the late 1990s Congress—in the wake of "[n]umerous studies conducted by the HHS Office and the Inspector General as well as GAO hav[ing] found the government-determined fee schedule for durable medical equipment (DME) too high for certain items," H.R. Rep. No. 108-178(II), at 192 (2003)—authorized the Secretary to undertake several demonstration projects implementing a competitive bidding process for setting DME prices. The basic structure of the process is straightforward: Rather than have the Secretary set prices directly, CMS invites all suppliers in a geographical area to submit bid prices at which they would be willing to furnish particular DME products. After receiving bids and removing those entities ineligible under accreditation, financial or other standards, CMS adds up the proposed market shares—starting

with the lowest bidder—until the entire market is covered, and awards exclusive contracts to those selected bidders at the median proposed price among the winners. A 1997 law "authorized the Secretary to conduct up to five demonstration projects to test competitive bidding as a way for Medicare to price and pay for" DME. H.R. Rep. No. 108-391, at 572 (2003).

Three demonstrations were ultimately conducted—two in Polk County, Florida and one in the fine city of San Antonio, Texas. *Id*. The consensus following these pilot programs was, and remains, that the introduction of competitive bidding into the DME market was a resounding success. As Congress would later observe: "The DME competitive bidding demonstration has been a success. The taxpayers and beneficiaries saved significantly and quality standards were higher under the demonstration." H.R. Rep. No. 108-178(II), at 192. And HHS concurred: "The demonstration led to lower Medicare fees for almost every item in almost every product category in each round of bidding. . . . resulting in a nearly 20 percent overall savings at each site." 71 F.R. 25654, 25657 (2006); *see also Hearing on Medicare's DMEPOS Competitive Bidding Program: Hearing before the Subcomm. On Health of the H. Comm. On Ways and Means*, 110th Cong. 82 (2008), at 33 (statement of Mr. Hoerger) ("2008 Hearing Tr.") (expert testimony that demonstrations "produced lower prices" while having "relatively little effect on beneficiary access, quality and product selection").

Satisfied with the demonstration results, Congress included in the MMA instructions for the Secretary to implement the DME Bidding Program nationwide. Codified at 42 U.S.C. § 1395w-3, the relevant statutory provision directs the Secretary to establish the DME Bidding Program, *id*. § 1395w-3(a), describes the conditions that must be met by suppliers before any contracts may be awarded, *id*. § 1395w-3(b)(2), establishes the terms that must be included in any contract, *id*. § 1395w-3(b)(3), and sets forth the process for payment. *Id*. § 1395w-3(b)(5).

Congress envisioned implementation of the DME Bidding Program over several phases, with "10 of the largest metropolitan statistical areas in 2007; 80 . . . in 2009; and remaining areas after 2009." H.R. Rep. No. 108-391, at 575.

The MMA sets forth conditions to be satisfied before CMS may award a contract under the DME Bidding Program, including that the supplier "meets applicable financial standards specified by the Secretary." 42 U.S.C. § 1395w-3(b)(2)(A)(1)(ii); *see also* H.R. Rep. No. 108-391, at 576 (explaining that CMS may not award contracts unless "entities meet financial standards specified by the Secretary, taking into account the needs of small providers"). To determine the appropriate financial standards, the MMA created a Program Advisory and Oversight Committee ("PAOC"), 42 U.S.C. § 1395w-3(c), to "provide advice to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services providers and beneficiaries, the establishment of quality standards, and other functions specified by the Secretary." H.R. Rep. No. 108-391, at 577; *see also* 42 U.S.C. § 1395w-3(c)(3)(A)(ii).

In 2004, the Secretary published notice in the *Federal Register* of public meetings hosted by PAOC on replacement of "the current DME payment methodology for certain items with a competitive acquisition process to improve the effectiveness of Medicare's methodology for setting DME payment amounts." 69 F.R. 52723, 52723 (2004). That notice explained that PAOC's role involved, *inter alia*, advising the Secretary on "financial standards for suppliers under the program." *Id.* The notice requested any written comments or questions, and announced that a summary of the meeting would be made publicly available. *Id.* After this and other public discussions were held, which included discussion on the "[f]inancial capabilities of bidding suppliers," the Secretary published a proposed rule in May 2006. 71 F.R. at 25658.

In the proposed rule, the Secretary explained that the purpose of evaluating financial standards is to assist CMS "in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts." *Id.* at 25675. The preamble further noted that CMS learned from the demonstrations that "general financial conditions, 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.* Thus, the Secretary indicated that the requests for bids "will identify the specific information" required of suppliers, and suggested that such information might include "a supplier's bank reference . . . credit history, insurance documentation, business capacity and line of credit." *Id.* In addition to the specific rules, the Secretary announced the creation of a public website, which would provide "access to all PAOC presentations, minutes, and updates for the" DME Bidding Program. *Id.* at 25658. The Secretary also set forth the role of financial standards in the Program, explaining that CMS would (1) look to all bidders to calculate the competitive bid range, then (2) eliminate those bidders that did not meet applicable financial standards, and finally (3) award contracts to the remaining bidders in sufficient number to provide for the entire market. *Id.* at 25677–78. Having set forth the purposes of the financial standards and the documentation involved, the Secretary "welcome[d] comments on the financial standards" and "the most appropriate documents that will support these standards." *Id.* at 25675.

After nearly a year passed, the Secretary promulgated a final rule establishing the DME Bidding Program. 72 F.R. 17992 (2007). In the preamble to that rule, the Secretary responded to a number of comments concerning financial standards and documentation. *See generally id.* at 18037–39. For example, in response to concerns about onerous documentation requirements, the

Secretary announced that CMS would require only submission of "certain schedules from . . . tax returns, a copy of the 10K filing report from the immediate 3 years prior . . . certain specified financial statement reports, such as cash flow statements, and a copy of [a] current credit report," *id*. at 18037, and explained that such information would allow CMS "to determine financial ratios, such as a supplier's debt-to-equity ratio, and credit worthiness, which will allow [it] to assess a supplier's financial viability." *Id*. Some commenters also focused on particular financial indicators that they believed should be included in the Program, such as the debt-to-equity ratio, the EBITDA-to-equity ratio, the quick ratio and a Dunn and Bradstreet accounts payable rating. *Id*. at 18037–38. In response to these comments, the Secretary stated that CMS "will use appropriate financial ratios," and listed examples such as "a supplier's debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company." *Id*. at 18038. At the same time, the Secretary cautioned that CMS "will be reviewing all financial information in the aggregate and will not be basing [its] decision on one ratio but rather overall financial soundness." *Id*. A subsequent announcement on the DME Bidding Program website explained that CMS would use ten particular financial ratios to evaluate a supplier's viability. *See* Center for Medicaid and Medicare Services, *CMS Announces Financial Measures for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program*, June 1, 2007, *available at* www.medicarenhic.com/dme/articles/060107_comp_bid.pdf (last visited Sep. 5, 2011) ("CMS Financial Measures").[3]

As to the specific regulation, the Secretary promulgated a rule requiring any bidding supplier to "submit along with its bid the applicable covered documents" to ensure that the

[3] In particular, the DME Bidding Program website specified that CMS would consider the "current ratio," "collection period," "accounts payable to sales," "quick ratio," "current liabilities to net worth," "return on sales," "sales to inventory," "working capital," "quality of earnings," and "operating cash flow to sales." CMS Financial Measures. It further indicated that CMS would "utiliz[e] the supplier's credit history." *Id*.

candidate meets required financial standards. 42 C.F.R. § 414.414(d)(1). Covered documents were defined elsewhere as any "financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards." *Id.* § 414.402. Together, these regulations establish that "[i]n order to be considered for a contract award, each DMEPOS supplier is required to meet applicable quality and financial standards." *All Fla. Network Corp. v. United States*, 82 Fed. Cl. 468, 470 (Ct. Cl. 2008).

CMS proceeded with Round 1 of the DME Bidding Program in the first 10 geographical areas, but in 2008—just before the results were announced—the House Committee on Ways and Means held a hearing "to review the development and execution of the 'Durable Medical Equipment Competitive Bidding Program' mandated in [the] MMA." 2008 Hearting Tr. at 6 (statement of Rep. Stark). The hearing was called "because of the concern from [members of Congress] who [were] hearing from the suppliers in their communities," prompting the need for, as one member put it, "oversight." *Id.* Though recognizing that the initial demonstrations had successfully reduced prices, *id.* (noting estimated savings of 26%), and combated fraud, *id.* (applauding "the accreditation process" as method to combat "excessive fraud and abuse"), the Committee reviewed a number of complaints from industry and beneficiary advocates, and several members expressed their desire to alter or eliminate the DME Bidding Program. *See generally id.* at 6–9. During the 2008 Hearing, a colloquy between Kerry Weems, then director of CMS, and several representatives concerning the transparency of the Program and the disqualification of a large number of suppliers in Round 1 for lack of proper financial documentation took place. *See, e.g.*, *id.* at 16 (statement of Mr. Weems) (acknowledging "that there is a problem with the fact that certain financial documentation was not supplied"); *id.* at 17

(statement of Mr. Weems) (discussing use of "certain financial rations [*sic*] that . . . tell [CMS] the financial strength of" particular bidders); *id*. at 24 (statement of Mr. Weems) (admitting that CMS "ha[s] not disclosed as a matter of the bid process . . . exactly how [CMS] use[s] the financial rations [*sic*] in judging the financial viability of each bidder").

The statute creating the DME Bidding Program was largely unaffected following this hearing, 74 F.R. 2873, 2875 (2009)—likely because of the Program's expected savings. *See* 2008 Hearing Tr. at 34–35 (statement of Rep. Stark) ("[T]o the extent we're going to change [the DME Bidding Program], the Congressional Budget Office, who is a fiddler to whom we have to dance here, has said that a one-year delay in round one would lose $3.5 billion in projected savings, . . . Over five years, the current program is north of $6 billion over the next five years. . . . [I]f we are going to solve this legislatively, and we may not, we're going to have [to] come up with 6 billion bucks over five years."). But the MIPPA did amend the statute in two ways that are collaterally relevant: first, Congress directed the Secretary to delay implementation of the program, such that a Round 1 rebid would be conducted in 2009 and Round 2 would be delayed until 2011, 74 F.R. at 2875; and second, Congress created a mechanism for supplier feedback that requires the Secretary to provide notice of any missing financial documents and an opportunity to supplement the bid. 42 U.S.C. § 1395w-3(a)(1)(F).

Following passage of the MIPPA, the Secretary promulgated an interim final rule to integrate changes to various laws—including the DME Bidding Program—affected by that Act. 74 F.R. 2873. As the Secretary explained, the MIPPA made "certain limited changes" to the DME Bidding Program. *Id*. at 2875. Noting that these changes "are largely self-implementing," the Secretary re-adopted the same methodologies (including the consideration of financial standards) that she had previously articulated. *Id*. at 2875–76; *see also id*. at 2876 ("The

[requests for bid] issued for the Round 1 rebid will require suppliers to submit the same categories of financial documents as we requested for the previous Round 1 competition.").[4] In light of the MIPPA's "new paragraph . . . set[ting] forth a process for supplier feedback on missing financial documents," *id*. at 2875, however, the Secretary amended the applicable regulations to provide a method for suppliers to obtain feedback concerning incomplete submissions. 42 C.F.R. § 414.414(d)(2). CMS then proceeded with the Round 1 rebid.

B. Factual and Procedural History

Before the results of the Round 1 rebid could be announced, plaintiffs filed suit in this Court. Complaint, May 10, 2010 [1]. The stated purposes of this action are to compel HHS and CMS "(1) [to] comply with the Medicare provisions . . . by specifying financial standards that [DME] suppliers must meet, taking into consideration the needs of small providers, (2) to comply with the APA and the Medicare provisions of the Social Security Act by providing proper notice and opportunity for public comment in proposing and specifying such financial standards, and (3) to publish in the *Federal Register*, or otherwise provide to Plaintiffs, the 'financial standards' [they are] applying to qualify such DME suppliers, if in fact they exist." *Id*. at ¶ 1. The Complaint centers around a host of alleged deficiencies in the processes used by the Secretary and the Director of CMS in developing the DME Bidding Program, including that "[t]he [2006] proposed rule did not contain any further information on the substance of the proposed financial standards," *id*. at ¶ 14, the preamble to the final rule "did not specify the 'appropriate financial ratios' to be used" by defendants, *id*. at ¶ 15, the substantive adopted regulation "did not specify financial standards that would be applied," *id*. at ¶ 16, "[n]owhere in

[4] CMS subsequently announced via the DME Bidding Program website that it would use the same ten ratios for the Round 1 rebid previously identified in the CMS Financial Measures bulletin. Centers for Medicaid & Medicare Services, *Financial Measures for the Medicare DMEPOS*, Sep. 24, 2009, *available at* http://www.dmecompetitivebid.com/cbic/cbicrd1.nsf/DocsCat/852573EE00644C008525763B0073EAB3?Open&cat=Suppliers~Bid%20Evaluation (last visited Sep. 5, 2011).

the [2009] interim final rule did Defendants specify the financial standards to be used," *id*. at ¶ 18, and that—despite numerous requests—defendants have not allowed DME suppliers to "comment on proposed financial standards" following the interim final rule. *Id*. at ¶ 23. In light of these purported shortcomings, plaintiffs allege that DME suppliers participating in the Round 1 rebid "do not know whether or not they have been determined by Defendants to be qualified bidders under whatever financial standards or judgments are, or have been, applied." *Id*. at ¶ 20. Plaintiffs further allege, "[o]n information and belief," that HHS and CMS are "evaluating the financial soundness of . . . bidders without having specified financial standards, . . . as required by statute, and are evaluating 'covered documents' for the financial soundness of providers on an *ad hoc* basis, without application of specified financial standards and without any specific means for considering the financial needs of small providers." *Id*. at ¶ 24. Based on these allegations, plaintiffs assert that HHS and CMS have violated § 553 of the APA and § 1395hh of the Medicare Act by failing to make the financial standards publicly available and provide a meaningful opportunity for comment, *id*. at ¶¶ 25–34 (Counts I & II), violated § 552(a)(1)(C) of FOIA by failing to publish the applicable financial standards in the *Federal Register*, *id*. at ¶¶ 35–39 (Count III), and violated § 706(2) of the APA by failing to rely upon specified financial standards and thus acting *ultra vires*. *Id*. at ¶¶ 40–41.

Defendants subsequently moved to dismiss plaintiffs' complaint. Motion to Dismiss, July 23, 2010 [9] ("MTD"). Defendants' motion sets forth three general bases for dismissal: first, that the MMA precludes judicial review of the Secretary's choice of financial standards, and thus this Court lacks subject-matter jurisdiction, *id*. at 18–24; second, that the Court lacks jurisdiction because the Complaint does not sufficiently allege the elements necessary to establish plaintiffs' standing, *id*. at 25–29; and finally, that the Complaint fails to state any claim

upon which relief may be granted and therefore must be dismissed under Federal Rule of Civil Procedure 12(b)(6). *Id*. at 29–37.

Several months after defendants' motion was fully briefed, plaintiffs moved to amend their Complaint following completion of the Round 1 rebid. Motion for Leave to File First Amended Complaint, Jan. 10, 2011 [15]. Defendants opposed plaintiffs' motion on the grounds that plaintiffs failed to comply with Local Rule 7(m) requiring the parties to meet and confer, and that the new allegations did not alter the three bases for dismissal—rendering amendment futile. Opposition to Motion for Leave, Jan. 12, 2011 [16]. Three months later, plaintiffs moved a second time to amend the Complaint, asserting a need to incorporate allegations concerning Round 2 bidding under the DME Program, Motion for Leave to File Second Amended Complaint, Apr. 12, 2011 [18], and defendants opposed this request on the same grounds. And just last week, plaintiffs again moved to amend—and defendants again opposed—this time because (1) areas of Texas covered by Texas Alliance's members are part of Round 2 of the DME Bidding Program and (2) plaintiffs wish to add a Medicare beneficiary as a plaintiff. Motion for Leave to File Third Amended Complaint, Aug. 29, 2011 [23].

Having reviewed the full record, as well as the applicable law, the Court,[5] for the reasons set forth below, will dismiss plaintiffs' suit for want of jurisdiction and for failure to state a claim, and will deny plaintiffs' requests to amend the Complaint as futile.

III. STANDARD

A. 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction

Federal district courts are courts of limited jurisdiction, *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994), and a Rule 12(b)(1) motion for dismissal presents a threshold

[5] This case was transferred by consent from Judge Kennedy to Chief Judge Lamberth a few months ago. Reassignment of Civil Case, May 4, 2011 [20].

challenge to a court's jurisdiction. *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987). In evaluating such a motion, the Court must "accept as true all of the factual allegations contained in the complaint," *Wilson v. District of Columbia*, 269 F.R.D. 8, 11 (D.D.C. 2010) (citing *Leatherman v. Tarrant Cty. Narcotics Intel. & Coordination Unit*, 507 U.S. 163, 164 (1993)), and should review the complaint liberally while accepting all inferences favorable to the plaintiff. *Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004). At the same time, the Court may consider relevant materials outside the pleadings, *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1107 (D.C. Cir. 2005), and must remain cognizant that "the plaintiff's factual allegations in the complaint will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." *Wilson*, 269 F.R.D. at 11 (quotations omitted). In defending against a Rule 12(b)(1) motion, the plaintiff bears the burden of demonstrating that jurisdiction exists. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008).

B. 12(b)(6) Motion to Dismiss for Failure to State a Claim

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a complaint. *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). To satisfy this test, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint," *Atherton v. District of Columbia*, 567 F.3d 672, 681 (D.C. Cir. 2009), and grant a plaintiff "the benefit of all inferences that can be derived from the facts alleged." *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994). At the same time, a court may not "accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in

the complaint." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). In other words, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id*.; *see also Atherton*, 567 F.3d at 681 (holding that complaint must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged").

IV. ANALYSIS

A. Statutory Preclusion

The Secretary's primary argument for dismissal is that judicial review of implementation of the DME Bidding Program—at least with respect to the Secretary's choice of financial standards—is precluded. The relevant statutory provision reads, in its entirety:

> There shall be no administrative or judicial review under section 1869, section 1878, 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) and the identification of areas under subsection (a)(1)(D)(iii);
> (D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);
> (E) the selection of items and services for competitive acquisition under subsection (a)(2);
> (F) the bidding structure and number of contractors selection under this section; or
> (G) the implementation of the special rule described in paragraph (10).

42 U.S.C. § 1395w-3(b)(11).[6] Relying on subsections (b)(11)(B) and (b)(11)(F), defendants argue that "[t]he 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 process.'" MTD at 22. The Court agrees.

[6] The practice of including similar preclusion clauses in parts of the Medicare Act is well established. *See, e.g.*, *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403–04 (D.C. Cir. 2005); *Amgen Inc. v. Smith*, 357 F.3d 103, 111–13 (D.C. Cir. 2004); *Bartlett v. Bowen*, 816 F.2d 695, 700–01 (D.C. Cir. 1987).

In evaluating whether Congress intended to preempt judicial review of the Secretary's actions, the Court begins, as it must, "with the strong presumption that Congress intends judicial review of administrative action." *Bowen v. Mich. Academy of Family Physicians*, 476 U.S. 667, 670 (1986). But this presumption, "like all presumptions used in interpreting statutes, 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." *Id.* at 673. In particular, the presumption of judicial review of agency action may be overcome "'upon a showing of clear and convincing evidence of a contrary legislative intent [to] restrict access to judicial review.'" *Id.* at 671 (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967)); *see also Bartlett v. Bowen*, 816 F.2d 695, 699 (D.C. Cir. 1987) ("It is axiomatic that this presumption can be overcome only by 'clear and convincing evidence' that Congress intended to restrict access to judicial review."). This standard—which is not applied "in the strict evidentiary sense"—"serves as a useful reminder to courts that, where substantial doubt about the congressional intent exists, the general presumption favoring judicial review of administrative action is controlling." *Bowen*, 476 U.S. at 672 n.3. To determine whether the statute precludes judicial review, the Court "turns to the statute's 'language, structure and purpose, its legislative history, and whether the claims can be afforded meaningful review.'" *Amgen Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (quoting *Thunder Basic Coal Co. v. Reich*, 510 U.S. 200, 206 (1994)). In particular, the presumption against preclusion "may be overcome by the language of the statute." *All Fla. Network*, 82 Fed. Cl. at 473 (citing *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 498–99 (1991)). Alternatively, the presumption "does not control in cases [where] the congressional intent to preclude judicial review is 'fairly discernable' in the detail of the legislative scheme."

Block v. Cmty. Nutrition Inst., 467 U.S. 340, 351 (1984). The Court finds that both the plain language of § 1395w-3(b)(11) and the statutory scheme, read in its entirety, foreclose judicial review of the Secretary's challenged actions.

1. The Language of §§ 1395w-3(b)(11)(B) & (F)

"It is a 'familiar canon of statutory construction that the starting point for interpreting a statute is the language of the statute itself.'" *All Fla. Network,* 82 Fed. Cl. at 472 (quoting *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980)). The Secretary points to two phrases in the judicial-review provision to support her argument that review is precluded in this instance: first, that judicial review of the "awarding of contracts" is foreclosed; and second, that judicial review of "the bidding structure" is not permitted. MTD at 19–20. The Court discusses each of these subsections in turn.

With respect to the "awarding of contracts," § 1395w-3 expressly ties the development and application of appropriate financial standards to the Secretary's decision to grant or deny a contract under the DME Bidding Program. Indeed, the *only* statutory reference to financial standards is found in the section entitled "Conditions for awarding contracts," which provides that the Secretary "may not award a contract to any entity . . . unless the Secretary finds [that] . . . [t]he entity meets applicable financial standards specified by the Secretary." 42 U.S.C. § 1395w-3(b)(2)(A)(ii). And while plaintiffs argue that the preclusion language is directed towards the act of awarding contracts—indicating congressional intention to preclude only post-bid review, Opposition to Motion to Dismiss 11, Aug. 6, 2010 [10] ("MTD Opp.")—it is well established that a statutory bar against bid protests also precludes "review of the administrative decisions leading up to the procurement." *Corel Corp. v. United States*, 165 F. Supp. 2d 12, 28–29 (D.D.C. 2001) (collecting cases). Plaintiffs' additional contention that "[a] reasonable and

common-sense reading [of the phrase 'awarding of contracts'] is that Congress did not want the courts and HHS to be bogged down with a plethora of fact-intensive lawsuits brought by individual bidders or contractors," MTD Opp. at 11, is also undermined by the Supreme Court's latest pronouncement on statutory preclusion, in which it explained that distinctions based upon "the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'non-collateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought" are without merit. *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13–14 (2000). In other words, the fundamental inquiries for the Court in this case—what financial standards the Secretary articulated, whether they are sufficiently specific or adequate to promote the underlying statutory goals, and whether the Secretary is complying with them—are the same as in any post-bid challenge. *See All Fla. Network*, 82 Fed. Cl. at 473 (remarking, in reviewing § 1395w-3(b)(11), that "eligibility determinations are part of the overall award scheme").[7] In this instance, there is simply "no reason to distinguish" among standards of eligibility, on the one hand, and the awarding of a contract, on the other. *Atl. Urological Assocs., P.A. v. Leavitt*, 549 F. Supp. 2d 20, 30 (D.D.C. 2008) (citing *Illinois Council*, 529 U.S. at 14).

Turning to the "bidding structure" for the DME Bidding Program, the Court finds that this provision forecloses pre-implementation challenges to the Secretary's specifications of appropriate financial standards. Unlike subsection (b)(11)(B)'s "awarding of contracts" language, this provision does not involve particular action undertaken by the Secretary, but precludes review of "the bidding structure" itself. 42 U.S.C. § 1395(b)(11)(F). The "structure"

[7] Plaintiffs correctly note that *All Fla. Network* involved a "post-bid protest." MTD Opp. at 13–14. But in light of *Illinois Council* and as further explained *infra*, this distinction does not limit the holding of that case, which is that the application of criteria for eligibility in the DME Bidding Program is inextricably intertwined with the decision to award (or not award) a contract.

of the DME Bidding Program is "the way in which the parts of something are put together or organized." *Webster's Third New Int'l Dictionary* 2267 (1965). And section (b)(2) provides a list of the "parts" that the Secretary is to compile into the DME Bidding Program—including the methods to determine whether a bidder "meets applicable quality standards," "meets applicable financial standards," whether "[t]he total amounts to be paid . . . are expected to be less than the total amounts that would otherwise be paid," and whether the "[a]ccess of individuals to a choice of multiple suppliers in the area is maintained." 42 U.S.C. § 1395w-3(b)(2)(A)(i)–(iv). And while plaintiffs insist that the financial standards cannot be considered part of the bidding structure, MTD Opp. at 17, they offer no other part of the DME Bidding Program to which this language refers. Indeed, the Court can conceive of no clearer means of precluding review of these aspects of the DME Bidding Program than that used in the preclusion provision—save, perhaps, the listing of each individual piece of that structure.[8] Permitting plaintiffs to "pars[e] the categories of decisions precluded from judicial review into challengeable sub-components would frustrate Congress' intent and potentially hamstring the Secretary's ability" to implement the DME Bidding Program. *All Fla. Network*, 82 Fed. Cl. at 470 (quotations omitted). Accordingly where, as here, the preclusion provision shields a particular agency decision from

[8] Plaintiffs assert that Congress was required to do just this, remarking that "notably absent from subsection (11) is any mention of preclusion regarding the specification of 'financial standards,'" MTD Opp. at 9, and arguing that the similar absence of language precluding review of the Secretary's determinations of quality standards calls for application of the *inclusio unius* doctrine. *Id.* at 9–10. Plaintiffs have this doctrine backwards. Had the preclusion provision *included* aspects of the Secretary's quality determinations, but *not* aspects of her financial determinations—both of which are part of the "bidding structure"—that would have been evidence that Congress intended to preclude review only of the choice of quality standards, and not financial standards. *See ABA v. FTC*, 671 F.2d 64, 86 (D.D.C. 2009) (explaining application of doctrine as "the listing of some things implies that all things not included in the list were purposefully excluded"). But the absence of both determinations—as well as *any* of the structural parts of the DME Bidding Program outlined in § 1395(b)(2)(A)—is actually persuasive evidence that Congress intended for each of these elements to be considered part of "the bidding structure" as a whole. And to the extent that plaintiffs' argument is simply that the preclusion provision must *explicitly* state "financial standards," that position is without merit. The *inclusio unius* canon of statutory interpretation "has force . . . only when there is no apparent reason for the inclusion" of one element "and the omission of a parallel" element. *Carter v. Dep't of Labor*, 751 F.2d 1398, 1401 (D.C. Cir. 1985). The fact that "bidding structure" necessarily encompasses "financial standards" is a sound reason for the drafters of § 1395w-3(b)(11) to have omitted specific mention of "financial standards" in § 1395(b)(11). *See Carolina Med. Sales, Inc. v. Leavitt*, 559 F. Supp. 2d 69, 78 (D.D.C. 2008) (rejecting application of *expressio unius* to § 1395w-3(b)(11)).

review—in this instance the structure for the bidding process—it also shields the sub-components of that process, which includes the financial standards. *Carolina Med. Sales, Inc. v. Leavitt*, 559 F. Supp. 2d 69, 78 (D.D.C. 2008) (citing *Am. Medical Ass'n v. Thompson*, No. 99 Civ. 7850, 2001 WL 619510 (N.D. Ill. May 29, 2001)).

Another court in this district has relied upon similar principles to find review precluded under § 1395w-3(b)(11). In *Carolina Med.*, the district court dismissed a complaint alleging that HHS and CMS promulgated rules governing certain aspects of the DME Bidding Program without adhering to notice-and-comment procedures, 559 F. Supp. 2d at 72, finding—in reliance on the express language in § 1395w-3(b)(10)(E)—that the preclusion provision "is broad, unqualified, and clear," and expresses Congress' intent to bar judicial review. *Id*. at 77. In doing so, the *Carolina Med.* Court rejected the argument—identical to plaintiffs' position here—that the omission of the particular challenged agency action from § 1395w-3(b)(11)'s list was dispositive. *See id*. ("The absence of any mention of delivery method. . . . does not detract from this conclusion. . . . [There is] no reason why Congress would—after imbuing the Secretary with unreviewable discretion . . . —decide to carve out an isolated patch for judicial review.").[9]

Finally, plaintiffs' reliance on *Sharp Healthcare v. Leavitt*, which held that §1395w-3(b)(11) does not preclude certain claims under the DME Bidding Program, 555 F. Supp. 2d 1121, 1125 (S.D. Cal. 2008), is flawed for several reasons. Beyond the obvious—that this Court is not bound to that decision—and the less obvious but more compelling—that this decision has been subsequently vacated, Order, *Sharp*, No. 08 Civ. 170, July 22, 2010 [53], thus "void[ing] the effect of [that] prior legal determination, *United States ex rel. Miller v. Bill Harbert Int'l*

[9] Plaintiffs observe that *Carolina Med.* involved a particular subsection shielding "the selection of items and services for competitive acquisition under subsection (a)(2)," 42 U.S.C. § 1395w-3(b)(11)(E), which is not at issue here. MTD Opp. at 12–13. While true, this fact does not undermine certain determinations reached by the *Carolina Med.* Court—such as the inapplicability of *inclusio unius* in light of §1395w-3(b)(11)'s broad language.

Constr., No. 95 Civ. 1231, 2011 U.S. Dist. LEXIS 96236, at *14 (D.D.C. Aug. 29, 2011)—this Court takes issue with various aspects of the reasoning, which are conveyed in a few scant paragraphs. Most fundamentally, the *Sharp* Court relies on the Supreme Court's interpretation of another Medicare preclusion statute in *Bowen* without accounting for critical differences between § 1395w-3(b)(11) and the statute at issue in *Bowen*. 555 F. Supp. 2d at 1124; *see also infra*. In addition, the *Sharp* Court relies heavily on its concern that the Secretary might act contrary to statutory commands, *id*. at 1125, without due regard for the well-established exception to preclusion in the case of *ultra vires* actions. *See infra*. *Sharp* thus does little to alter the Court's finding that §§ 1395w-3(b)(11)(B) & (F) preclude challenges to the Secretary's articulation of financial standards for the DME Bidding Program.

2. The Statutory Scheme

In addition to the specific statutory language, the Court may also "examine th[e] statutory scheme to determine whether Congress precluded all judicial review." *Block*, 467 U.S. at 346; *see also id*. at 349 ("[T]he presumption favoring judicial review of administrative action may be overcome by inferences of intent drawn from the statutory scheme as a whole."). Reading § 1395w-3 in its entirety and along with the preclusion provision, a clear narrative emerges: Congress precluded from administrative and judicial review all aspects of the DME Bidding Program concerning its design and implementation, but left open challenges to post-bid conduct. For instance, Congress precluded review of acceptable payment amounts, 42 U.S.C. § 1395(b)(11)(A), the factors that the Secretary would consider in awarding contracts, *id*. § 1395(b)(11)(B), the designation of areas where the Program is to be implemented, *id*. § 1395(b)(11)(C), the timing of implementation, *id*. § 1395(b)(11)(D), the choice of which DME would be included, *id*. § 1395(b)(11)(E), the structure of the Program, *id*. § 1395(b)(11)(F), and

the implementation of any special rules for particular types of DME. *Id*. § 1395(b)(11)(G). By contrast, the preclusion provision does not foreclose review of the precise terms to be included in a contract once bidders are chosen, *id*. § 1395(b)(3)(B), disclosures to be made by DME suppliers once a contract has been entered into, *id*. § 1395(b)(3)(C), the process of paying the winning bidders, *id*. § 1395(b)(6), or challenges to the Secretary's decision to terminate a contract before it expires. *See* 42 C.F.R. § 414.423 (setting forth process for administrative review of pre-term cancellation). In light of the clear division between review of the initial implementation of the DME Bidding Program—which is precluded—and review of post-bidding actions—which often is not—the Federal Circuit recently observed that "Congress clearly intended that Medicare could proceed with these initial administrative processes without risk of litigation blocking the execution of the program." *Cardiosom, L.L.C. v. United States*, No. 2010-5109, 2011 U.S. App. LEXIS 18127, at *7 (Fed. Cir. Aug. 31, 2011); *see also Carolina Med.*, 559 F. Supp. 2d at 76 ("[T]he provision clearly indicates that Congress contemplated a detailed, scheduled deployment of the competitive bidding program and imbued the Secretary with the authority—immune from judicial review—to economize by accelerating the introduction of cost-effective items and services."). The Court agrees, and also concurs with the Federal Circuit's observation that "[t]he purpose of withholding judicial review in these instances is to insulate these management decisions by the Medicare Administration from the potential of inordinate delays that would transpire if every such management decision were open to an upfront challenge by some disappointed group." *Cardiosom*, 2011 U.S. App. LEXIS 18127, at *8 (citing H.R. Rep. No. 108-391, at 576–77). The Secretary's choice of appropriate financial standards to apply in the DME Bidding Process is just such a management decision, and thus the Court finds that review of this action is precluded.

Rather than address these structural arguments, plaintiffs place heavy reliance on the Supreme Court's statement in *Bowen* that "prohibition of judicial review of benefit payments under Medicare 'simply does not speak to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves.'" MTD Opp. at 14 (quoting *Bowen*, 476 U.S. at 675). This reliance is misplaced, however, as *Bowen* was decided under a different statutory regime. Specifically, the relevant provision in *Bowen* provided that "the determination of the amount of benefits under part A, shall be made by the Secretary in accordance with regulations prescribed by him," and "[a]ny individual dissatisfied with any determination . . . shall be entitled to a hearing thereon by the Secretary . . . and to judicial review of the Secretary's final decision." 476 U.S. at 674 n.5 (quoting portion of 42 U.S.C. § 1395ff as written at time). Beyond the obvious fact that § 1395w-3(b)(11) expressly precludes judicial review, while the provision at issue in *Bowen* "is an explicit authorization of judicial review, not a bar," *id*. at 674, the statutory scheme in *Bowen* undermines any attempt to apply the quoted language to this case. The provision at issue in *Bowen* references §§ 405(g) & (h) of the Social Security Act, which create an administrative process of review—followed by appeals to the courts—and render all findings of the Secretary final and immune from review, respectively. The government in *Bowen* argued that the provision's reference to these sections required the Court to adhere to an earlier line of precedent holding that a fair reading of §§ 405(g) & (h) is that general federal jurisdiction was barred over any challenges to the procedures used by the Secretary. The Court declined this invitation, however, observing that the statutory reference to § 405(g) was only for "the determination of the amount of benefits"—thereby distinguishing between method and determination review in the manner quoted by plaintiffs, *Bowen*, 476 U.S. at 674–75 & n.5—and explaining that because the legislative history of the statute before it

"provides specific evidence of Congress' intent to foreclose review *only* of 'amount determinations,'" *id*. at 680 (emphasis added), the general bar on such procedural claims under the Social Security Act did not apply to claims under Medicare Part B. *Id*. at 679–80.

This brief discussion should serve to illuminate the distinct differences between the circumstances in *Bowen* and those here. First, unlike the statute in *Bowen*, § 1395w-3(b)(11) contains *both* a provision concerning the actual CMS action—the "awarding of contracts"—*and* a provision concerning the broader design of the DME Bidding Program—the "bidding structure." *Supra*. Thus, *Bowen*'s reasoning concerning the distinction between *method* and *determination*—if it remains good law[10]—is inapplicable where the statute at issue, such as § 1395(b)(11), precludes judicial review of *both* the "method" and the "determination." Second, also unlike in *Bowen*, plaintiffs point to nothing in the record or legislative history—save speculation and innuendo—to suggest that Congress did not intend to bar judicial review of the entirety of the Secretary's development of the DME Bidding Program.[11]

Moreover, a few months after the *Bowen* decision was issued, Congress amended the relevant provisions of the Medicare Act to make §§ 405(g) & (h) applicable to challenges under Part B "to the same extent as it applies" to Part A. *Illinois Council*, 529 U.S. at 8. Applying this new provision, the *Illinois Council* Court stated:

> [Our prior decisions] foreclose distinctions based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'non-collateral' nature of the

[10] As set forth *infra*, this aspect of the ruling in *Bowen* has been expressly overruled following congressional action and subsequent interpretation by the Supreme Court. *See infra*.

[11] Similarly, the Supreme Court's conclusions in *McNary v. Haitian Refugee Ctr., Inc.* "emphasizing the critical difference between an individual 'amount determination' and a challenge to the procedures for making such determinations, 498 U.S. 479, 497–98 (1991)—relied upon by plaintiffs, MTD Opp. at 7–8—also turn on a statutory provision that shields only final "determinations." *Id*. at 486; *see also Illinois Council*, 529 U.S. at 14 (emphasizing different statutory context in which *McNary* was decided). And even further afield is plaintiffs' citation to *Gutierrez v. Lamagno*, in which the Court's refusal to find preclusion resulted from the absence of any "persuasive reason for restricting access to judicial review [that] is discernible from the statutory fog." 515 U.S. 417, 425 (1995).

> issues, or the 'declaratory' versus 'injunctive' nature of the relief sought. Nor can the Court accept a distinction that limits § 405(h)'s scope to claims for monetary benefits or that involve 'amounts,' as neither the language nor the purposes of § 405 support such a distinction.

Id. at 13–14; *see also Atl. Urological Assocs.*, 549 F. Supp. 2d at 30 (noting that subsequent decisions disavowed the 'amount' versus 'method' dichotomy). The *Illinois Council* Court thus limited *Bowen* to circumstances in which there would be "no review at all" of constitutional challenges to agency action under Medicare part B, 529 U.S. at 19, and held that preclusion "applies to disputes over the methods used to determine reimbursement just as it applies to disputes over reimbursement amount determinations." *Am. Med. Techs. v. Johnson*, 598 F. Supp. 2d 78, 81 (D.D.C. 2009).[12]

3. The Court Lacks Subject-Matter Jurisdiction

Having found that judicial review of the Secretary's choice and promulgation of financial standards is precluded, the Court concludes that it lacks subject-matter jurisdiction over each of plaintiffs' claims. Courts have routinely upheld the denial of administrative or judicial review of HHS actions where the relevant Medicare provision states that "[t]here shall be no administrative or judicial review." *Am. Soc'y of Dermatology v. Shalala*, 962 F. Supp. 141, 145–47 (D.D.C. 1996); *see also Amgen*, 357 F.3d at 111–12 (holding that where preclusion language is clear, absence of alternative outlets for review is "unsurprising"). Accordingly, consideration of any claim under § 1395(b)(11) is plainly precluded. *See Carolina Med.*, 559 F. Supp. 2d at 74–78 (precluding review of alleged violation of § 1395hh where § 1395w-3(b)(11) prohibited review

[12] Plaintiffs cite to *Am. Nurses Ass'n v. Leavitt*, 593 F. Supp. 2d 126 (D.D.C. 2009) for the proposition that the method versus determination distinction drawn in *Bowen* remains viable. MTD Opp. at 14. As an initial matter, the court in that case failed entirely to consider the Supreme Court's subsequent opinion in *Illinois Council*, and thus reliance upon this holding is problematic at best. More fundamentally, as in *Bowen*, the statute before the district court in *Am. Nurses* spoke "only to the mandated review procedure for [entities] dissatisfied with *a determination* by the Secretary." 593 F. Supp. 2d at 135 (emphasis added). By contrast, § 1395w-3(b)(11), like the amended statute in *Illinois Council*, speaks to both methods *and* determinations. *Supra*.

of the substance of agency's decision). And the APA, which forms the underlying remedial platform for all of plaintiffs' claims, contains a specific provision withdrawing jurisdiction where "statutes preclude judicial review." 5 U.S.C. § 701(a)(1); *see Block*, 467 U.S. at 345 (observing that APA "confers a general cause of action upon persons 'adversely affected or aggrieved by agency action within the meaning of a relevant statute,'" but "withdraws that cause of action to the extent the relevant statute 'precludes judicial review'") (quoting APA §§ 701(a)(1) & 702); *Amgen*, 357 F.3d at 113 ("If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective."); *see also Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) (finding that preclusion provision "exempts [agency] from the strictures of the APA in cases involving the APA's procedural requirements").

One exception remains. "[T]he case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Lutherans*, 321 F.3d at 1173. Thus, "to the extent that statutes preclude judicial review," APA § 701(a)(1) "does not repeal the review of *ultra vires* actions . . . . When an executive acts *ultra vires*, courts are normally available to reestablish the limits on his authority." *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988). This doctrine rests on the presumption of judicial review, which is "particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority." *Amgen*, 357 F.3d at 111. And in order to determine whether review is precluded, the Court must look briefly to the merits of plaintiffs' allegations to determine whether the question is jurisdictionally barred. *See id*. at 113 ("[T]he determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine

whether the challenged agency action falls within the scope of the preclusion on judicial review."). In this instance, this is a relatively straightforward task—as discussed at greater length *infra*, plaintiffs' allegations of *ultra vires* action on behalf of HHE and CMS, which includes no details or basis to support such an inference, is plainly conclusory, and will be disregarded by the Court. *See Am. Med. Techs.*, 598 F. Supp. 2d at 80 ("'[T]he court need not accept inferences drawn by plaintiffs if such inferences are unsupported by the allegations set out in the complaint. Nor must the court accept legal conclusions cast in the form of factual allegations.'") (quoting *Kowal*, 16 F.3d at 1276). Accordingly, the Court finds that all of plaintiffs' claims in this instance are precluded by § 1395(b)(11) of the MMA and MIPPA.

Having concluded that it lacks subject-matter jurisdiction, the Court's consideration of this matter would normally be at an end. *See All Fla. Network*, 82 Fed. Cl. at 472 ("Jurisdiction is a prerequisite which must be met prior to considering any substantive issues."). But in light of the dearth of clear law interpreting § 1395w-3, the Court—out of an abundance of caution—will proceed to consider defendants' remaining arguments.

B. Standing

In addition to express statutory preclusion, defendants assert that "the Court also lacks jurisdiction because Plaintiffs' alleged injuries are insufficient to confer Article III jurisdiction." MTD at 25. This Court, like all Article III tribunals, is one of limited jurisdiction and "cannot decide cases that [it] lack[s] constitutional authority to decide." *Ctr. for Law & Educ. v. DOE*, 396 F.3d 1152, 1156 (D.C. Cir. 2005). "The core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III," *Cty. of Del. v. DOT*, 554 F.3d 143, 147 (D.C. Cir. 2009), which "defines with respect to the Judicial Branch the idea of separate of powers on which the Federal Government is founded." *Allen v. Wright*, 468 U.S.

737, 750 (1984); *see also Warth v. Seldin*, 422 U.S. 490, 498 (1975) ("[Standing] is founded in concern about the proper—and properly limited—role of the courts in a democratic society."). "In essence the question of standing is whether a litigant is entitled to have the court decide the merits of the dispute or of particular issues." *Warth*, 422 U.S. at 498.[13]

"The party invoking federal jurisdiction bears the burden of establishing" standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). In this instance, plaintiffs' claims are not based on any denial of benefits within the DME Bidding Program, but rather on prospective claims concerning purported inadequacies in the procedures employed by the Secretary. In such circumstances, plaintiffs must rely on their purported procedural injury, which may confer standing "provided that [the procedural] requirement 'was designed to protect some threatened concrete interest' of the litigant." *Cty. of Del.*, 554 F.3d at 147 (quoting *Lujan*, 504 U.S. at 573 n.8). This test, while different in some sense from the typical standing inquiry, requires both that a concrete injury exist and that the injury is caused by the alleged procedural defect. *Ctr. for Law*, 396 F.3d at 1157. The Court finds each element of plaintiffs' standing lacking.

1. Concrete Interest

With respect to a concrete interest, plaintiffs generally allege that defendants' purported procedural failures "cause a distinct risk of harm to Plaintiffs' concrete Medicare DME supplier interests." Complaint ¶ 7. Reading plaintiffs' subsequent proposed amended complaints, along with their opposition to defendants' motion to dismiss, the Court identifies three possible injuries: (1) an increased risk that plaintiffs or their members will not receive contracts under the DME Bidding Program, (2) the cost of applying to the DME Bidding Program, and (3) a risk to

[13] Plaintiffs suggest that defendants "do[] not challenge Plaintiffs' standing to claim inadequate notice and comment pursuant to APA § 553 or failure to publish final rules pursuant to FOIA § 552." MTD Opp. at 19. But "Article III standing is a jurisdictional requirement that cannot be waived by the parties." *Cherry v. FCC*, 641 F.3d 494, 497 (D.C. Cir. 2011). Any claim of waiver is therefore without merit, and the Court will consider standing as to all claims. *See Akinseye v. Dist. of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003) ("[N]o action of the parties can confer subject-matter jurisdiction upon a federal court.").

DME beneficiaries of increases in costs or decreases in quality of services.[14] These latter two interests may be easily dispatched. As to the costs of application, a supplier's decision to apply or not apply to the DME Bidding Program belongs to the supplier alone—in either case, the choice is not without risk (whether through the inability to obtain a contract by not participating or through the costs of unsuccessful participation.) Such risks, however, are insufficient to confer standing on the party. *See Nat'l Family Planning & Reproductive Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006) (explaining that Circuit Court has "consistently held that self-inflicted harm doesn't satisfy the basic requirements for standing"). Moreover, procedural injury standing extends only to concrete risks that the procedural requirement in question was *designed to protect*. *Cty. of Del.*, 554 F.3d at 147; *see also Ctr. for Law*, 396 F.3d at 1157 ("Not all procedural-rights violations are sufficient for standing; a plaintiff must show that 'the procedures in question are *designed* to protect some threatened concrete interest *of his* that is the ultimate basis of his standing.") (quoting *Lujan*, 504 U.S. at 573 n.8; emphasis in original). As the Secretary explained in her proposed rulemaking, the financial standards are used for several purposes, including "assessing the expected quality [and] total potential capacity of suppliers," and "ensuring that selected suppliers are able to continue to serve market demand." 71 F.R. at 25675. None of these purposes, however, extends to protection of potential suppliers bidding for contracts in the DME Bidding Program—nor do plaintiffs point to any statutory provision or legislative history suggesting otherwise. *See Cal. Forestry Ass'n v. Thomas*, 936 F. Supp. 13, 21 (D.D.C. 1996) ("A plaintiff whose interests are marginally related to . . . the purposes implicit in the statute lacks standing to sue.") (quotations omitted). Finally, the risks involved both to DME suppliers and to Medicare beneficiaries are far too speculative to sustain

[14] This interest was added by the proposed third amended complaint, in which plaintiffs seek to add a Medicare DME beneficiary as an additional plaintiff.

the Court's exercise of its jurisdiction. To successfully establish standing, plaintiffs must show that the purported failure to conduct notice-and-comment rulemaking has "created a '*demonstrably* increased risk' that 'actually threatens the plaintiff's particular interests.'" *Ctr. for Law*, 396 F.3d at 1161 (quoting *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 659, 667 (D.C. Cir. 1996) (en banc); emphasis in original). With respect to the costs of application, plaintiffs' standing argument is that (1) under the current financial standards certain suppliers would be ruled ineligible for the DME Bidding Process, but (2) proper notice-and-comment rulemaking would have altered the standards used by the Secretary, and (3) under the new financial standards those suppliers would be found eligible. Similarly, the argument concerning harm to beneficiaries is that (1) under the current financial standards the Medicare beneficiary would obtain a rate and quality of care that (2) would be altered by new financial standards (whatever they might be) and (3) would lead to higher costs or lower-quality services. These highly attenuated scenarios are insufficient to confer Article III standing. *See Jacobrown v. United States*, 764 F. Supp. 2d 221, 227 (D.D.C. 2011) (holding that standing does not exist "where the court 'would have to accept a number of very speculative inferences and assumptions in any endeavor to connect the alleged injury with the challenged conduct'") (quoting *Winspinsinger v. Watson*, 628 F.2d 133, 139 (D.C. Cir. 1980)).

2. Causation

Turning to plaintiffs' only remaining injury—the risk of rejection in the DME Bidding Process—"to establish a so-called procedural injury, the plaintiff must . . . show that it is 'substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest.'" *Cty. of Del.*, 554 F.3d at 147 (quoting *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 665 (D.C. Cir. 1996) (en banc)). Under this standard, the procedural violation, assuming

one exists, must be "fairly traceable" to the alleged injury. *Ctr. for Law*, 396 F.3d at 1161. Plaintiffs allege three types of procedural violations—that the Secretary failed to offer concrete financial standards for notice and comment, failed to publish those standards, and disregards those standards in implementing the DME Bidding Program. MTD Opp. at 18. The first two fail to establish causation, while the latter is unsupported by the administrative record.

As to the alleged failures to publish and offer for notice and comment, plaintiffs cannot explain *how* the lack of specification of such standards could alter the result of the DME Bidding Process. Even assuming that the Secretary gave no notice of the proposed standards, the fundamental issue—whether plaintiffs could receive a contract—is not determined by the *publication* of those standards, but whether a supplier *meets* the underlying viability requirements. "In order to establish causation sufficient for standing, a plaintiff asserting procedural injuries must demonstrate that there is a 'substantial probability that the substantive agency action that disregarded a procedural requirement created a demonstrable risk . . . of injury to the particularized interests of the plaintiff.'" *Cty. of Del.*, 554 F.3d at 148 (quoting *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 669 (D.C. Cir. 1996) (en banc)). Nothing about the publication of particular financial standards, however, is capable of altering a supplier's *actual* financial condition. If a bidder will meet published standards, they would also meet those standards if they were unpublished, and thus no harm derives from the lack of publication. Similarly, if a bidder will not meet some unpublished standards, no publication of such standards will alter this result—unless that bidder was to manipulate its financial records (a possibility the Court obviously does not consider.) "A prospective plaintiff must demonstrate that the defendant caused the particularized injury, and *not just* the alleged procedural violation." *Ctr. for Law*, 396 F.3d at 1159 (quotations omitted; emphasis in original). In *Ctr. For Law*, the

Circuit Court dismissed for lack of standing where the plaintiffs speculated as to their increased risk, but "offered th[e] Court no actual demonstration of increased risk." *Id*. at 1161. Plaintiffs do no better here, and therefore lack standing under applicable law.

Finally, plaintiffs' *ultra vires* allegation—that CMS is not adhering to any financial standards at all but is rendering *ad hoc* or arbitrary decisions—is entirely unsupported by the record, which is littered with references by the Secretary to the financial standards generally, as well as specific examples of such standards—both in and out of the *Federal Register*—that the Secretary intends to rely upon. "Unadorned speculation will not suffice to invoke the judicial power." *Ctr. for Law*, 396 F.3d at 1159. Plaintiffs' allege no facts to support an inference that the Secretary and CMS will not rely upon and consider the published financial standards, but merely insist that the Secretary is acting arbitrarily and thus *ultra vires*—the very sort of "label and conclusion" pleading that is insufficient to substantiate plaintiffs' standing. *See Judd v. FCC*, 723 F. Supp. 2d 221, 224 (D.D.C. 2010) (dismissing case for lack of standing where plaintiff did not more than plead that defendant-agency acted "unconstitutionally").[15]

3. Redressability

Plaintiffs' standing argument is also undermined by the Court's ability to correct the potential risk of a failed bid. Plaintiffs dismiss any concern regarding redressability, relying instead on footnote 7 in the Supreme Court's *Lujan* decision, in which the Court explained that "'procedural rights' are special" such that a person can establish standing "without meeting all the normal standards for redressability and immediacy." 504 U.S. 555, 573 n.7 (1992). As an

[15] Plaintiffs cite *Sierra Club v. EPA* for the proposition that "[i]n many if not most cases the petitioner's standing to seek review of administrative action is self-evident." 292 F.3d 895, 899–900 (D.C. Cir. 2002). But even in that case the Circuit Court recognized that this would not always be true, and that in such circumstances "the petitioner must supplement the record to the extent necessary to explain and substantiate its entitlement to judicial review." *Id*. at 900. Given the nonexistence of any link between plaintiffs' financial interests in obtaining a contract and the need to ensure that bidding entities are substantial enough to adequately supply the market throughout the course of a contract term, 71 F.R. at 25765, this is such a case where additional information is necessary, and plaintiffs have failed entirely to allege sufficient facts to establish standing.

initial matter, in the very next footnote the Court dismissed any notion that the "special" nature of procedural rights disregarded any causation requirement, *see* 504 U.S. at 573 n.8 ("If we understand [the dissent] correctly, it means that the Government's violation of a certain (undescribed) class of procedural duty satisfies the concrete-injury requirement by itself, without any showing that the procedural violation endangers a concrete interest of the plaintiff . . . . We cannot agree."), and thus plaintiffs' failure to establish causation remains fatal. *See Ctr. for Law*, 396 F.3d at 1157 (holding that allegation of procedural injury does not affect "the issues of injury in fact or causation"). Furthermore, the D.C. Circuit has rejected plaintiffs' contention that *Lujan* entirely eliminated the requirement of redressability. *See id*. ("Where plaintiffs allege injury resulting from violation of a *procedural* right . . . the courts relax—*while not wholly eliminating*—the issues of imminence and redressability.") (emphasis added).[16] Indeed, the D.C. Circuit has previously applied the redressability requirement in the context of a procedural injury case. *See, e.g., Cty. of Del.*, 554 F.3d at 149–50.

To establish redressability, "the court must examine 'whether the relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury alleged.'" *Id*. at 149 (quoting *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 659, 663–64 (D.C. Cir. 1996) (en banc)). This element is lacking for many of the same reasons that plaintiffs lack causation—even if the Court were to compel that the agency submit the financial standards to additional notice and comment, or otherwise publish all ratios used or the specific formula adopted, such publication would not transform a financially unsound entity into a viable candidate for the DME Bidding Program. *See Newdow v. Roberts*, 603 F.3d 1002, 1015 (D.C. Cir. 2010) ("Typically,

[16] Plaintiffs rely on *Chamber of Commerce v. SEC*, but in that case the Circuit Court was evaluating a line of cases "involv[ing] the outright dodge of APA procedures that led the court to permit a limited showing" of redressability. 443 F.3d 890, 904 (D.C. Cir. 2006); *see also AFL-CIO v. Chao*, 496 F. Supp. 2d 76, 89 (D.D.C. 2007) (distinguishing *Chamber of Commerce* when opportunity for notice and comment was provided). Plaintiffs allege no facts demonstrating that the Secretary's purported rulemaking deficiencies rise to this level.

redressability and traceability overlap as two sides of a causation coin.") (quotation omitted). Where, as here, overturning a particular agency action would not alter the final outcome, redressability remains unsatisfied. *Cty. of Del.*, 554 F.3d at 149–50. Thus, for all the reasons set forth above, the Court concludes that plaintiffs lack standing to maintain their challenge to the Secretary's implementation of the DME Bidding Program.

C. Adequacy of the Secretary's Implementation of the DME Bidding Program

In addition to their subject-matter jurisdiction arguments, defendants move to dismiss each of plaintiffs' claims on the merits. Plaintiffs generally identify three different procedural wrongs on which they base their suit. First, plaintiffs point to defendants' purported "failure to provide adequate notice and comment for specification of 'financial standards'" as required by both 5 U.S.C. § 553 and 42 U.S.C. § 1395hh. MTD Opp. at 24–25. Second, plaintiffs protest defendants' alleged "failure to publish in the *Federal Register* or otherwise actually divulge to Plaintiffs the specific financial standards it would apply, and is now applying." *Id*. at 25. Finally, plaintiffs allege that defendants "fail[ed] to comply with the statutory mandate [in § 1395] to specify 'financial standards,'" and are thus acting *ultra vires*. *Id*. at 25. The Court discusses each of these purported inadequacies in turn.

1. Notice-and-Comment Rulemaking

Under applicable law, the Secretary must publish all substantive rules for the DME Bidding Program in the *Federal Register* for public notice and comment. *See* 5 U.S.C. § 553(b)(3) ("General notice of proposed rule making shall be published in the Federal Register . . . . The notice shall include . . . either the terms or substance of the proposed rule or a description of the subjects and issues involved."); 42 U.S.C. § 1395hh(b)(1) ("[B]efore issuing in final form any regulation . . . the Secretary shall provide for notice of the proposed regulation in the Federal

Register and a period of not less than 60 days for public comment thereon."). According to plaintiffs, though the MMA instructs that the Secretary may not award any contract before determining whether a bidder "meets applicable financial standards *specified* by the Secretary," 42 U.S.C. § 1395w-3(b)(2)(A) (emphasis added), in the rules published for notice and comment, defendants "have only required submission of certain financial documents, and have not specified what financial standards they will use to evaluate such documents." Complaint ¶ 28; *see also id*. at ¶ 33 (same). In light of these purported shortcomings, plaintiffs ask this Court to set aside the Secretary's 2009 interim final rule under APA § 706(2). Complaint ¶¶ 30 & 34. Having reviewed the administrative record, the Court is unconvinced.

In evaluating defendants' motion to dismiss, the Court "may consider the facts alleged in the complaint, documents attached thereto or incorporated therein, and matters of which it may take judicial notice," *Stewart v. Nat'l Educ. Ass'n*, 471 F.3d 169, 173 (D.C. Cir. 2006)—including publications in the *Federal Register*. *Banner Health v. Sebelius*, No. 10 Civ. 1638, 2011 U.S. Dist. LEXIS 76706, at *39 (D.D.C. July 15, 2011). Reviewing the record, there can be no serious dispute that plaintiffs were given an adequate opportunity to comment on the financial standards. To briefly recap, after PAOC held several public meetings seeking input on the DME Bidding Program, the Secretary published a notice of proposed rulemaking that, *inter alia*, noted the various purposes for reviewing financial standards—such as the estimation of total capacity and ability to serve market demand through the duration of applicable contracts—explained that factors such as adequate financial ratios, positive credit history, net worth and solvency were important in the earlier demonstrations, and discussed various types of documentation likely to be requested in the specific requests for bids. *See generally* 71 F.R. at 25675. In closing, the Secretary expressly "welcome[d] comments on the financial standards."

Id.[17] "'Notice is sufficient if it affords interested parties a reasonable opportunity to participate in the rulemaking process, and if the parties have not been deprived of the opportunity to present relevant information by lack of notice that the issue was there.'" *Am. Radio Relay League, Inc. v. FCC*, 524 F.2d 227, 236 (D.C. Cir. 2008) (quoting *WJG Tel. Co. v. FCC*, 675 F.3d 386, 389 (D.C. Cir. 1982)). In this instance, the Secretary specified what financial documents would be necessary, described the purposes behind the evaluation of financial viability, listed the types of financial ratios that might be used, and invited comments and suggestions concerning these standards. The law requires no more—particularly when the record shows the process was sufficient to elicit comments directed at both the level of detail concerning financial standards and the use of particular financial standards, such as debt-to-equity ratio and credit rating. *See First Am. Discount Corp. v. CFTC*, 222 F.3d 1008, 1015 (D.C. Cir. 2000) (finding record of comments on subjects complained of by plaintiffs to constitute evidence that sufficient notice-and-comment process was undertaken).

The Court suspects that plaintiffs' argument is not that defendants allowed *no* notice and comment of potential financial standards, but rather that the notice and comment was insufficient because the Secretary's proposed rule did not adequately specify the *precise* methodology used to calculate financial soundness. *See* Complaint ¶ 28 (protesting that defendants "have not specified what financial standards they will use"); MTD Opp. at 25 (insisting that proposed rule "did not propose any *specific* financial standards") (emphasis added). The Secretary cannot be

[17] To the extent plaintiffs found their claims on the lack of proposed rules preceding publication of the 2009 interim final rule, that claim would be futile. With respect to the financial standards, there were no substantive changes between the 2006 proposed rule, the 2007 final rule, and the 2009 interim final rule—a fact plaintiffs concede. *See* Complaint ¶ 18 ("The interim final rule altered only very slightly and insignificantly the substantive rules regarding 'Financial standards' that were contained in the 2007 final rule."). In such circumstances, any need for notice and comment is obviated both by the express language of the Medicare Act, as well as the APA's good cause exception. *See* 42 U.S.C. § 1395hh(a)(4) (articulating exception to notice and comment rulemaking where subsequent rules are "logical outgrowth" of prior rules); *see also Methodist Hosp. v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994) (applying APA's "good cause" exception to notice-and-comment rulemaking to "logical outgrowth" doctrine).

compelled to publish a proposed rule for notice and comment that goes further than required by the underlying statute; accordingly, the key issue is whether the Secretary is required to articulate financial standards at the level of specificity urged by plaintiffs.

Turning to this underlying question, the relevant language of both the MMA and the MIPPA states only that the Secretary may not award a contract unless a potential bidder "meets applicable financial standards specified by the Secretary," 42 U.S.C. § 1395(b)(2)(A)(ii)—the text itself provides no more guidance beyond this general statement. Where Congress "has 'not specified the level of specificity expected of the agency, the agency is entitled to broad deference in picking a suitable level.'" *Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 217 (D.C. Cir. 2007); *see also Animal Legal Defense Fund, Inc. v. Glickman*, 204 F.3d 229, 235 (D.C. Cir. 2000) ("[W]e accord agencies broad deference in choosing the level of generality at which to articulate rules."). Similarly, if the underlying statutory language does not require a particular methodology, the Court cannot demand that the agency implement such a test. *See New Mexico v. EPA*, 114 F.3d 290, 295 (D.C. Cir. 1997) (holding that EPA need not incorporate particular tests when evaluating applications if relevant statutory language "does not explicitly require" such tests). Thus, for example, in *Cement Kiln* the D.C. Circuit upheld EPA's regulation instructing applicants to submit "'additional information . . . necessary to determine whether additional controls are necessary to ensure protection of human health and the environment," 493 F.3d at 213, where the underlying statute required applicants to submit "information as may be required" in any request for an applicable permit. *Id*. at 217 (citing 42 U.S.C. § 6925(b)). In doing so, the Circuit Court relied on nine factors that EPA had published and that the agency would evaluate in reviewing this additional information, *id*. at 220, explaining that "[s]ince this is EPA's interpretation of its own regulation, it 'is controlling unless plainly erroneous or

inconsistent with the regulation.'" *Id*. (quoting *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2349 (2007)).

In this instance, the Secretary laid out several purposes behind requesting particular financial information, including the ability to assess the "expected quality," "total potential capacity," and ability to "serve market demand" of potential suppliers. 71 F.R. at 25675. She also articulated particular documents that might be needed, gave various examples of financial information that would be evaluated, and directed interested parties to a website listing ten specific financial ratios that CMS would consider. Thus, just as in *Cement Kiln*, because the MMA and MIPPA "do[] not mandate any particular level of specificity at which [the agency] must define the [financial standards] . . . [the Court] must therefore defer to a reasonable [agency] interpretation as to the degree of detail required." 493 F.3d at 218.

The Secretary's choice to employ broad principles rather than precise formulas with respect to applicable financial standards is supported by the legislative history of the underlying statute. The MMA was passed as part of a section entitled "Combatting [*sic*] Waste, Fraud and Abuse," H.R. Rep. No. 108-178(II), at 189, and was designed to both combat fraud and provide the Secretary with flexibility to make necessary changes as the Program expands. *See* 2008 Hearing Tr. at 6 (statement of Rep. Stark) (noting importance of accreditation process in combating "excessive fraud and waste" in DME industry); 71 F.R. at 25659 (describing "many examples of fraud and abuse" in process for DME acquisition under Medicare before DME Bidding Program); *id*. at 25675 (noting that agency "will further consider which individual measures should be required"). "[J]udicial deference is at its highest in reviewing an agency's choice among competing policy considerations . . . including the choice . . . of the level of generality at which it will promulgate norms implementing a legislative mandate." *Metro Wash.*

Airports Auth. Prof. Fire Fighters Ass'n Local 3217 v. United States, 959 F.2d 297, 300 (D.C. Cir. 1992). In this instance, defendants cogently explain the purposes behind the general standard chosen by the Secretary. With respect to combating fraud, defendants state:

> Armed with the knowledge of CMS's minimum financial qualifications standards, firms in danger of falling below CMS's 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 [such entities] knew precisely what information the Secretary deemed most important.

MTD at 34. And the need for flexibility is inherent as the DME Bidding Program moves from the limited-demonstration context to a nationwide rollout, where the financial capabilities of potential suppliers may vary by region. "Provided an agency's interpretation of its own regulations does not violate the constitution or a federal statute, it must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Nat'l Med. Enters. v. Shalala*, 43 F.3d 691, 697 (D.C. Cir. 1995) (quotations omitted). In this instance, the need to maintain a general, flexible standard accords with the underlying purposes of the DME Bidding Program, and does not otherwise violate the plain terms of § 1395w-3. *See Animal Legal Defense*, 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."). And because plaintiffs point to nothing in either the statute or legislative history indicating that Congress requires the Secretary to publish a specific methodology for calculating financial viability, the Court will not impose such a demand in this case. *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 192 (D.C. Cir. 1993).

Finally, the Secretary's choice of a broadly worded standard rather than a precise methodology was also confirmed by congressional action. At the hearing before the House Committee on Ways and Means that preceded enactment of the MIPPA, Congress received

substantial testimony concerning the financial standards promulgated by the Secretary, as well as those standard's perceived lack of specificity. *See* 2008 Hearing Tr. at 17 (statement of Rep. Johnson) (lamenting lack of "cross-talk between the guys submitting bids to tell them that they didn't have all the [financial] information"); *id*. (statement of Mr. Weems) (explaining that CMS would "compute certain financial rations [*sic*] that would tell us the financial strength of that company"); *id*. at 25 (statement of Mr. Weems) (informing Congress that CMS had not "disclosed . . . exactly how we use the financial rations [*sic*] in judging the financial viability of each bidder. . . . We have told them the ratios that we would use, but we have not told them how that would be scored"); *id*. (statement of Rep. Tiberi) ("Some would say that the process . . . 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 . . . suppliers."); *id*. at 30 (statement of Mr. Ryan) (complaining that "the development and implementation of this bidding program have been shrouded in secrecy"). Yet despite Congress having been put on notice of concerns as to the lack of precise financial standards, *CBS, Inc. v. FCC*, 453 U.S. 367, 383–84 (1981), and despite its acquiescence to suppliers' plea "to immediately halt the implementation of this program" and "independently evaluate[]" the concerns raised at the hearing, 2008 Hearing Tr. at 30 (statement of Mr. Ryan), Congress did not see fit to alter its directions to the Secretary concerning financial standards *at all*. "'[T]he 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.*, 453 U.S. at 382 (quoting *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 381 (1969)). "Such deference 'is particularly appropriate where . . . an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory

objectives.'" *Id*. (quoting *United States v. Rutherford*, 442 U.S. 544, 554 (1979)). In this instance, Congress was made expressly aware of the precise concerns that plaintiffs articulate with respect to the specificity of the Secretary's rulemaking, but did nothing to alter the statute in response. "'Congress' failure to repeal or revise the statute in the face of such administrative interpretation is persuasive evidence that that interpretation is the one intended by Congress.'" *CBS, Inc.*, 453 U.S. at 385 (quoting *Zemel v. Rusk*, 381 U.S. 1, 11 (1965)).

Having found that the Secretary's choice of a general description of applicable financial standards under the DME Bidding Program is consistent with the text of the MMA, promotes the purposes behind the Program, and has been affirmed by Congress, the Court concludes that the Secretary's notice and request for comment on these broad principles—rather than on more precisely defined calculations—violates neither APA § 553 nor 42 U.S.C. § 1395hh, and thus plaintiffs fail to state a legal claim under either statute.[18]

2. Publication of Standards

Turning to plaintiffs' allegations concerning adequate publication of the financial standards, FOIA provides that, "[e]xcept to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published." 5 U.S.C. § 552(a)(1). Plaintiffs' claim premised on this section fails for two independent reasons.

[18] To the extent plaintiffs' argument is that the financial ratios specified on the DME Bidding Program's website should have been part of the official notice-and-comment process, this protest fails. Interpretive rules, which "merely clarify or explain existing laws or regulations," are not subject to § 553's notice-and-comment requirements. *Nat'l Med. Enters.*, 43 F.3d at 697. In this instance, the Secretary's specification of ten particular financial ratios did not alter suppliers' requirements concerning which financial records must be submitted, nor did it alter the requirement that those entities meet financial standards used to "assess[] the expected quality [and] total potential capacity of suppliers," and "ensur[e] that selected suppliers are able to continue to serve market demand." 71 F.R. at 25675. As interpretive rules, these ratios merely clarified *how* the Secretary will determine whether a bidder meets these requirements—they do not alter the substance of the regulations themselves. *See Nat'l Med. Enters.*, 43 F.3d at 697 (finding computation to be "interpretive" "because it solely concerned an agency's interpretation of the term 'average pay'"). Nor does the possibility that use of these particular ratios might affect CMS's choice of suppliers alter this result. *Chamber of Commerce v. Dep't of Labor*, 174 F.3d 206, 211 (D.C. Cir. 1999).

As an initial matter, §552(a)(1)'s publication requirement is subject to an express exception for actual notice. *See* 42 U.S.C. § 552(a)(1) ("Except to the extent that a person has actual and timely notice of the terms thereof . . . ."); *see also Kennecott Utah Copper Corp. v. Dep't of the Interior*, 88 F.3d 1191, 1203 (D.C. Cir. 1996) (noting that § 552(a)(1) applies "unless . . . the person had actual and timely notice of" regulatory requirements). Accordingly, "to make out a claim under [§552(a)(1)], a litigant must demonstrate that it . . . did not have actual notice of the content of that policy." *Mass. Mfg. Extension P'ship v. Lock*, 723 F. Supp. 2d 27, 41 (D.D.C. 2010). In the published rules, the Secretary explained the need for consideration of financial standards, and published particular examples of standards that would be considered. 71 F.R. at 65765. This was, of course, preceded by a substantial public education program, and was followed by development of a website that provided increased detail on the particular financial standards and ratios to be used in the DME Bidding Program. *See supra* Section II.A. Indeed, the Secretary published information about this website, and referred interested parties to it, in the original rules. 71 F.R. at 25658. Plaintiffs, however, simply ignore this publicly-available information, and instead allege that they "do not have actual knowledge of the specified financial standards applied, or being applied, by Defendants." Complaint at ¶ 38. This recitation—which is the *only* allegation concerning plaintiffs' knowledge—is conclusory and need not be accepted by the Court. *Mass. Mfg.*, 723 F. Supp. 2d at 41. Accordingly, the Court finds that plaintiffs have failed to allege sufficient facts to support an inference that they lacked actual knowledge of the applicable standards.[19]

[19] Moreover, because plaintiffs do not allege that they have been rejected from the DME Bidding Program due to the unavailability of particular financial standards, the only remedy available to plaintiffs under this provision is to compel the Secretary to provide such information. Complaint ¶ 39. Defendants have repeatedly articulated published financial ratios in the course of this litigation; accordingly, plaintiffs FOIA claim is now moot, and must be dismissed. *See Lemon v. Geren*, 514 F.3d 1312, 1315–16 (D.C. Cir. 2008) ("A case becomes moot when intervening events make it impossible to grant the prevailing party effective relief.") (quotations omitted).

The second shortcoming with regard to plaintiffs' allegations is the absence of any adverse effect that plaintiffs have suffered as a result of the purported non-publication. The purpose of § 552 is to "protect[] a person from being 'adversely affected by' a regulation required to be published in the Federal Register," *Kennecott*, 88 F.3d at 1203, and thus a plaintiff "must show that he was adversely affected by a lack of publication or that he would have been able to pursue an alternative course of conduct had the information been published." *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1136 (D.C. Cir. 1996). Plaintiffs, however, allege no injury or loss under the statute as a result of the lack of information. Indeed, similar to their standing problems, plaintiffs simply cannot explain how publication of more specific information will change *anything*. Plaintiffs' members' financial conditions cannot be changed, but remain unalterable *facts* that either will or will not meet applicable financial standards—regardless of whether the Secretary publishes such standards. Absent some other explanation—which plaintiffs do not provide—the lack of publication could not have "adversely affected" plaintiffs.

3. *Ultra Vires* Action

Finally, plaintiffs' allegation that defendants have acted *ultra vires* is insufficient to withstand a Rule 12(b)(6) challenge. As an initial matter, though plaintiffs are correct that the Secretary's rules are general in nature, nothing in the statute requires the Secretary to rely upon a precise or particular method for calculating financial soundness. *See supra* Section IV.A. The Secretary's actions here—which illuminate the purposes behind the standards, give examples of ratios used, and publish interpretive rules for application of those standards—plainly evince that the Secretary has satisfied this command. Indeed, the very fact that the Secretary has repeatedly pointed to particular goals and specific financial measures belies any contention of arbitrary or *ad hoc* decisionmaking. And in light of the regulatory record in this matter, plaintiffs' allegation

that defendants "have failed to specify financial standards that DME suppliers must meet . . . as mandated by the MMA, even internally and regardless of public notice and comment requirements, and are failing to apply such standards in evaluating and qualifying DME supplies," Complaint ¶ 41, is insufficient to overcome the presumption of agency regularity, *See La. Ass'n of Indep. Producers & Royalty Owners v. FERC*, 958 F.2d 1101, 1111 (D.C. Cir. 1992) ("The Coalition cannot, by sheer multiplication of innuendo, overcome the strong presumption of agency regularity. . . . Despite all their sound and fury, the attacks of the Coalition ultimately prove impotent.") (citations omitted), and must be rejected as conclusory. *See Stewart*, 471 F.3d at 173 ("[T]he court need not accept legal conclusions cast in the form of factual allegations.") (quotations omitted).

* * *

One final comment is in order. Plaintiffs spill much ink in their opposition to defendants' motion to dismiss on the proper scope of Federal Rule of Civil Procedure 8. Plaintiffs begin by noting that "[a] motion to dismiss for failure to state a claim upon which relief can be granted under FRCP 12(b)(6) *is necessarily* a claim that the Plaintiffs' Complaint does not satisfy FRCP 8(a)(2)." MTD Opp. at 23 (emphasis added). This is incorrect. Rule 12(b)(6) and Rule 8, while interrelated, are not identical; the former "tests the legal sufficiency of the complaint" while the latter requires that a complaint give defendants "fair notice of the claim." *Kingman Park Civic Ass'n v. Williams*, 348 F.3d 1033, 1040 (D.C. Cir. 2003); *see also Herero People's Reparations Corp. v. Deutsche Bank AG*, No. 01 Civ. 1868, 2003 U.S. Dist. LEXIS 27094, at *39 (D.D.C. July 31, 2003) (noting that complaint fails if it does not satisfy "Rule 8 *or* Rule 12") (emphasis added). It is quite easy to imagine scenarios in which the operative complaint sets forth facts sufficient to give notice of claims, yet simultaneously fails to state a *legal claim for relief*. For

example, a Title VII plaintiff may fully allege the elements of a discrimination claim, but the allegations may also make clear that the plaintiff has filed suit beyond the applicable statute of limitations—foreclosing any entitlement to relief. In dismissing such a suit, the Court surely does not conclude that the allegations failed to give the defendants *adequate notice* of the facts and claims, but rather finds that the facts—as alleged—do not state a *legal claim for relief*.

Turning to this case, when determining if the Complaint states a legal basis for relief, the Court is "not . . . required to speculate that factual propositions unmentioned, or evidentiary links unrevealed, are among the facts plaintiff intends to prove at trial." *ACLU v. Barr*, 952 F.2d 457, 472 (D.C. Cir. 1991) (citing 5A Wright & Miller, *Federal Practice and Procedure* ¶ 1357, at 311 (2d ed. 1990)). And the Court "accept[s] neither inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint, nor legal conclusions cast in the form of factual allegations." *Browning*, 292 F.3d at 242 (quotations omitted). The judicially noticeable administrative record defines the scope of the notice-and-comment rulemaking undertaken by the Secretary, and the Court—relying on those facts—has determined that the Complaint does not make out a *legal claim for relief*. In doing so the Court does not suggest that defendants—or it—are somehow unaware or not on notice of the substance of plaintiffs' claims. Rather, the Court has simply relied on matters published in the *Federal Register* to dismiss a complaint under Rule 12(b)(6), where those publicly available facts contradict and undermine plaintiffs' allegations. *See, e.g.*, *Am. Farm Bureau v. EPA*, 121 F. Supp. 2d 84, 105 (D.D.C. 2000). Plaintiffs' reliance on Rule 8 for legal cover is therefore entirely misplaced.[20]

[20] Having concluded that the Court lacks subject-matter jurisdiction and that the Complaint fails to state a claim for relief, the Court need not linger long on plaintiffs' multiple requests to amend the Complaint. As defendants correctly point out—and plaintiffs do not dispute—the new complaints do not add any allegations that would alter the Court's analysis of statutory preclusion or of the merits of plaintiffs' claims. And while the new complaints do add certain allegations concerning standing, these new allegations are insufficient. *See supra* Section IV.B.1. Thus, as plaintiffs' requested amendments do not remedy these multiple deficiencies, the Court will deny their motions. *Bowie v. Maddox*, 642 F.3d 1122, 1132 (D.C. Cir. 2011).

V. CONCLUSION

Congress has directed HHS and CMS to develop a competitive bidding program for the purchase of DME, has imbued the Secretary with considerable discretion to design and implement the Program, and has shielded that process from judicial review. In response, the Secretary has chosen to articulate a general standard to evaluate DME suppliers' financial viability—setting forth examples of financial metrics that will be considered and explaining the purposes for conducting such a review—and has provided several opportunities for public comment on the incorporation of these standards into the Program. Plaintiffs now ask this Court to hold that the Secretary's choice of a broad-based test for financial viability is insufficient, and to direct the Secretary to redesign the Program to incorporate a more precise formula. But the underlying statute neither permits such review nor requires the increased specification plaintiffs seek, and plaintiffs' perceived injuries are insufficient to invoke the judicial power. This action must therefore be dismissed.

A separate Order consistent with these findings shall issue this date.

Signed by Royce C. Lamberth, Chief Judge, on September 9, 2011.