RE-SCHEDULED FOR ORAL ARGUMENT ON APRIL 18, 2012, 2:00 PM
No. 11-5265

IN THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Texas Alliance For Home Care Services
and **Dallas Oxygen Corporation**
Plaintiffs-Appellants

v.

Kathleen Sebelius, in her official capacity as Secretary,
U.S. Department of Health and Human Services, and
Marilyn Tavenner, in her official capacity as Acting
Administrator, Centers for Medicare and
Medicaid Services
Defendants-Appellees

On Appeal from the United States District Court
for the District of Columbia, No. 1:10-cv-747-RCL

REPLY BRIEF FOR THE APPELLANTS

WILLIAM G. KELLY, JR.
MULTINATIONAL LEGAL SERVICES, PLLC
1850 Fall Line Dr.
Driggs, ID 83422
(208) 354-3050
wgkelly@silverstar.com

BRENDAN J. KLAPROTH
MULTINATIONAL LEGAL SERVICE, PLLC
1601 Connecticut Ave., NW -- Suite 500
Washington, DC 20009
(202) 797-7124
brendan.klaproth@gmail.com

March 7, 2012

TABLE OF CONTENTS

TABLE OFAUTHORITIES……………………………………………………iii

SUMMARY OF THE REPLY ARGUMENT……………………………………..1

REPLY ARGUMENT…...…………………………………………………………3

I. Preclusion. The agency has not shown the required clear and convincing evidence of Congressional intent to preclude judicial review for non-compliance with its general mandates in the APA and the Medicare provisions; and the plain language of the statute, legislative history, and agency regulations indicate the opposite ……..…....3

A. The "awarding of contracts."…………….…………………………….....3

B. The "bidding structure.”..……………………..…………………………...5

C. General points regarding the statutory scheme……………….……………8

II. Standing. The agency ignores fundamental law on self-evident standing and the causation element of standing, the sufficiency of threatened harm vs. demonstrated past harm to satisfy standing, and the progression of the DME program into Round 2 with continuation of threatened harms……………………………………………………...11

III. Notice and comment. The agency still has not shown, and cannot show, how the "standards" that it asserts were sufficiently specified have satisfied requirements for sufficient notice and opportunity to comment. (Sec. III, A in the agency brief)………………...13

IV. Specification of standards. The agency is notably ambivalent about what financial standards it supposedly has specified, and none of the standards that it asserts it has specified contain an identifiable "standard" as that term is commonly understood. In addition, the agency's rulemaking does not satisfy requirements

for a statement of basis and purpose. (Section 3, B in the agency brief)……………………………………...18

CONCLUSION………………………………………………………………...25

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

Cases

∗Advanced Mgmt Technol., Inc. v. FAA,
211 F.3d 633 (D.C. Cir. 2000)..12

Am. Assoc. for Homecare v. Leavitt,
No. 8-cv-992, 2008 WL 2580217 (D.D.C., June 30, 2008)……......………..8

American Radio Relay League, Inc. v. FCC,
524 F.3d 227 (D.C. Cir. 2008)..15

Cardiosom, L.L.C. v. United States,
656 F.3d 1322 (Fed. Cir. 2011) 9

Carolina Med. Sales, Inc. v. EPA,
559 F.Supp. 2d 69 (D.D.C 2008)...7, 9

CBS, Inc. v. FCC,
453 U.S. 367 (1981)... 24, 25

Cement Kiln Recyling Coalition v. EPA,
493 F.3d 207 (D.C. Cir 2007)... 20, 21, 22

Chamber of Commerce of the U.S. v. SEC,
443 F.3d 890 (D.C. Cir. 2006)..14

*Chevron USA. Inc. v. Natural Res. Def. Council, Inc.,
467 U.S. 837 (1984)... 18, 23

Authorities upon which we chiefly rely are marked with asterisks.

City of Dania Beach, Fla. v. FAA,
485 F.3d 1181 (D.C. Cir. 2007)……………………………………………13

Conn. Light & Power Co. v. NRC,
673 F.2d 525 (D.C. Cir. 1982)...15

*Dole Food Corp. v. Patrickson,
538 U.S. 468 (2003)...12

*Ethyl Corp. v. EPA,
306 F.3d 1144 (D.C. Cir. 2002)...22

Felter v. Kempthorne,
473 F.3d 1255 (D.C. Cir. 2007)………..………………………………….23

Fertilizer Inst. v. EPA,
935 F.2d 1303 (D.C. Cir. 1991)...15

First Am. Discount Corp. v. CFTC,
222 F.3d 1008 (D.C. Cir. 2000)...15

Gen Am. Transp. Corp. v. ICC,
872 F.2d 1048 (D.C. Cir. 1989).. 24-25, 25

*General Elec. Co. v. Jackson,
610 F.3d 110 (D.C. Cir. 2010)………………………………………….10

Heckler v. Ringer,
466 U.S. 602 (1984)...9

Home Box Office, Inc. v. FCC,
567 F.2d 9 (D.C. Cir 1977)..14

*Horsehead Res. Dev. Co, Inc. v. Browner,
16 F.3d 1246 (D.C. Cir. 1994)... 14, 15

Koszola v. FDIC,
393 F.3d 1294 (D.C. Cir. 2005)……………………………………………..1

Lemon v. Green,
514 F.3d 1312 (D.C. Cir. 2008)……………………………………………..13

*Lindahl v. OPM,
470 U.S. 768 (1985)...3

*McNary v. Haitian Refugee Center, Inc.,
498 U.S. 479 (1991)..3, 10

*MST Express v. DOT,
108 F.3d 401 (D.C. Cir. 1997).. 15, 20, 22, 23

*Nat'l Mining Ass'n v. MSHA,
512 F.3d 696 (D.C. Cir. 2008)...23

Natural Res. Def. Council v. EPA,
824 F.2d 1258 (1st Cir. 1987)..14

*Oceana, Inc. v. Locke, ___ F.3d ___,
2011 WL 2802989 (D.C. Cir. July 19, 2011).................................... 7, 21, 22

Prometheus Radio Project v. FCC,
652 F.3d 431 (3d Cir. 2011) 14

*Richardson v. United States,
193 F.3d 545 (D.C. Cir. 1999)..13

Safe Extensions, Inc. v. FAA,
509 F.3d 593 (D.C. Cir. 2007)..10

Shalala v. Illinois Council on Long Term Care, Inc.,
529 U.S. 1 (2000)…………………………………………………….....5, 9

Sharp Healthcare v. Leavitt,
555 F. Supp. 2d 1121 (S.D. Cal. 2008) 7

Small Refiner Lead Phase-Down Task Force v. EPA,
705 F.2d 506 (D.C Cir. 1983)..14

Solid Waste Agency of N. Cook County v. U.S. Army Corps of Engineers,
531 U.S. 159 (2001)..26

State of New Mexico v. EPA,
114 F.3d 290 (D.C. Cir. 1997)..22

*Sugar Cane Growers Co-op of Fla. v. Veneman,
289 F.3d 89 (D.C. Cir. 2002)..15

*United States v. Rapone,
131 F.3d 188 (D.C. Cir. 1997)…………………………………………..23

Statutes

5 U.S.C. § 553(b) 8
5 U.S.C. § 553(b)(3)(B) 16
5 U.S.C. § 553(c) 8, 23
5 U.S.C. § 701 10
5 U.S.C. § 706 16
42 U.S.C. § 1395f(l)(5) 4
42 U.S.C. § 1395hh 8
42 U.S.C. § 1395i-5(c)(2)(D) 4
42 U.S.C. § 1395l(i)(2)(D)(vi) 4
42 U.S.C. § 1395l(m)(4) 4
42 U.S.C. § 1395l(t)(12) 4
42 U.S.C. § 1395l(u)(4)(E) 4
42 U.S.C. § 1395l(x)(4) 4
42 U.S.C. § 1395m(l)(12)(B)(v) 4
42 U.S.C. § 1395u(b)(10)(D) 4
42 U.S.C. § 1395u(o)(7) 4
42 U.S.C. § 1395w-3 6
42 U.S.C. § 1395w-3(a)(1)(B)(i)(II) 9
42 U.S.C. § 1395w-3(a)(1)(F)(iv) 6
42 U.S.C. § 1395w-3b(g) 2

Rulemaking Notices

72 Fed. Reg. 17992 (April 10, 2007) 14, 17

76 Fed. Reg. 70228 (Nov. 10, 2011)...20

Regulations

42 C.F.R § 414.402 20

42 C.F.R § 414.412 7

42 C.F.R. § 414.414(d) 6, 7, 20

42 C.F.R. § 414.414(e)...7

42 C.F.R. § 414.416 7

Other Authorities

Fed. R. Civ. P. 15(a)(2)...13

SUMMARY OF THE REPLY ARGUMENT

The agency's brief does not provide any clear and convincing evidence that the preclusion of review of the "awarding of contracts" and the "bidding structure" were intended to foreclose judicial review of the systemic collateral issues of lack of notice and comment and non-compliance with the statutory mandate to specify financial standards, taking into account the needs of small providers. At best, the agency's interpretations of those preclusion provisions are barely colorable, falling well short of the clear and convincing standard. Contrary readings of the preclusion language that avoid preclusion are far more plausible. Any such ambiguity must be resolved in favor of allowing judicial review.[1]

The agency's arguments on standing ignore fundamental law on "self-evident" standing and causation in rulemaking cases in which the plaintiff is the object of the rulemaking. In addition, the agency disregards the sufficiency of threatened, as opposed to actually realized, harm. The agency also ignores the progression of the DME program into Round 2 (and a new rebid of Round 1) with a timeline that currently provides for submission of "covered [financial] documents" by 2/29/12, awarding of contracts by Spring 2013, and contracts going

[1] The "clear and convincing" standard has been described by this Court as meaning more than "merely probable," and between the standards of preponderance of the evidence and beyond a reasonable doubt, and also approving of a description of it as "'highly probable.'" Koszola v. FDIC, 393 F.3d 1294, 1300 (D.C. Cir. 2005).

into effect in mid-2013. The pendency of Round 2 poses new threats of harm, as alleged in the motions to amend. In addition, Round 1 contracts will have to be re-bid by 2013, with renewed threats of harm.

A pervasive and determinative flaw in the agency's arguments on notice and comment and compliance with the financial standards mandate is its ambivalence regarding what it contends is the standard or standards it is defending. It asserts that the final rule preamble statement regarding "overall financial soundness" or "viability" is sufficient, and also that the specification of the types of ratios and documents it would consider are sufficient standards. The agency ignores, however, the record evidence that it is employing "scoring," "thresholds," or the need to meet "particular ratios" as standards, while withholding those standards from the public and the suppliers and not subjecting them to notice and comment.

The agency's final substantive rule on "financial standards" merely provides for submission of financial documents (and review for completeness), and it does not contain any identifiable standard to guide agency discretion in evaluating that information for determining financial soundness. The undisclosed standards have never been exposed to notice and comment. Further, the agency has never articulated its reasoning in adopting any of the purported "standards."

REPLY ARGUMENT

I. Preclusion. The agency has not shown the required clear and convincing evidence of Congressional intent to preclude judicial review for non-compliance with its general mandates in the APA and the Medicare provisions; and the plain language of the statute, legislative history, and agency regulations indicate the opposite.

A. The "awarding of contracts."

In arguing that the language "awarding of contracts" plainly precludes the systemic (or "collateral") challenges in this case, the agency first points (at 23) to the statutory language indicating that meeting the financial standards is a "condition" for receiving a contract award. But this does not help the suppliers' position because, although the financial standards requirement is under the headings of "general" "Conditions" of the "Program requirements," the preclusion language does not refer to the general "conditions" for awarding of contracts. And, as noted in the suppliers' brief (at 17, citing McNary and Lindahl), the Supreme Court has observed that Congress is well aware of the strong presumption against preclusion, and can readily use broad language -- which in this case could be, for example, language precluding review of "any decision by the Secretary in implementing the Program." To accomplish the sort of broad preclusion the agency advocates, Congress would have used broad language instead of carefully delineating seven distinct areas in which no review would be allowed. Congress is

accustomed to providing specifically delineated preclusions in the Medicare statute, as shown by many such provisions.[2]

The agency chooses to ignore the evidence of legislative intent from the Congressional conference report explaining identical wording ("awarding of contracts") in the similar preclusion provisions of the companion section of the MMA on competitive bidding for furnishing of drugs and biologicals in section 303 of the MMA. (The DME provisions were in 302). 42 U.S.C. § 1395w-3b(g); Pl. Br. at 18. The conference report explained the "awarding of contracts" preclusion language as applying to "contract awards." That report language plainly confirms that preclusion applies only to individual contract award determinations (including denials), not to all general programmatic issues that might be related to the "awarding" of contracts.

The agency argument that the preclusion for "awarding of contracts" necessarily encompasses the financial standards because otherwise a bidder could obtain review of a contract award "simply by couching its claim as a challenge to the criteria employed in making the award" is not accurate. Under the suppliers' reading of the preclusion, a bidder could not obtain judicial review of a specific decision not to award a contract that was based on **application** of the general financial criteria to its **specific** situation, or other supplier-specific determinations

[2] See, *e.g.*, 42 U.S.C. §§ 1395f(l)(5),1395i-5(c)(2)(D),1395l(i)(2)(D)(vi), 1395l(m)(4),1395l(t)(12),1395l(u)(4)(E),1395l(x)(4),1395m(l)(12)(B)(v), 1395u(b)(10)(D),1395u(o)(7).

covered by the preclusions; however, it could obtain judicial review of the criteria themselves based on allegations that they are not in accordance with law or were not promulgated with procedures required by law. The agency's argument is apparently intended to suggest that rejected bidders could bring a multitude of suits based on challenges to the financial standards. That is not true. Once a Court of Appeals rules on those general issues, it is unlikely that there will be any more suits, and certainly not a multitude, simply because the issues are systemic and the decision will set binding precedent.

The agency incorrectly argues that the Illinois Council line of cases forecloses challenges based on collateral issues. Instead, Illinois Council and similar cases have simply required that such collateral challenges be first "channeled" through an administrative review process provided by the statute, unless circumstances would result in such a requirement resulting in essentially no review at all. In the present case, there is no administrative review process available, and the agency is arguing for no review at all, not a deferral of judicial review until after administrative review.

B. The "bidding structure."

To support its contention that this language precludes judicial review for compliance with Congressional mandates, the agency employs some linguistic sleight-of-hand: "bidding structure" becomes the bidding "program" (at 25-26). If the statute did state that challenges to the "bidding program" are precluded, the

agency could have an argument, because the "bidding program" would arguably refer to everything in § 1395w-3. But of course the statute does not state that, and if it did, no other preclusion provisions would have been necessary.

The agency argument that "how bid price offers must be submitted and how the agency will evaluate them" on its face includes financial standards is unsupportable. Individual price offers and their evaluation have nothing to do with financial standards as a prerequisite for making such offers. A supplier could qualify under the financial standards but not submit a winning bid, or any bid at all; or it could submit a winning bid but be disqualified on the basis of the financial standards. Moreover, the statute itself expressly distinguishes "covered [financial] documents" from bid submissions in stating that the term "covered documents" "does not include other documents, **such as the bid itself** or accreditation documentation." 42 U.S.C. § 1395w-3(a)(1)(F)(iv) (emphasis added).

The agency also misstates the suppliers' position on the separation in the regulations between the financial standards and regulations on submission and evaluation of bids. The agency states (at 25) that the "very regulation" that requires submission of certain financial documentation and which the suppliers invoke, 42 C.F.R. § 414.414(d), sets out the bid evaluation process. Section 414.414(d) says nothing about bid evaluation, it only addresses submission of financial documents, and the suppliers' brief clearly points out (at 26) that §

414.414(d) is separate from the bid submission and evaluation regulations cited in their brief, namely §§ 414.412, 414.414(e), and 414.416.

In addition, the agency attempts to deter the Court from consulting the reasoning in Sharp Healthcare, which is the only case that has involved review of the "bidding structure" language.[3] Although the April 4, 2008 district court opinion we cite is not binding precedent, just as the district court opinion below is not binding or entitled to deference,[4] its reasoning is sound and well-articulated and should be consulted. The agency acknowledges that this is appropriate by repeatedly referring to the reasoning and statements of the district court in this case and Carolina Med. Sales as if they should be entitled to deference. The significance of Sharp Healthcare is that a federal judge read the specific plain wording of "bidding structure" as not providing clear and convincing evidence with regard to whether it encompassed an issue outside of one relating to the procedures or process for bidding.

---

[3] The agency has portrayed the proceedings inaccurately. The order cited by the agency as mooting the case only mooted the case temporarily by allowing the plaintiffs leave to amend their Complaint while **denying** a motion to vacate the opinion. The case continued, and the subject opinion was not vacated until July 22, 2010 (doc. 53), pursuant to the parties' July 21 joint motion to vacate in accordance with a settlement agreement (doc. 52). The suppliers' district court brief in the present case was due August 6, 2010.

[4] Oceana, Inc. v. Locke, ___ F.3d ___, No. 10-5299, 2011 WL 2802989 at *2 (D.C. Cir. July 19, 2011).

C. General points regarding the statutory scheme.

As with many statutes, Congress wanted to avoid extensive delays; but it also intended that implementation of the statute should comply with its mandates for notice-and-comment rulemaking (5 U.S.C. § 553(b) and (c) and 42 U.S.C. § 1395hh) and specification of financial standards. When Congress delayed the program for two years pursuant to MIPPA, it did so in order to ensure that the program would be conducted in a fair and reasonable manner. It is the agency's failure to comply with the Congressional mandates that would be the cause for any further delay. *Vacatur* of rules for procedural and substantive reasons ordinarily incurs some delay, but any such delay would be entirely the fault of the agency.[5]

The agency' statement that "it is utterly implausible that Congress would ... have intended private suppliers to be able to delay **indefinitely** the implementation of the program through litigation" (at 30, emphasis added) is utterly ridiculous. A new legally-compliant rulemaking for financial standards could be carried out in well under a year, and the current tentative timeline for Round 2 does not call for contract awards to be made until Spring 2013 (App. a194[6]). Moreover, MIPPA

---

[5] The agency has been on notice of the strong legal objections to its failure to specify financial standards since the filing of Am. Assoc. for Homecare v. Leavitt in 2008. See Certif. as to Parties, Rulings, and Related Cases (at 3) in the suppliers' opening brief.

[6] The tentative timeline was last updated on Jan. 30, 2012, but has not changed. There is no specific target date for decisions based on financial documents and standards, only the target date of 2/29/12 for submission of financial documents.

called for Round 2 to be conducted during 2011,[7] and the agency has already delayed the program until at least the middle of 2013.[8]

The agency argues (at 28) that the preclusion provisions were intended to preclude judicial review of "all aspects of the design and implementation of the competitive bidding program." But the agency cannot point to any statutory language or legislative history indicating this, and instead relies on (at 28-29) what are clearly dicta in Carolina Med. Sales and Cardiosom.[9]

Finally, the agency attempts (at 31-32) to distinguish a number of cases that the suppliers contend support the proposition that collateral challenges that would be otherwise non-reviewable are distinct from individual determinations that must be channeled through an available administrative process before judicial review.[10]

---

[7] 42 U.S.C. § 1395w-3(a)(1)(B)(i)(II).

[8] The agency's reference (at 29) to a 2008 estimate of lost cost savings for one year is also not appropriate. Congress decided on the delay, and the agency has added to that delay. Moreover, the validity of such estimates is questionable, since Round 2 and the 3-year rebids could show substantial changes in industry competitive structure and the levels of bids submitted as a result.

[9] It is accepted practice, and a matter of candor with the Court, to note in citations that a referenced portion of an opinion is dictum. See THE BLUEBOOK, 18th ed. 2005, at 91, sec. 10.6.1.

[10] For example, the agency cites Ringer (at 30-31) for the proposition that the Supreme Court has applied preclusion in circumstances similar to this case even though the practical consequence would be no review at all. But that mischaracterizes Ringer, which held, consistent with Illinois Council and other "channeling" decisions, that a collateral issue intertwined with an individual claim

However, those cases were cited by the suppliers for the firmly-established principle that Congressional intent to cut off judicial review must be "clear and convincing," and that the presumption in favor of judicial review is particularly strong when compliance with a statutory mandate is at issue and a finding of preclusion would mean no review at all.[11] The agency's brief contains no acknowledgment of the "clear and convincing" standard, or the strong judicial preference for avoiding preclusion when it would result in no review at all.

All in all, the agency has not carried its heavy burden of producing clear and convincing evidence of Congressional intent to preclude judicial review of systemic issues of compliance with statutory mandates by reference to

---

for reimbursement must be channeled through an available administrative process before being presented to a court. As this Court stated in General Elec. Co. v. Jackson, a recent D.C. Circuit case cited by the agency (at 31), after discussing Ringer, "our cases interpreting McNary hew to this distinction between collateral and particularized claims," and collateral claims "falling outside the text of a jurisdiction-channeling provision" are judicially reviewable. 610 F.3d at 126-27. That is the case here.

[11] For example, the suppliers cited Safe Extensions for this standard, and the agency attempts to distinguish it by stating that it "did not even involve an argument that Congress had foreclosed administrative review." In that case, however, the government argued that judicial review was foreclosed by the APA (5 U.S.C. § 701) because there was no "law to apply." This Court, citing the strong presumption against foreclosure of judicial review, found that there was sufficient law to apply. The agency's delicate wording cannot avoid the thrust of the decision, which rejected foreclosure of judicial review. Many of the decisions cited by both sides in this case can be distinguished on their facts; but the present case must be decided according to basic, well-settled, legal principles applied to the specific statutory and rulemaking language and provisions at issue.

unambiguous statutory language, legislative history, or the statutory scheme; instead it has only advanced what it apparently regards as colorable interpretations.

II. <u>Standing</u>. The agency ignores fundamental law on self-evident standing and the causation element of standing, the sufficiency of threatened harm vs. demonstrated past harm to satisfy standing, and the progression of the DME program into Round 2 with continuation of threatened harms.

The agency's arguments in this section of their brief (at 32-38) suffer from three basic flaws:

1. First, the agency ignores this Circuit's position on "self-evident" standing in a case alleging deficient rulemaking where the plaintiff is an entity subject to the rulemaking (in this case, a supplier that must meet financial standards specified by the agency in order to obtain a contract), and it makes conclusory statements about the speculative nature of other types of threatened harm by attempting to parse the causal connection into many elements, when the standard is simply whether the threatened loss or distinct risk of loss is on the whole "fairly traceable" to alleged agency non-compliance.

2. Second, the agency repeatedly argues that the suppliers have not demonstrated standing because they have not alleged that they have **already** suffered **actual** loss from being disqualified from bidding. It is, however, firmly-established law that standing can be based on imminent or threatened harm, or distinct risk of loss, rather than actually realized loss, particularly in cases alleging deficient rulemaking. (Pl. Br. at 29-30) It is also established law that standing is

determined based on the facts as they existed (or were alleged to exist) at the time the Complaint was filed.[12]

3. Third, the agency ignores (1) that the competitive bidding process has now moved into Round 2, with contracts not targeted to be awarded until Spring 2013 (App. a194), (2) that the suppliers' moved to amend the Complaint to allege the timetable for Round 2, with contract awards not yet made, and (3) that there is a distinct risk that the suppliers will be denied contract awards due to alleged failure to comply with financial standards that now appear to exist but which were never proposed for notice and comment and that have never been published.[13] Unless this Court agrees that the initial Complaint failed to state a claim upon which relief could be granted, those motions for leave to amend should be granted. "Leave to amend a complaint should be freely given in the absence of undue delay,

[12] Dole Food Corp. v. Patrickson, 538 U.S. 468, 478 (2003) (citing cases); Advanced Mgmt Technol., Inc. v. FAA, 211 F.3d 633, 636 (D.C. Cir. 2000). When the original Complaint was filed, May 10, 2010, no contracts had been awarded under the Round 1 rebid. (¶ 22, App. a12). If the motions for leave to amend are granted (actually, only the third motion need be granted) because the Court determines that the Complaint states a claim upon which relief can be granted, those motions also allege that the Plaintiffs face certain distinct, concrete risks in the upcoming Round 2 bidding resulting from the agency's failure to specify or divulge the financial standards they must meet. It is apparent from the motions, proposed amended Complaints, and the record, that Round 2 contracts have not yet been awarded. See MLTAC-3, motion and ¶¶ 7, 8, 9, 18, App. a94, a96, a99-101, a104, and a194.

[13] Even the Round1 rebid contracts that were awarded in November 2010 must be rebid after three years, apparently in 2013, as required by 42 U.S.C. § 1395w-3(b)(3)(B).

bad faith, undue prejudice to the opposing party, repeated failure to cure deficiencies, or futility." Richardson v. United States, 193 F.3d 545, 548-49 (D.C. Cir. 1999); Fed. R. Civ. P. 15(a)(2).

With regard to the standing of Ms. Sopko, a DME beneficiary in a Round 2 CBA who was proposed to be added as a plaintiff in MLTAC-3, her risk of harm from diminished quality of DME service due to lack of financial standards that would weed out suppliers who are not financially sound is no more speculative or attenuated than the potential harm from diminishment of aesthetic pleasures routinely recognized as a basis for standing in NEPA cases alleging failure to prepare an adequate EIS. *See, e.g.*, Lemon v. Green, 514 F.3d 1312, 1314-15 (D.C. Cir. 2008); City of Dania Beach, Fla., v. FAA, 485 F.3d 1181, 1185-87 (D.C. Cir. 2007).

III. Notice and comment. The agency still has not shown, and cannot show, how any of the supposed "standards" that it asserts were sufficiently specified have satisfied requirements for sufficient notice and opportunity to comment. (Sec. III, A in the agency brief)

Adequate notice and meaningful opportunity for comment require that the agency present an actual proposal in the NPRM, supported by reasoning and discussion sufficient to allow for informed critique. A simple "We welcome

comments" on a general rulemaking subject does not suffice. (Pl. Br. at 36-37)[14] The agency brief does not acknowledge or discuss the case law on this subject.

The agency relies (at 41) on "financial viability" or "overall financial soundness" as its final financial standard, but it cannot show how this purported standard was ever proposed as a standard in the NPRM or how it was a logical outgrowth of a standard proposed in the NPRM. There was, therefore, an utter failure of the agency to provide adequate notice and opportunity for comment.

As a consequence of a lack of any proposal for a standard of "overall financial soundness" in the NPRM, there were no comments on such a standard discussed in the preamble to the final rule. 72 Fed. Reg. 17992, 18037-38 (April 10, 2007); Add. A-41-43. Instead, the comments on "financial standards" discussed in that preamble focused on the need to specify financial criteria or particular financial ratios as standards. This demonstrates that the agency's notice-and-comment error was not harmless, and that the suppliers were prejudiced in not having a concrete, focused, reasoned proposal to comment on.[15] While such

---

[14] Other circuits follow the D.C. Circuit on this. *See, e.g.*, Prometheus Radio Project v. FCC, 652 F.3d 431, 449-54 (3d Cir. 2011) (citing and quoting Horsehead Res. Dev. Co. and Home Box Office); Natural Res. Def. Council v. EPA, 824 F.2d 1258, 1285 (1st Cir. 1987) (citing and quoting Small Refiner Lead Phase-Down Task Force).

[15] In cases involving an utter failure of notice and comment, as here, this Circuit has not required a particularly robust showing, if any, of prejudice to affected entities. Chamber of Commerce of the U.S. v. SEC, 443 F.3d 890, 904 (D.C. Cir.

comments show that the commenters were aware of the general subject of the need to meet financial standards specified by the agency, they do not show that they knew what standards the agency was proposing; they show just the opposite.[16]

The agency argues that the present case is nothing like Conn. Light & Power Co. or Am. Radio Relay League because it is not hiding information supporting the rule in a manner that made it impossible to provide meaningful comment. This contention is plainly contrary to the administrative record. The NPRM indicated that the agency was developing some (undisclosed) "methodology" to be used to evaluate the financial information it would require to be submitted. The use of such a "methodology" that was undisclosed through rulemaking was held to violate notice and comment requirements in MST Express, 108 F.3d at 403, 406.

Although the agency appears careful not to admit overtly in its brief that such a methodology in fact exists, the administrative record shows, consistent with that NPRM statement on "methodology," that the agency is employing quantitative standards in order to evaluate such financial information, and that it has kept such

---

2006); Sugar Cane Growers Co-op of Fla. v. Veneman, 289 F.3d 89, 96 (D.C. Cir. 2002).

[16] In any event, comments on a particular subject cannot be used to "bootstrap" a non-proposal into a proposal. *See* Horsehead Res. Dev. Co, Inc. v. Browner, 16 F.3d 1246, 1268 (D.C. Cir. 1994); Fertilizer Inst. v. EPA, 935 F.2d 1303, 1312 (D.C. Cir. 1991). First Am. Discount Corp., cited by the agency (at 40), involved, unlike the present case, a detailed proposal, and the court determined that the final rule was a logical outgrowth of the proposal, and that in any event any deficiency in notice and comment would be considered a harmless error.

standards (or "methodology") hidden. App. a189 (4th column and footnote -- "financial score ... calculated"), a161 (sec. 4. -- "CMS' established financial thresholds"), Add. A-43 ("If suppliers do not meet certain ratios, they could be disqualified ....").[17] The agency even strongly suggests that such quantitative evaluation standards exist by arguing (at 48) that their non-disclosure was acquiesced in, or ratified by, Congress because Mr. Weems of CMS told a Subcommittee that they were not telling suppliers how their financial information was being scored, and Congress "chose not to require the Secretary to disclose the minimum financial ratio scores used to determine eligibility ...." (*Id.*)

Such financial "scores," "thresholds," or "certain ratios" that must be met were never proposed for comment and therefore could not be a "logical outgrowth" of a proposal of the NPRM. They have been kept hidden and disguised.[18] This fact alone should definitively determine that notice and comment was inadequate and now must be conducted in accordance with law and procedures required by law. 5. U.S.C. § 706.[19]

---

[17] See also the CMS statement in n. 19, *infra*.

[18] The agency has never suggested that it could assert a "good cause" exception to notice and comment requirements pursuant to 5 U.S.C. § 553(b)(3)(B).

[19] The agency's references to PAOC meetings as providing sufficient notice of an agency proposal for financial standards are not relevant. The PAOC was only an advisory body, and it never made any recommendations on financial standards. And PAOC meeting summaries cited by the agency (at 8) do not show that the agency ever provided notice of any agency proposal for financial standards at such

The agency should clarify for the Court whether it is in fact employing undisclosed financial "scores," "thresholds," cutoffs, or "particular financial ratios" as financial standards, or whether it is relying on the principle of "overall financial soundness" as its sole financial standard. The agency cannot have it both ways.

Furthermore, the agency has not explained why the NPRM contained no discussion of how its purported "standards" would take into account the needs of small providers. The requirement for specifying financial standards, "taking into account the needs of small providers," requires that the needs of small businesses be considered in setting the standards, not just in requiring documentation. This point is especially important because the agency has estimated that small businesses comprise roughly 85 percent of the DME industry.[20]

At the beginning of the next section of its brief (III, B, at 41), the agency indicates that it appears that lack of sufficient notice and opportunity for comment

---

meetings, much less a proposal from which a standard of "overall financial soundness" could be considered a logical outgrowth. Moreover, there is no evidence that Plaintiffs attended such meetings, and this Circuit has never found that Internet information is an acceptable substitute for Federal Register notice of rulemaking proposals, as the suppliers noted in their opening brief (at 38). Furthermore, the PAOC meeting summaries cited by the agency support the suppliers' assertion here that the agency is employing hidden standards. At the Oct. 11, 2007 meeting, after the final rule, suppliers and a PAOC member asked whether the financial standards would be published, and "CMS responded that the financial ratios were published ... [but that] the specific scoring would not be released to preserve the integrity of the process." (Summary at 1)

[20] 72 Fed. Reg. 17992, 18082 (April 10, 2007).

is not the Plaintiffs "principal objection" to the agency's rulemaking.[21] That is inaccurate. The lack of sufficient notice and opportunity to comment as well as the lack of specification of actual financial "standards," "taking into account the needs of small suppliers," are both important. Even if this Court were to decide that the purported standards promulgated (or undisclosed and used) by the agency can survive a Chevron analysis (discussed in the next section), it is clear that they were never proposed as standards for comment.

IV. Specification of standards. The agency is notably ambivalent about what financial standards it supposedly has specified, and none of the standards that it asserts it has specified contain an identifiable "standard" as that term is commonly understood. In addition, the agency's rulemaking does not satisfy requirements for a statement of basis and purpose. (Section 3,B in the agency brief)

In this portion of its brief, the agency continues to induce confusion about what "financial standards" it is defending. Up to this point, the agency had argued that "overall financial soundness," or simply "financial soundness" -- a term that simply expresses the obvious purpose that the standards are supposed to serve -- is the ultimate standard. (At, *e.g.*, 15, 22, 39, 41, 43, 46, 49) The district court also apparently based its decision on its view that "overall financial soundness" was the agency's final standard. Here, however, the agency now argues (at 42) that it has specified financial standards in the form of the requirements for submission of "covered documents" and in the description of the [company-specific] financial

[21] The agency's statement of issues (at 2-3) does not even mention the notice and comment issue.

ratios that "will typically be considered in evaluating financial standards," and it defends "Those standards" as sufficient even if "'vaguely articulated.'"

The agency cannot seem to make up its mind about what its financial standards are. Notably, in this section of its brief the agency makes no reference to its admitted use of undisclosed, and presumably numeric, scores, thresholds, cutoffs, or particular ratios to determine financial soundness -- until it serves its purpose to argue (at 48) that there was Congressional ratification by acquiescence of its non-disclosure of "minimum financial ratio scores" (*id*). The agency's use of these undisclosed standards contradicts its repeated assertions that either financial soundness, or perhaps company-specific documents and ratios derived from "covered documents," are sufficient standards.

While it seemingly cannot decide what to defend as its specified standards, the agency feels free (at 41-42) to characterize the suppliers' as arguing in favor of "a minimum numeric score under a particular financial ratio or ratios," which they have not. The suppliers have never stated that; nor have they stated what they otherwise believe should be the specific content of the financial standards. They have only asserted (at 45) that the standards must be "a type of measurement capable of uniform application." The agency has yet to articulate a proposal for genuine standards, and the suppliers must then have the opportunity to comment on such a proposal. At this point, the suppliers cannot make such comments without an agency proposal upon which to comment. The suppliers acknowledge that the

agency has considerable flexibility in formulating standards, and perhaps such standards might have substantial non-numeric content. However, at this time they can only contend that what the agency has proposed and finally promulgated are not in any way standards that comply with statutory mandates -- not what the standards should be.

The agency's final regulation on "Financial standards" reads in full, apart from the process for reviewing "covered documents" for completeness:

> *Financial standards*--(1) *General rule*. Each supplier must submit along with its bid the applicable covered documents (as defined in § 414.402) specified in the request for bids.

42 C.F.R. § 414.414(d), 76 Fed. Reg. 70228, 70315 (Nov. 10, 2011), Add. A-50. There is no mention of a standard of "overall financial soundness" nor the need to "meet certain [financial] ratios" or what those "certain financial ratios" are that could disqualify a supplier. Those statements are in the preamble, and they cannot reasonably be considered an "interpretation" of the substantive regulatory language.

The agency places heavy reliance on Cement Kiln in stating (at 46) that "[t]he challenged rule in this case is quite similar to a rule upheld in Cement Kiln." But the challenged rule (whatever it might be), the rulemaking, and the statutory mandate in this case do not resemble the rule upheld in Cement Kiln, or the underlying statute. Instead, the rule in this case is like the ones such as in MST Express that provided no guidance at all with regard to what standards would have

to be met. (See Pl. Br. at 51-52) The regulation upheld in Cement Kiln was found to contain an "identifiable standard," and that standard was upheld in large part because it authorized agency officials to request additional risk information only if they found "that compliance with the [MACT standards] alone may not be protective of human health or the environment." Cement Kiln, 493 F.3d at 218-20, 224, 228-29 (Appendix).[22] In addition, the eight (or nine) "factors" specified in the EPA regulation to be considered in determining the need for additional information were, although qualitative, far more specific, and gave far more guidance, than the simple listing of company-specific financial ratios relied on by the agency in this case (and which were not a part of the substantive regulation). Those site-specific environmental factors to be considered were also consistent with the statutory mandate. Moreover, a portion of the statutory mandate at issue in Cement Kiln specifically gave the agency much broader discretion than in this case. One of the RCRA provisions involved stated that "[e]ach permit issued under this section shall contain such terms and conditions as the [permitting authority] determines necessary to protect human health and the environment." *Id*. at 212.

[22] There was no assertion in Cement Kiln that the MACT standards (maximum achievable control technology standards for air emissions) were inadequate. Although the court stated that the nine "factors" to be considered that followed this statement added "further" specificity to determinations regarding the sufficiency of the MACT standards on a site-specific basis, it does not appear that the regulations as a whole would have been found sufficiently specific without the MACT inadequacy determination requirement.

The agency's attempt to distinguish Oceana (at 43), this Court's most recent decision on the required specificity for a meaningful standard, is unavailing. The reasons for finding the regulation in Oceana to be an unreasonable interpretation of the statute and impermissibly vague were that the rule gave the agency complete discretion and did "little to channel the agency's exercise of discretion." Oceana at *4. The rule and the factors it included for consideration, the Court said, "merely restate the agency's statutory obligations, [and] do not meaningfully constrain the agency ..." *Id*. The court contrasted that rule with the rule that had been at issue in Cement Kiln. The Court also noted the findings of insufficient standards in Ethyl Corp. v. EPA, 306 F.3d 1144 (D.C. Cir. 2002) and MST Express. *Id*. at *3. In the present case, the "financial standards" promulgated by the agency, whether confined to what is in the substantive rule (simply a requirement for submission of documents) or broadened to include a "principle" of "overall financial soundness" determined from a list of company-specific financial ratios, do nothing to channel the agency's discretion and amount simply to a restatement of the intent underlying the statutory mandate. As in Oceana, the supposed "financial standards" in the final rule(s) are "meaningless." *Id*.

State of New Mexico v. EPA, 114 F.3d 290 (D.C. Cir. 1997), relied on by the agency (at 45), is also very different from the present case. In that case, the court recognized that, in order to be feasible, the "criteria" that the agency was required to develop for the Waste Isolation Pilot Project had to be quite general in

order to maintain the flexibility to take into account changes that might occur over the next 10,000 years. The court commented that "[e]verything else being equal, the better a petitioner can demonstrate the feasibility of greater specificity the more convincing its attack on agency vagueness. For instance, where the agency itself has adopted highly specific *internal guidelines* governing the same subject, see MST Express ... , it cannot very plausibly deny feasibility." 114 F.3d at 294 (original emphasis). In the present case, the agency cannot argue that very general standards are the only ones feasible, because the record shows that they are employing more specific standards internally.

In addition to the supposed financial standards being standardless or impermissibly vague,[23] the agency cannot show how its rulemaking contains the reasoning for adopting the purported "financial standards" and rejecting comments that it should set definite criteria, as required by the "basis and purpose" language of the APA, 5 U.S.C. § 553(c). The APA requires that the agency at least "identifies the major policy issues raised in the rulemaking and coherently explains why the agency resolved the issues as it did." Nat'l Mining Ass'n v. MSHA, 512 F.3d 696, 700-01 (D.C. Cir. 2008) (citing cases). The agency's final rule(s) here

[23] The agency asserts that any supplier reliance on Chevron step two is not properly before this Court because it was not discussed in the supplier's district court brief. This Court has rejected such assertions. *See* United States v. Rapone, 131 F.3d 188, 197 (D.C. Cir. 1997) ("As the [Supreme] Court explained, when an appellate court reviews a question of law *de novo*, the court must use its 'full knowledge of its own [and other relevant] precedents.'") *See also, e.g.*, Felter v. Kempthorne, 473 F.3d 1255, 1261 (D.C. Cir. 2007).

does not contain any such explanation regarding the purported standard of "overall financial soundness," and why it could not adopt specific uniform criteria. The agency has not responded to this point, which was raised by suppliers in their opening brief (at 54), because it cannot.

Finally, the agency argues (at 47-48) that Congress ratified by acquiescence its failure to disclose the actual standards it is applying. The agency relies on the single statement of Mr. Weems to a Subcommittee approximately two months before the MMA was enacted. But, to start with, Mr. Weems statement, made only in response to a very general question about "transparency," did not state that the agency actually had standards that it was not disclosing. Mr. Weems only stated that the agency was not telling the suppliers how the financial ratios would be scored. That statement is ambiguous with regard to whether he was informing the Members present that some scoring system actually existed and was being withheld. Moreover, he did not reference the Congressional mandate requiring "financial standards" or indicate that there was any controversy concerning the matter and that the agency had adopted a certain interpretation of that mandate. Additionally, there is no indication that Members were aware of the implications of his statement, and there was no further questioning, discussion, or debate on the matter.

In support of its position on Congressional ratification by acquiescence, the agency cites CBS, Inc. v. FCC, 453 U.S. 367, 383-84 (1981) and Gen Am. Transp.

Corp. v. ICC, 872 F.2d 1048, 1053 n.10 (D.C. Cir. 1989). Neither case supports the agency position. In CBS, the Supreme Court recognized Congressional agreement with an agency interpretation that had been repeatedly brought to its attention over at least the last six years, and discussed in hearings by Members, and which the court found was consistent with the language and legislative history of the statute. CBS, 453 U.S. at 382-85. In the footnote in Gen. Am. Transp. that the agency cites, this Court acknowledged only that Congressional revisitation of a statute without revision could be considered "evidence" of Congressional approval, even absent proof of actual Congressional awareness or approval; but that statement applied only to a "longstanding" agency interpretation, which is not the case here. *And see* Solid Waste Agency of N. Cook County v. U.S. Army Corps of Engineers, 531 U.S. 159, 169-70 (2001) (commenting on the dangers in relying on Congressional acquiescence and the need to employ the concept only with great care).

CONCLUSION

The agency, and district court, positions on preclusion, standing, notice and comment, and compliance with the statutory mandate are all unsupported. The statutory preclusion language and statutory scheme do not show clear and convincing evidence of Congressional intent to preclude judicial review. Both the original Complaint, and the Complaint as it would have been supplemented by the motions to amend, provided sufficient legal and factual grounds for standing. The

original Complaint contained more than sufficient legal and factual allegations to state claims for relief, and it should not have been dismissed on that basis. The district court decision should be reversed and the agency final rule should be vacated, with remand to the agency to conduct legally-compliant rulemaking on financial standards, taking into account the needs of small providers.

Respectfully submitted,

March 7, 2012

/s/ William G. Kelly, Jr.
WILLIAM G. KELLY, JR.
Multinational Legal Services, PLLC
1850 Fall Line Dr.
Driggs, ID 83422
(208) 354-3050
wgkelly@silverstar.com
Counsel for Plaintiffs-Appellants

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief, using Times New Roman 14-point font, contains 6,680 words according to the word count provided by Microsoft Word 2003. The text of the brief complies with the type-volume limitations, typeface requirements, and type style requirements of Federal Rules of Appellate Procedure 32(a) and D.C. Circuit Rule 32(a).

March 7, 2012

/s/ William G. Kelly, Jr.

William G. Kelly, Jr.
MULTINATIONAL LEGAL SERVICES, PLLC
1850 Fall Line Dr.
Driggs, ID 83422
(208) 354-3050
wgkelly@silverstar.com

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2012, I caused a copy of the foregoing Reply Brief for the Appellants to be filed with the Clerk of the United States Court of Appeals for the District of Columbia Circuit by using the Court's appellate CM/ECF system. I also certify that I will cause eight paper copies to be delivered to the Clerk of the Court via USPS First Class Mail, or equivalent, within two business days of that date. Service will be made upon the following counsel for Appellees also via the CM/ECF system, with two paper copies to each within two business days via USPS First Class Mail or equivalent.

Sharon Swingle
U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave., NW -- Rm. 7250
Washington, DC 20530
(202) 353-2689
Sharon.Swingle@usdoj.gov

Michael Raab
U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave., NW -- Rm. 7250
Washington, DC 20530
(202) 514-4053
Michael.Raab@usdoj.gov

/s/ William G. Kelly, Jr.
William G. Kelly, Jr.
MULTINATIONAL LEGAL SERVICES, PLLC
1850 Fall Line Dr.
Driggs, ID 83422
(208) 354-3050
wgkelly@silverstar.com