UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEXAS ALLIANCE FOR HOME CARE SERVICES, et al., Plaintiffs, vs. KATHLEEN SEBELIUS, Secretary of the U.S. Department of Health and Human Services, et al., Defendants.	)	Civil Action No. 1:10-cv-00747 (HHK)

PLAINTIFFS' MEMORANDUM IN RESPONSE TO DEFENDANTS' MOTION TO DISMISS
(corrected copy)

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(corrected copy)

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I. Background

A. Nature of the Case and Its Current Posture

This case involves issues regarding implementation of the Medicare provisions applicable to HHS' selection of contract providers of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). 42 U.S.C.A § 1395w-3. Plaintiffs' Complaint seeks APA judicial review of Defendants' (hereafter "HHS") (a) failure to provide sufficient *Federal Register* notice and opportunity for public comment on its regulatory proposal for "financial standards . . . taking into account the needs of small providers" required to be "specified" by the Secretary under the DMEPOS statutory provisions in order to qualify bidders such as Plaintiffs to be suppliers, in violation of the notice and comment provisions of the APA, 5 U.S.C. § 553(b) and (c), and of the Medicare statutory provisions for notice and comment, 42 U.S.C. § 1395hh; (b) failure to publish in the *Federal Register*, or provide actual notice to, applicant suppliers regarding the required specific "financial standards" that DMEPOS bidders must meet, in violation of the Freedom of Information Act, 5 U.S.C. § 552; and (c) failure to specify and apply, even internally, to bidder applications submitted by Plaintiffs the specific "financial standards" as required by the statute to be specified.

HHS is currently evaluating DMEPOS Round I re-bid applications and bidders, including Plaintiffs and their completed bid applications, to determine to which bidders they will offer DMEPOS contracts, and they have announced that they expect to announce winning contractors, and begin contractor education, in "Early Fall 2010." The new contracts are then expected to go into effect in January 2011. The next round of bidding, the Round II re-bid, will then be conducted during 2011, and Round III after that. All of the re-bid rounds are governed by the same statutory provisions, including the requirement that bidders be determined by HHS to meet

"financial standards, taking into account the needs of small providers" "specified" by HHS.

At present, and since the DMEPOS competitive bidding program was legislatively enacted in 2003, Plaintiffs and other DMEPOS suppliers subject to Round I re-bids are furnishing DMEPOS to Medicare beneficiary patients under the existing Medicare fee schedules. The same is true for other current DMEPOS suppliers who will be subject to Round II and III re-bids in the future.

Before the court is HHS' Motion to Dismiss under Fed. R. Civ. P. 12(b)(1) and 12(b)(6) (hereafter "FRCP"). The 12(b)(1) portion of the Motion argues (1) that any judicial review of the claims for relief made in the complaint is precluded by the statutory prohibitions of judicial review of the "the awarding of contracts" and of "the bidding structure" in 42 U.S.C.A. § 1395w-3(b)(11)[1];" and (2) that the Plaintiffs have not sufficiently alleged Article III standing. The 12(b)(6) portion of the motion argues that the complaint fails to state a claim upon which relief can be granted. Importantly, although HHS' Motion appears to seek dismissal of the entire Complaint, their supporting Memorandum does not challenge under FRCP 12(b)(6), with any legal argument, that Plaintiffs have failed to state claims upon which relief can be granted in their First and Second Causes of Action regarding failure to provide adequate notice and opportunity to comment on the required specification of "financial standards."[2] Therefore, if the

[1] This statutory provision is cited to U.S.C.A. instead of U.S.C. because the provision was amended in 2008, and the latest version of the U.S.C. is 2006. The provision was renumbered as paragraph (11) instead of (10) in 2008. Provisions that were not amended in 2008 are cited to U.S.C.

[2] At various points in its Memorandum, HHS refers in a cursory manner to having conducted notice and comment rulemaking (pp. 1 and 8 in the introductory and factual sections and pp. 19 and 28 in the Argument section), but they only make conclusory and clearly inaccurate statements. For example they state that Plaintiffs' claim of inadequate notice and comment is simply a "guise" for a challenge to the substance of the financial standards (19); that there can be "no question" that Plaintiffs had ample opportunity to comment (19); that Plaintiffs "do not challenge" the adequacy of the notice and comment proceedings (28); and that "[e]ven if the notice and comment procedures ... were somehow deficient," Plaintiffs cannot show substantial probability of injury to establish standing. Def. Mem. at 28-29). HHS never argues that

Court concludes that it has subject matter jurisdiction because judicial review is not precluded by law and because Plaintiffs have adequately alleged Article III standing, thereby denying the 12(b)(1) portion of the Motion to Dismiss, this case cannot be wholly dismissed for failure to state a claim upon which relief can be granted because the Motion and Memorandum do not challenge the notice and comment claims for relief.[3]

B. Statutory and Regulatory Background

Congress established the DEMPOS competitive bidding program in 2003 to eventually replace the existing fee schedule approach in hopes of saving money. 42 U.S.C. § 1395w-3, Pub. L. No. 108-173 § 302, 117 Stat. 2223. Under the 2003 legislation (usually referred to as the Medicare Modernization Act or "MMA"), Round I of the new competitive bidding system was to occur in 2007, with contracts being awarded in 2008. In 2008, due in large part to controversy over rejection of bids for supposed failure of bidders to submit all required documentation, Congress amended the DMEPOS provisions to provide procedures for review of such documentation and delayed the competitive bidding program for two years, so that Round I would not begin until 2009.[4] These changes were part of the 2008 Medicare Improvements and Patients and Providers Act, or "MIPPA," Pub. L. No. 110-275 §154, 122 Stat. 2560. However, the statutory provisions involved in this suit have not changed in substance since 2003 (other than the 2008 renumbering of § 1395w-3(b)(10) to (11) and addition of another paragraph

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Plaintiffs have failed to state a valid claim for relief with regard to inadequate notice and opportunity to comment. They never even argue that, under the law regarding notice and comment, the notice and opportunity to comment were legally sufficient. Plaintiffs contend that HHS has waived this issue for 12(b)(6) by not raising it in their initial memorandum. See n. 16, *infra*.

[3] This Circuit has repeatedly held that "'an argument first made in a reply brief ordinarily comes too late for our consideration.'" *See Amgen, Inc. v. Smith*, 357 F.3d 103, 117-18 (D.C. Cir. 2004) and cases cited therein.

[4] The Westlaw version of U.S.C.A. is inaccurate in not reflecting the delay in Round I bidding from 2007 to 2009.

precluding judicial review that is not at issue in this case). Contracts to be awarded under the Round I re-bid are expected to become effective in January 2011. Until each new round of DMEPOS re-bid contracts go into effect in their three phases, the DMEPOS program will be conducted as it was before 2003 under existing contracts and the fee schedule.[5]

When Congress adopted a competitive bidding program for DMEPOS in 2003, it mandated that HHS must find that a DMEPOS competitive bidder meets "financial standards specified by the Secretary, taking into account the needs of small providers" in order for the bidder to be considered for a contract award. 42 U.S.C. § 1395w-3(b)(2)(A)(ii). Whether a bidder meets the "specified" "financial standards" is only one of a number of conditions that must be satisfied in order for it to obtain a contract award. For example, a successful bidder must meet specified "quality standards;"[6] the total amounts to be paid to all contractors (*i.e.*, successful bidders) in a particular competitive acquisition area must be below a certain amount; and access of individuals to a choice of suppliers in the particular area must be maintained. In addition, the Secretary may impose "terms and conditions" in any contract, may limit the number of contractors in a particular area to the number needed to meet projected demand, and must take into account a bidder's ability to meet projected demand in the geographic area covered by the contract. 42 U.S.C. §§ 1395w-3(b).

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[5] If this suit were to result in any delay in implementation of Round I due to *vacatur* of the final rulemaking and HHS having to provide adequate notice and comment rulemaking on the financial standards portion of the rulemaking and then apply the financial standards to Round I re-bid bidders, the delay would be small compared to those that have already taken place. Seven years have already passed since Congress amended the law to require competitive bidding instead of a fee-based system, with no apparent significant adverse impacts. Congress also was not concerned with additional delay when it postponed the program, with minor changes, for more than two years in 2008. Additionally, DMEPOS is only a very small part of the Medicare budget.

[6] 42 U.S.C. § 1395w-3(b)(2)(A)(i) (the provision immediately preceding the provision requiring bidders to be found to meet specified "financial standards"). The statute allowed the quality standards to be established "by program instruction or otherwise" and to be published on the website of the Centers for Medicare & Medicaid Services, pursuant to 42 U.S.C. § 1395m(a)(20)(E). The requirement for specification of "financial standards" does not allow this.

HHS briefly raised the subject of "financial standards" in the 2006 *Federal Register* notice of proposed rulemaking for implementation of the MMA. 71 Fed. Reg. 25654, 23675 (May 1, 2006). Although the notice stated that it would "welcome comments on the financial standards," it did not propose any particular standards, provide any reasoning, or discuss the issue or alternative approaches, and the substantive portion of the proposal (as opposed to the preamble) proposed only a requirement that "[a]ll suppliers must meet the applicable financial standards specified in the request for bids."[7] 71 Fed. Reg. at 25700.[8]

A notice of final rulemaking was issued on April 10, 2007. 72 Fed. Reg. 17992. The notice of final rulemaking also discussed "financial standards" in the preamble, but did so only in terms of the financial documents required from bidders and the financial information in those documents that would be considered, stating that HHS would "use appropriate financial ratios" to evaluate bidders and giving some examples of such ratios that it "might consider." 72 Fed. Reg. at 18072. The substantive portion of the notice stated with regard to financial standards only that "[e]ach supplier must submit along with its bid the applicable financial documentation specified in the request for bids." 72 Fed. Reg. at 18088.

On January 16, 2009, HHS issued an "interim final rule" to implement the changes made by MIPPA.[9] 74 Fed Reg. 2873. The interim final rule addressed "financial standards" in

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[7] The request for bids ("RFB") was not published as part of the notice of proposed rulemaking.

[8] There is a typographical error in the Complaint regarding this citation. Paragraph 14 incorrectly cites the *Federal Register* volume as 75 instead of 71; however, it is clear from the previous paragraph that the correct volume is volume 71. There is also a typographical error in paragraph 15 regarding the final rule. The volume given is 68, when the correct volume is 72, and 68 is the issue number within the volume. The date and page numbers are correct, however.

[9] This circuit has held that an interim final rule is a final rule. *Career College Ass'n v. Riley*, 74 F.3d 1265, 1268 (D.C. Cir. 1996); *Beverly Enter., Inc. v. Herman*, 50 F. Supp. 2d 7, 17 (D.D.C. 1999). The only difference between an interim final rule and a final rule is that an interim final rule can only stay in effect for a certain period of time. *Id*. During that time, the agency might also seek public comment on the interim final rule. Thus, there is final agency action for purposes of APA judicial review. *And see* 42 U.S.C. § 1395hh(a)(3)(A) and (C).

essentially the same manner as in the 2007 final rule, simply requiring submission of financial documents without specifying what standards would be applied in evaluating those documents and determining eligibility for contracts. 74 Fed. Reg. at 2880 3d col.

C. Factual Background

Following the above 2008 Congressional mandate to restart the DMEPOS bidding process and the above January 2009 interim final rule, HHS announced via website on August 3, 2009, a timeline for implementation of the Round I re-bid process. Available at https://www2.cms.gov/DMEPOSCompetitiveBid/01A0_Timeline.asp#TopOfPage (last accessed August 3, 2010). Accreditation under the quality standards was to be completed by September 30, 2009. The actual re-bid process began with a 60-day period beginning October 21, 2009 during which bidders were required to submit required financial documents. The timeline sets "target dates" for beginning the contracting process in July 2010 and announcing selected contract suppliers in September 2010. The timeline's target date for actual implementation of the Round I re-bid contracts and prices is January 1, 2011. .

It is not known whether bidders who do not receive contract offers will be notified of the specific reasons why they were not selected -- in particular whether they failed to meet specified financial standards and why they were determined not to meet those standards.

Plaintiff Texas Alliance for Home Care Services represents DMEPOS suppliers in Texas, many of which were accredited and submitted the required financial documentation in 2009. The majority of those suppliers are small businesses. Plaintiff Dallas Oxygen Supply, a member of the Texas Alliance for Home Care Services, and currently a DMEPOS supplier, was re-accredited in 2009 and submitted the required financial documentation in 2009.

II. Standard of Review

The standard of review is different for each of the three arguments presented by HHS for dismissal of the Complaint (preclusion, lack of standing, and no statement of a claim upon which relief can be granted), and the applicable standard will be set out in connection with each argument. Common to all three, however, are the canons that the court "accepts as true all of the factual allegations contained in the complaint and draws all inferences in favor of the nonmoving party." *City of Harper Woods Employees' Retirement System v. Olver*, 589 F.3d 1292,1298 (D.C. Cir. 2009).

III. Argument

A. Judicial Review Is Not Precluded

Plaintiffs claim a right to judicial review of final agency action under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* The APA applies "except to the extent that ... statutes preclude judicial review." 5 U.S.C. § 701(a)(1).

In APA cases there is "strong" presumption in favor of APA judicial review of final agency action, and against preclusion, and a party opposing judicial review faces the "heavy burden" of showing, by "persuasive" and "clear and convincing evidence," that Congress intended to preclude judicial review. The required "clear and convincing" evidence of Congressional intent to preclude judicial review must be based on "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." "The right to judicial review is too important to be excluded on ... slender and indeterminate evidence of legislative intent." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670-73 (1986) ("*Bowen*"). *See also McNary v. Haitian Refugee Ctr., 498 U.S. 479,*

496-99 (1991); Gutierrez de Martinez v. Lamagno, 515 U.S. 417, 423-25 (1995); Bartlett v. Bowen, 816 F.2d 695, 699 (D.C. Cir. 1987); *Am. Soc'y of Dermatology v. Shalala*, 962 F. Supp. 141, 145-46 (D.D.C. 1996); *Sharp Healthcare v. Leavitt*, 555 F. Supp. 2d 1121, 1124-25 (S.D. Cal. 2008) (prohibition of judicial review of "bidding structure" in DMEPOS bidding provisions of Medicare did not preclude judicial review of determination of who is required to bid and review of alleged failure to provide notice and comment under APA § 553; the prohibition was ambiguous). The *Sharp Healthcare* opinion makes an obvious but important point: If Congressional intent argued to preclude judicial review is ambiguous or vague, and therefore not clear and convincing, the court must find that judicial review is not precluded. *Id.*

The strong presumption in favor of judicial review is "particularly strong" in a case in which the preclusion issue is intertwined with issues of whether the agency exceeded its statutory authority, as it is here. *Amgen, Inc. v. Smith*, 357 F.3d 103, 111-12 (D.C. Cir. 2004). *Bowen* also concluded, in upholding judicial review, that "[w]e ordinarily presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command." *Bowen*, 476 U.S. at 681. *And see Sharp Healthcare*, 555 F. Supp. 2d at 1125. That is the situation here, where Plaintiffs allege that HHS has failed to obey the statutory command to specify "financial standards" that must be met by bidders as one element of qualifying as a potential contract supplier.

HHS does not reference or discuss any expressions of legislative intent relevant to the provisions they contend preclude judicial review, and Plaintiffs have not found any either. Therefore, HHS bears the "heavy burden" of showing that the plain wording of the provisions, or the "detail of the legislative scheme," provides "clear and convincing evidence" of Congressional intent to preclude judicial review, with particular consideration that Congress intends that its

statutory mandates be obeyed (in this case, the mandate to specify "financial standards").

The statutory provisions that HHS relies on to argue that there is clear and convincing evidence of Congressional intent to preclude judicial review of its compliance with the Medicare mandate to specify "financial standards," and of the APA and Medicare requirements for adequate notice and opportunity to comment on proposed rules, are paragraphs (B) and (F) in 42 U.S.C.A. § 1395w-3(b)(11). Subsection (b)(11) reads in its entirety as follows, with emphasis added to the provisions relied on by HHS[10]:

> (11) NO ADMINISTRATIVE OR JUDICIAL REVIEW. -- There shall be no administrative or judicial review under section 1395ff, section 1395oo of this title, or otherwise, of --
>
> (A) the establishment of payment amounts under paragraph (5);
>
> **(B) the awarding of contracts under this section**;
>
> (C) the designation of competitive acquisition areas under subsection (a)(1)(A) of this section and the identification of areas under subsection (a)(1)(D)(iii) of this section;
>
> (D) the phased-in implementation under subsection (a)(1)(B) of this section and implementation of subsection (a)(1)(D) of this section;
>
> (E) the selection of items and service for competitive acquisition under subsection (a)(2) of this section;
>
> **(F) the bidding structure** and number of contractors selected under this section; or
>
> (G) the implementation of the special rule described in paragraph (10).

One of the first things that stands out about subsection (11) is that it does not purport to be, as HHS suggests (p. 21), "'a scheme to insulate the entire [DEMPOS] program from review.'" Congress, very familiar with judicial review and how to preclude it, could easily have used language simply to preclude any action by the Secretary under the DMEPOS provisions; instead it only listed certain types of Secretarial actions. Most notably absent from subsection (11) is any mention of preclusion regarding the specification of "financial standards." Also conspicuously absent is preclusion of judicial review of the required specification of quality

[10] 42 U.S.C. § 1395ff addresses Medicare payments to individual beneficiaries. 42 U.S.C. § 1395oo addresses decisions by the Provider Reimbursement Review Board concerning reimbursement of Medicare benefits.

standards (a requirement contained in the provision immediately preceding the requirement to specify financial standards). Because the provision includes some aspects of the program and not others, the doctrine of *inclusio unius est exclusio alterius* applies at the outset. *See Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit*, 507 U.S. 163, 168 (1993).

HHS, however, apparently contends that the plain wording of "awarding of contracts" precludes judicial review for failure to comply with APA and Medicare requirements for notice and comment on the specification of financial standards, and for the requirement for specification itself, because the specification of financial standards and a determination that those standards have been met is a precondition to the "awarding of contracts." In other words, HHS contends that the preclusion provision should be altered to read something like "agency action in any way relating to the awarding of contracts," rather than simply "the awarding of contracts." But that is not what the law states.

The plain meaning of "awarding of contracts" is the actual awarding of, or a decision not to award, a specific contract to a specific entity, which has not yet occurred. As the Complaint alleges, "No contracts have yet been awarded." Compl. ¶ 22.

This plain meaning of the preclusion language "awarding of contracts" as applying only to the actual awarding of a specific contract to a specific entity is supported not only by its wording, but also by the language used in other sections of the DMEPOS provisions and as a matter of common sense.

Multiple provisions of the DMEPOS program refer to the awarding of contracts as an actual transaction between the Government and an individual entity or multiple entities.[11] The statute states that --

[11] In contrast, there is one provision that is worded as Defendants apparently would like paragraph (B) in the judicial review subsection to read. In subsection 1395w-3(b)(6)(D), on

- "the contracts awarded under this section before the date of enactment of this subparagraph are terminated" and no payment shall be made "based on such contract" (42 U.S.C. § 1395w-3(a)(1)(D)(i)(I));
- the Secretary "may not award a contract to any entity" unless the Secretary finds that the entity meets certain conditions, including meeting "applicable financial standards specified by the Secretary" (42 U.S.C. § 1395w-3(b)(2)(A));
- the Secretary may specify terms and conditions for a "contract entered into with an entity" (42 U.S.C. § 1395w-3(b)(3)(A));
- "[i]n awarding contracts" the Secretary may limit the number of contractors who receive contracts (42 U.S.C. § 1395w-3(b)(4)(A));
- the Secretary "shall award contracts to multiple entities" in each area for an item or service (42 U.S.C. § 1395w-3(b)(4)(B)); and
- no payments shall be made unless the Secretary "has awarded a contract" to a contractor (42 U.S.C. § 1395w-3(b)(6)(A)).

A reasonable and common-sense reading and meaning of the restriction on judicial review of the "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 challenging HHS decisions as to whether they were treated unfairly or failed to meet certain program requirements, such as whether they met specific financial standards or quality

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"Protection of small suppliers," the statute states that "[in] developing procedures relating to ... the awarding of contracts under this section" [emphasis added], the Secretary shall take steps to ensure that small suppliers have an opportunity to be considered for participation in the program. This language does not refer to the awarding of a contract to a specific entity or entities, and instead is much broader. Nor are such "steps" included in the preclusion provision.

standards.[12] Such a simple and reasonable interpretation is a far cry from an interpretation that Congress intended to immunize HHS from having to comply with the notice and comment requirements of the APA, Medicare, and FOIA, and a statutory mandate such as the requirement that the Secretary specify financial standards.

Although a *Bowen* analysis must be based on the language of the statute and other clear and convincing evidence of Congressional intent, HHS contends that there are numerous case precedents supporting their view that judicial review is precluded under the facts of this case, and that this court should follow those precedents. HHS asserts broadly that two cases in particular support the proposition that the list of subjects on which judicial review is precluded encompasses all aspects -- "design and implementation" -- of the DMEPOS competitive bidding program. Def. Mem. at 21-24. Of course the judicial review section does not state this, and it could have stated simply just that, and the cases cited and discussed -- *Carolina Med. Sales* and *All Florida Network*[13] -- are not relevant to the case at hand and cannot substitute for a reasoned *Bowen* analysis.

In *Carolina Med. Sales*, the plaintiffs argued that the designation by HHS of mail-order diabetic supplies as an item or service for competitive bidding was not justified under the statute, and that the preclusion of judicial review of "the selection [by the Secretary] of items and services for competitive acquisition under subsection (a)(2)" by paragraph (E) of 1395w-3(b)(11) did not apply. The court dismissed the complaint solely on the basis that this "explicit language" of paragraph (E) barred judicial review. *Carolina Med. Sales*, 559 F. Supp. 2d at 77. *And see id.* at 73 ("[T]he court disposes of this motion [to dismiss] on the grounds that the MMA precludes

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[12] Such a reading is reinforced by the subsection (b)(10) references to Medicare sections 1395ff and 1395oo, both of which involve fact-intensive determinations regarding individual benefits payments and reimbursement of providers. See n. 10, *supra*.

[13] *Carolina Med. Sales v. Leavitt*, 559 F. Supp. 2d 69 (D.D.C. 2008); *All Fla. Network Corp. v. United States*, 82 Fed. Cl. 468 (Fed. Cl. 2008).

judicial review of the Secretary's challenged decision to include mail-order diabetic supplies in the bidding program ...."), and at 75 ("[T]the question turns on whether § 1395w-3(b)(10)(E) precludes review."). The HHS suggestions that the court's decision addressed an issue of inadequate notice and comment under the APA (Def. Mem. at n. 20), and that the decision turned on whether 1395w-3(b)(11) contains "'broad, general'" language" from with the court "concluded" that the itemized list of subjects on which judicial review is precluded "'indicate[s] a scheme to insulate the entire program from review," are distortions of the court's opinion. The decision did not address notice and comment, and the statement in the opinion that "[t]he scope of the other areas of preclusion indicate [sic] a scheme to insulate the entire program from review, as does the broad, general language used" is a clear example of an *obiter dictum*.

HHS' citation of *All Fla. Network* is more on target in the sense that the decision was based on the 1395w-3(b)(11)(B) preclusion for the "awarding of contracts;" however, it essentially supports Plaintiffs' reading of the phrase "awarding of contracts" as referring to the actual awarding of specific contracts, or decision not to award, to specific entities. *All Fla. Network* involved a "post-award bid protest." 82 Fed. Cl. at 469. The Network had submitted bids and financial documents on behalf of its members to HHS. On the date when winning bidders (*i.e.*, those who had been awarded contracts) were announced, HHS (represented by its CBIC, the competitive bidding implementation contractor) sent the Network notification that it did not meet enrollment standards and had not submitted the required financial documents and therefore could not be awarded a contract. After the Network notified the CBIC and HHS that their determinations were erroneous, HHS conducted a further review and concluded that certain required financial documents (income statements) were still missing and that therefore it would not accept the bids and award contracts. The Network argued in court that because it could

demonstrate that this determination of missing documents was erroneous, HHS acted in an arbitrary and capricious manner and its decision did not have a rational basis. HHS moved to dismiss for lack of subject matter jurisdiction based on the statute's preclusion of judicial review of the "awarding of contracts." The court agreed with HHS that the preclusion of judicial review was "'clear and explicit'" in its plain language and therefore judicial review was precluded. *All Fla. Network*, 82 Fed. Cl. at 472-73. The court also stated that "Congress intended the Secretary of HHS to have the authority to expeditiously implement the DMEPOS bidding program . . . and [it] therefore precluded judicial review of "specific decisions" (emphasis added) pertaining to the "'awarding of contracts.'" *Id*. at 474. Thus, *All Fla Network* stands for the proposition that the preclusion regarding "awarding of contracts" embraces the making of specific contract award decisions involving specific entities. However, the case says nothing about preclusion of judicial review of the statutory mandate and duty of HHS to specify the "financial standards" that will be applied in qualifying all bidders, or its duty to follow notice and comment procedures in doing so.

Such a distinction -- between the establishment of standards or methods and the application of those standards or methods to a particular entity -- in preclusion cases was recognized in *Bowen* when the court explained 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." *Bowen*, 476 U.S. at 675 (original emphasis). The validity of this distinction expressed in *Bowen* was recognized very recently by this court in *Am. Nurses Ass'n v. Leavitt*, 593 F. Supp. 2d 126, 135-36 (D.D.C. 2009).

The two cases discussed by HHS for the proposition that courts have consistently given

effect to Medicare preclusion provisions did not involve the preclusion provisions involved here, and they actually support Plaintiffs' case for denial of the Motion to Dismiss.

In *Amgen Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), the first case discussed by HHS (at 23), the court dismissed the complaint based on a preclusion provision that is not relevant to this case. Moreover, in doing so, this circuit stated an important principle that is applicable to this case and that overcomes the preclusion arguments here. The court recognized the principle that the *Bowen* presumption of judicial review "is particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority," and when a preclusion issue is intertwined with an issue of whether an agency acted within its statutory authority, the court must determine whether the agency acted within its authority, and if it did not, such a determination of *ultra vires* action will generally override any preclusion language that is "less than absolute." *Amgen*, 357 F.3d at 111-12. In other words, an asserted preclusion provision must be construed in light of the ambit of the agency's authority, and if the agency's action is found to be *ultra vires*, an alleged preclusion provision that is anything less than "absolute" will not be construed so as to prevent judicial review of agency action that is allegedly unauthorized. *Id.* at 111-14 (citing *Leedom v. Kyne*, 358 U.S. 184, 190 (1958)). In the case at hand, not only are the preclusion provisions relied on by HHS at most ambiguous, but also, a finding of preclusion would prevent the court from addressing Plaintiffs' allegations that HHS has acted contrary to statutory mandates by not providing sufficient notice and opportunity for comment, by not specifying "financial standards" to apply to bidders, and that, even if they have prescribed financial standards internally without disclosing them to the public, they have acted contrary to the Freedom of Information Act by not publishing such standards in the *Federal Register* as required by 5 U.S.C. § 552. This court should not interpret the DMEPOS preclusion provisions

in such a way that it would not be able to address fundamental Congressional mandates.

The second case discussed by HHS (at 24), *Am. Soc'y of Cataract and Refractive Surgery v. Thompson*, 279 F.3d 447 (7th Cir. 2002) ("*ASCRS*"), also addressed a preclusion provision not at issue in the present case. In *ASCRS*, the court found that the preclusion provision was clear and explicit in barring the type of challenge mounted against the agency. *ASCRS*, 279 F.3d at 452 ("clear and explicit" prohibition of judicial review), 454 ("Petitioners' challenge is precisely what Congress sought to prohibit."). However, the court accepted Plaintiffs' argument, based on *Leedom vs. Kyne*, as in *Amgen, supra*, that even if there was a bar to judicial review, it would review whether the Defendant had "violated a clear statutory mandate and exceeded the scope of her delegated authority; but the court concluded that because "on the merits, we would find the Secretary's regulation to be a reasonable interpretation of an unclear statutory mandate, we do not find petitioners' argument [against preclusion] to be meritorious." *Id*. at 456.

HHS cites, at p. 23, without any discussion or explanation of the legal arguments they support, seven other cases that they concede involved other Medicare "no review" provisions not involved in this case, and then states rhetorically (at p. 24), with regard to those cases and the other two cases discussed above, that "this voluminous case law makes clear [that] Plaintiffs attack on the Secretary's financial standards process is but the latest in a long line of impermissible challenges that courts have rightly declined to entertain." Since the relevance of those seven cases in terms of the case at hand is not explained, Plaintiffs will not even attempt to discuss them other than to point out that, as HHS admits, they involved different preclusion provisions of Medicare, and obviously each case, with its different claims for relief and involving different preclusion provisions, must be considered on its own merits, applying the principles from *Bowen* and considering the unique wording and context of those particular

statutory provisions.

HHS' assertion that judicial review of the failure to provide adequate notice and comment for the specification of financial standards, and failure to specify any financial standards at all,[14] is also precluded by the language in paragraph (10)(F) prohibiting judicial review of "the bidding structure" is particularly far-fetched. The only explanation HHS offers for how this wording relates to the mandate to specify financial standards is the conclusory statement that "the Secretary's requirement that suppliers must provide certain financial documentation as a prerequisite for consideration is part of 'the bidding structure.'" Def. Mem. at 22. It certainly is not "clear and convincing" that Congress intended the phrase "bidding structure" to encompass specification of financial standards. If Congress had so intended, it obviously could have expressly designated specification of financial standards as immune from judicial review, as it did with other specific types of Secretarial determinations. The language is at most vague, not clear and convincing, as determined in *Sharp Healthcare*, *supra*, 555 F. Supp. 2d at 1124-25, with regard to that particular preclusion language. *Sharp Healthcare* also noted the related point from *Bowen* (476 U.S. at 681) that inherent in the Secretary's argument for preclusion was "the notion that he may disregard Congress' express statutory command", and that this would contradict the particularly strong presumption that "'Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command.'"

HHS has simply not sustained its heavy burden of overcoming by clear and convincing evidence of Congressional intent the very strong presumption in favor of judicial review, particularly when the issue of preclusion is intertwined, as it is here, with an issue of whether an

[14] To be clear, the Complaint here does not allege, as HHS suggests repeatedly, that HHS promulgated standards that were not sufficiently precise; the Complaint alleges that HHS has not properly proposed for comment or promulgated any standards at all.

agency has complied with a statutory mandate (*i.e.*, the mandate to specify financial standards and to do so with adequate notice and opportunity for comment).

B. Plaintiffs Have Standing To Bring This Suit.[15]

Plaintiffs allege basically three claims for relief. Although there are four claims for relief stated, the first two (¶¶ 25-34) are in essence of the same type -- claiming failure to provide sufficient notice and meaningful opportunity to comment -- albeit based on different statutory provisions requiring notice and comment -- namely 5 U.S.C. 553 of the APA and a related provision in the Medicare statute, 42 U.S.C. § 1395hh. These two claims come within the APA judicial review provision of 5 U.S.C. § 706(2)(D), which provides that courts shall hold unlawful and set aside agency action found to have been taken "without observance of procedure required by law." The second type of claim (numbered 3, ¶¶ 35-39) focuses on failure to comply with the publication provisions of the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, requiring publication of all agency rules. HHS appears to contend that in fact it has prescribed financial standards, albeit internally and without the proper notice and comment and final rulemaking, but, as Plaintiffs allege, they have not publicized such financial standards as required by the APA or FOIA. The remedy for this is to require either publication of the financial standards, as well as their basis, or production of those standards to Plaintiffs. The third, and last, type of claim (number 4, ¶¶ 40-41) is substantive-- that HHS has failed to comply with the statutory mandate to specify financial standards.

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[15] Defendants have not alleged that Plaintiffs lack prudential standing. Plaintiffs' prudential standing is obvious as persons "adversely affected or aggrieved within the meaning of a relevant statute" by agency action under 5 U.S.C. § 702. *See Int'l Brotherhood of Teamsters v. Pena*, 17 F.3d 1478, 1483-84 (D.C. Cir. 1994) ("[A] party within the zone of interest of any substantive authority generally will be within the zone of interests of any procedural requirement governing exercise of that authority ...."). *And see Ctr. for Auto Safety v. Nat'l Hwy. Traffic Safety Admin.*, 342 F. Supp. 2d 1, 12 (D.D.C. 2004) (appearing to apply this principle to Article III standing also).

The HHS motion to dismiss contends that "the injuries Plaintiffs allege are purely procedural in nature; they do not allege that they have suffered any actual or imminent injury as a result of the DEMEPOS competitive bidding process," citing only a paragraph from the Complaint (¶ 22) stating that no DMEPOS contracts have yet been awarded.

HHS contends only that Plaintiffs lack standing for a "procedural step," which they identify -- inaccurately -- as alleged failure to specify financial standards that Plaintiffs state as a claim for relief. Def. Mem. at 29. HHS does not challenge Plaintiffs' standing to claim inadequate notice and comment pursuant to APA § 553 or failure to publish final rules pursuant to FOIA § 552. HHS has thus waived claims for failure of standing with regard to those claims in their Motion. Nevertheless, Plaintiffs will briefly address how they have sufficiently claimed standing with regard to those two procedural claims (failure to prescribe financial standards with adequate notice and comment and failure to publish final rules on financial standards with an adequate explanation of their basis), in the event that the court construes the vague and sometimes contradictory HHS assertions differently.

In any federal case, the plaintiff bears the burden of establishing jurisdiction. HHS appears to suggest that the Complaint does not sustain this burden because it has not sufficiently alleged the risk of harm to Plaintiffs that is connected to the alleged procedural and substantive failures of HHS.

The Complaint is clear that Plaintiffs are accredited DMEPOS bidders who have submitted the required financial documentation and whose bid and contract applications are now undergoing review by HHS, and that such review must include a determination of whether they have met "financial standards" specified by the Secretary. If, as Plaintiffs allege, there are no valid "financial standards" because there was no sufficient notice and comment or promulgation

of the required standards, or no standards whatever, the Plaintiffs obviously face the distinct and imminent risk that they will not be offered a DMEPOS supplier contract because the do not meet undisclosed and invalid financial standards, assuming such standards exist.

"At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we 'presume that general allegations embrace those specific facts that are necessary to support the claim.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) ("*Lujan*") (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 889 (1990). In ruling on a 12(b)(1) motion to dismiss, a court must accept the factual allegations as true, must construe the allegations in the light most favorable to the plaintiff, and must draw all reasonable inferences in the plaintiff's favor.

Additionally, in considering a 12(b)(1) motion to dismiss, a court may consider such materials outside the pleadings as it deems appropriate to resolve the question of whether it has jurisdiction. *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1108 (D.C. Cir. 2005); *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987); *Borg-Warner Protective Serv. Corp. v. U.S. EEOC*, 81 F. Supp. 2d 20, 23 (D.D.C. 2000).

In an APA rulemaking case in which the plaintiff would be affected by the rulemaking, the plaintiff's standing can usually be considered "self-evident." *Sierra Club v. U.S. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002). "[I]f the complainant is 'an object of the action (or foregone action) at issue' -- as is the case usually in review of a rulemaking ... there should be 'little question that the action or inaction has caused him injury and that a judgment preventing or requiring the action will redress it.'" *Id*. at 900 (citing *Lujan*, 504 U.S. at 561-62). In this case, Plaintiffs' standing is "self-evident" from the facts alleged in the Complaint because it is clear that they are at a distinct and imminent risk of being adversely affected by the rulemaking at

issue if they are rejected as DMEPOS contractors due to HHS' opinion that they do not meet unspecified and procedurally invalid rules regarding "financial standards." Compl. ¶ 7.

Plaintiffs allege that the HHS rulemaking was procedurally defective with regard to specification of financial standards because HHS failed to provide adequate notice and opportunity to comment. Plaintiffs allege that they are subject to the HHS rulemaking regarding "financial standards" as applicants to be DMEPOS contract suppliers (¶¶ 8, 9); that they are "affected parties" in the rulemaking (¶¶ 26); that the HHS notice of proposed rulemaking "did not actually specify proposed standards on which Plaintiffs and others could comment" (¶¶ 10, 26), and that it did not contain adequate information on the substance of the proposed financial standards (¶ 14); and that therefore HHS has failed to comply with the notice and comment requirements of 5 U.S.C. § 553 and 42 U.S.C. §1395hh (¶¶ 28, 33). Such allegations are sufficient to survive a 12(b)(1) challenge for lack of standing in a rulemaking case.

HHS contends inaccurately that the only procedural step Plaintiffs allege to be defective is the failure to specify the financial standards. Def. Mem. at 29. Plaintiffs have alleged that the failure to specify financial standards was contrary to the statutory mandate to specify, but that allegation and claim for relief is separate and distinct from the claims of procedural defect with regard to insufficient notice and comment and failure to publish. Compl. ¶¶ 40-41, 35-39.

HHS does, however, articulate the correct standard for determining whether a plaintiff has standing to seek judicial review of a procedural defect in the form of inadequate notice and opportunity for comment. HHS states that the "the procedural requirement at issue" must have been "'designed to protect some threatened concrete interest'" of the plaintiff, citing *County of Del., Pa. v. U.S. Dep't of Transp*., 554 F.3d 143, 147 (D.C. Cir. 2009), and that "'Plaintiffs 'must show that the government act performed without the procedure in question will cause a distinct

risk to a particularized interest of the plaintiff[s].' *Ctr. for Law and Educ. v. U.S. Dep't of Educ*., 396 F.3d 1152, 1167 (D.C. Cir. 2005)." Def. Mem. at 26. However, HHS then proceeds to ignore the procedural defect issue of inadequate notice and comment.

As is clear from the Complaint (¶¶ 1, 7, 8, 9, 20, 21, 24, 26, 28, 33), and is "self-evident," the Plaintiffs' "threatened concrete interest" is their interest in obtaining a DMEPOS supplier contract, which they have obviously invested significant time and expense in applying for (¶¶ 8,9), and they are at imminent and "distinct risk" of not obtaining a contract offer. This is their "particularized interest" in there not having been adequate notice and comment (as well as there not having been any final rulemaking whatever specifying the required "financial standards").

HHS claims that Plaintiffs lack standing because their risk and threat of imminent harm is "uncertain." Def. Mem. at 29. In a case of allegedly inadequate notice and comment, the effect of such a procedural failure will always be of necessity "uncertain." One cannot establish what would happen if HHS had conducted proper notice and comment proceedings, and therefore harm is always "uncertain." The federal courts have long recognized this, and have set a more relaxed standard for the establishment of standing to challenge a rulemaking for lack of adequate notice and comment.[16]

Ironically, HHS cites *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), for the proposition that Plaintiffs must demonstrate "injury in fact," and that Plaintiffs have not alleged any "actual or imminent injury as a result of the DMEPOS competitive bidding process." Def. Mem. at 25. However, *Lujan* makes clear that no showing of certainty of harm is required in the case of a procedural defect. The Court stated:

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[16] As stated previously herein (n. 2, *supra*), we contend that the HHS Motion and Memorandum has not challenged Plaintiffs' notice and comment claim for relief or their standing to raise that issue, but we will nevertheless briefly address here those matters in case they are raised in their reply memorandum. In doing so, we do not concede that HHS has made the notice and comment issue a part of their Motion to Dismiss, and we contend, therefore, that the issue has been waived for purposes of a motion to dismiss.

> There is much truth to the assertion that "procedural rights" are special: The person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy. Thus, under our case law, one living adjacent to the site for proposed construction of a federally licensed dam has standing to challenge the licensing agency's failure to prepare an environmental impact statement, even though he cannot establish with any certainty that the statement will cause the license to be withheld or altered.

Lujan, 504 U.S. at 572 n. 7 (emphasis added). *And see County of Del, Pa. v. U.S. Dept. of Transp*., 554 F.3d 143, 147 (D.C. Cir. 2009); *Chamber of Commerce of U.S. v. SEC*, 443 F.3d. 890, 904 (D.C. Cir. 2006); *City of Waukesha v. U.S. EPA*, 320 F.3d 228, 234 (D.C. Cir. 2003); *Sugar Cane Growers Co-op of Fla. v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin*., 342 F.Supp.2d 1, 11-12 (D.D.C. 2004), *aff'd on other grounds*, 452 F.3d 798 (D.C. Cir. 2006).

In summary, Plaintiffs have alleged that they have DMEPOS contract applications under review at HHS, that the statute requires that HHS determine whether they meet financial standards that HHS has specified, and that HHS has neither allowed adequate notice and comment on such standards nor actually specified such standards. From these facts it can easily be inferred, and indeed it is obvious and "self-evident," that Plaintiffs are at a distinct risk of imminent particularized harm in the form of having their contract applications illegally rejected.

C. Plaintiffs Have Stated Multiple Claims Upon Which Relief Can Be Granted.

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), which states that a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief ...." The examples of complaints in the Appendix of Forms to the FRCP shows how bare-bones a satisfactory complaint can be.

The U.S. Supreme Court has recently reviewed and restated with some specificity the

standards that complaints must meet under FRCP 8(a)(2) in order to avoid dismissal for failure to state a claim upon which relief can be granted. *Ashcroft v. Iqbal*, 556 U.S. --, --, 129 S. Ct. 1937, 1949-50 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 554-57, 570 (2007). The standards explained in both opinions are substantially the same: FRCP 8(a)(2) requires only "'a short and plain statement of the claim showing 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 ...." (*Twombly*, 550 U.S. at 555 (citation omitted)); the "short and plain statement" required by the rule "does not require 'detailed factual allegations,' but it demands more than an unadorned the-defendant-unlawfully-harmed-me accusation." "To survive at claim to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" (*Iqbal*, 129 S.Ct. at 1949). Determining plausibility will require the reviewing court "to draw on its judicial experience and common sense." *Id*. at 1950.

In deciding a 12(b)(6) motion, the court must construe the complaint in a light most favorable to the plaintiff and must accept as true all facts and make reasonable factual inferences. "The complaint must be 'liberally construed in favor of the plaintiff,' who must be granted the benefit of all inferences that can be derived from the facts alleged.'" *Aktieselskabet AF 21. Nov. 2001 v. Fame Jeans Inc.* ("*Bestseller*"), 525 F.3d 8, 83-85 (D.C. Cir. 2008); *Leitner v. United States*, -- F. Supp. 2d ---, Civil No. 092342, WL 2891198, at *3-4 (D.D.C. July 22, 2010).

The Complaint fully complies with these requirements for all of its claims for relief. The Complaint sets forth three claims for relief, with the first two -- for HHS' failure to provide adequate notice and comment for specification of "financial standards -- being essentially the

same although based on different statutory provisions (5 U.S.C. § 553 and 42 U.S.C. § 1395hh). The other two claims are (1) for failure to comply with the statutory mandate to specify "financial standards," and (2) for failure to publish in the *Federal Register* or otherwise actually divulge to Plaintiffs the specific financial standards it would apply, and is now applying, in order to qualify bidders.[17]

All of these claims are made clearly and are supported by factual allegations. The claim of failure to provide adequate notice and comment is supported, as it must be, by the administrative record -- *i.e.*, the notice of proposed rulemaking. Plaintiffs quote the actual language of the notice (both preamble and substantive portions). The quoted portion of the preamble did not propose any specific financial standards, and the substantive portion of the proposal stated only that "[a]ll suppliers must meet standards specified in the request for bids." The "request for bids" was not a part of the notice of proposed rulemaking. Compl. ¶¶ 13, 14. The First and Second causes of action incorporate those factual allegations (¶¶ 25, 31) and connect the factual allegations of ¶¶ 13 and 14 with allegations that that the proposed rulemaking "did not, in fact, set out proposed 'financial standards' that Plaintiffs and other affected parties and the public could reasonably be expected to comment on"(¶ 26), or "provide a meaningful opportunity for public comment" (¶ 33), and that therefore HHS violated the notice and comment requirements of the APA, 5 U.S.C. § 553 (b) and (c), and of the Medicare statute, 42 U.S.C. § 1395hh(b). In a suit for review of administrative action alleging improper rulemaking due to failure to provide adequate notice and comment such as this, Plaintiffs can do no more than state the relevant statutory requirements, reference and quote, as factual allegations, those portions of the administrative rulemaking record supporting their causes of action, and specify the causes of action that are related to the administrative record. Such allegations are surely sufficient to allow

[17] As we noted at the outset, HHS has not moved to dismiss based on a failure to allege adequately that they failed to provide adequate notice and comment.

HHS, and the court, to understand the nature of the claims and their factual basis and to provide a sufficient basis from which the court could infer that the claims are plausible.

Plaintiffs' Fourth Cause of Action (¶¶ 40, 41) alleges that even in its final rule and interim final rule, and even internally, HHS has failed to comply with the statutory mandate to specify "financial standards." Plaintiffs allege the substance of the statute that requires HHS to specify "financial standards." (¶ 12). Plaintiffs quote the relevant portion of the preamble and the substantive portion of the 2007 final rule (¶¶ 15,16), and they allege that it stated only that bidders must submit certain financial documentation and "did not specify the financial standards that would be applied to such documentation." ¶ 16. Plaintiffs also quoted the relevant portion of the 2009 interim final rule and alleged that it also "did not specify the financial standards that would be used to evaluate the 'covered [required financial] documents.'" ¶ 18. As with the claim that HHS failed to comply with notice and comment requirements, this claim rests on the factual assertions of what was contained in the final and interim final rules, as well as the reasonable inference that because HHS has not divulged the required financial standards to DMEPOS suppliers or the public in any manner, as required by law, they do not in fact exist, and HHS is making decisions regarding the financial condition of DMEPOS applicants on an *ad hoc* and arbitrary and capricious basis.[18] For purposes of a claim that HHS has not complied with the

[18] In their Memorandum, Defendants are cagily ambiguous on this matter. On the one hand they argue that it was reasonable to interpret "financial standards" as only certain types of financial information rather than the standards that would be applied to that information. On the other hand, they argue it was reasonable not to disclose the financial standards they are applying to that information because that might enable fraud to occur. The argument concerning non-disclosure in order to avoid possible fraud is not based on any statutory authority. Agencies cannot ignore Congressional mandates simply because they believe the mandate is not a good idea. Disclosure of many regulatory standards poses the potential for fraud in reporting information to the Government, but there are severe penalties for such fraud. *See, e.g.*, 18 U.S.C. §§ 1001, 1035, 1347. The insistence by HHS that requiring information and stating the types of information that will be reviewed is sufficient to constitute "standards" is like EPA setting water quality standards by requiring submission of sampling data on E. coli, nitrates, and heavy metals and stating that they will review that data to determine whether, in their judgment, the water is

statutory mandate to specify "financial standards," Plaintiff could only state the facts in the administrative record, which in this case were the relevant portions of the final rule and interim final rule.

As with the notice and comment claims, HHS does not address the Third Cause of Action, which alleges that HHS has failed to divulge, through *Federal Register* publication or otherwise, the specific "financial standards" required by statute, even if they did not develop them through adequate notice-and-comment rulemaking. ¶¶ 35-39. The factual allegations supporting this claim are the same as those for the other claims -- the administrative record regarding what has been published in the *Federal Register*. The allegation in ¶ 38 that Plaintiffs do not have actual knowledge of the financial standards being applied is based on the fact that the "request for bids," which HHS states contained the financial standards, also "did not specify such financial standards." ¶16.

In arguing for dismissal of the Complaint, HHS attempts to argue not the insufficiency of the Complaint, but the merits of the issue regarding compliance with the statutory mandate raised in the Fourth Cause of Action -- failure to specify the financial standards. Def. Mem. at 29-37. This is not appropriate in a motion to dismiss, which is supposed to address only whether the Complaint is sufficient to put HHS on "short and plain notice" as to the claims for relief being made, and Plaintiffs do not have to, and will not, respond to those arguments at his point in the proceedings. Such argument over the ultimate validity of the claims for relief will be appropriate in connection with a motion for summary judgment. Nevertheless, HHS' arguments on this point, as well as their casual references to the notice and comment issue, demonstrate that they have been given "'fair notice of what the ... claim is and the grounds upon which it rests.'" *Twombly*, 550 U.S. at 555.

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clean enough, but they will not disclose how they make such judgments because those submitting the data might falsify it.

IV. Conclusion

For the reasons stated above, the HHS Motion to Dismiss should be denied.

In view of the HHS timeline for making Round I contract award determinations and implementing the contracts (see p. 6, *supra*.), Plaintiffs request the court to expedite these proceedings by setting a schedule for any discovery, dispositive motions, and any oral argument, that will avoid the necessity for filing of a motion for a preliminary injunction to maintain the status quo. The objective of such schedule would be to dispose of this case on the merits before Round I re-bid contracts go into effect by January 1, 2011, as currently targeted by HHS. Such scheduling could avoid any disruptions in Round I DMEPOS contracting and reimbursement payments.[19]

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(corrected August 13, 2010)

Respectfully submitted,

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[19] Current DMEPOS contractors bidding in Round I, including Plaintiffs, who do not receive a new contract this year could lose their Medicare business, and some could effectively be out of business, by January 1, 2011. Those who do receive contracts might later have them cancelled due to *vacatur* of the interim final rule. If the Round I contracts were stayed, however, existing contracts would continue under the pre-existing fee schedule.