[ORAL ARGUMENT SCHEDULED FOR APRIL 19, 2012]

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, United States 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

BRIEF FOR DEFENDANTS-APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(1), appellees Kathleen Sebelius and Marilyn Tavenner respectfully submit this certificate as to parties, rulings and related cases:

(A) Parties:

The plaintiffs in the district court, which are appellants in this Court, were Texas Alliance For Home Care Services and Dallas Oxygen Corporation.

The defendants in the district court, who are appellees in this Court, were Kathleen Sebelius, in her official capacity as Secretary, United States Department of Health and Human Services; and Marilyn Tavenner, in her official capacity as Acting Administrator, Centers for Medicare and Medicaid Services.

There were no other parties or amici curiae in the district court.

(B) Ruling Under Review

The ruling under review is the September 9, 2011 order of the district court (Chief Judge Royce C. Lamberth) dismissing the plaintiff's claims.

(C) Related Cases

There are no related cases within the meaning of D.C. Circuit Rule 28(1) of which I am aware.

/s/ Sharon Swingle
Sharon Swingle
Counsel for Defendants-Appellees

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STATEMENT OF JURISDICTION

The plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. § 1331. The district court dismissed the plaintiffs' claims on September 9, 2011, holding that it lacked subject matter jurisdiction over the claims under 42 U.S.C. § 1395w-3(b)(11), and that, in any event, the claims were legally insufficient under Federal Rule of Civil Procedure 12(b)(6). Joint Appendix (JA) 112-157.

The plaintiffs filed a timely notice of appeal on October 3, 2011. *See* JA 4 (docket entry). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES PRESENTED

Congress directed the Secretary of Health and Human Services to implement a competitive bidding program, which is intended to allow Medicare beneficiaries to obtain durable medical equipment and other items at competitive prices. The competitive bidding program is governed by 42 U.S.C. § 1395w-3, which requires the Secretary to conduct competitive bidding in stages and to award contracts to competitive bidders that, *inter alia*, "meet[] applicable financial standards specified by the Secretary * * *." The plaintiffs are a trade association and an individual company that challenge the adequacy of the Secretary's rulemaking in adopting financial standards as well as the substance of those standards. The questions presented are:

1. Whether the district court correctly held that it lacked subject matter jurisdiction under 42 U.S.C. § 1395w-3(b)(11), which provides that there "shall be no administrative or judicial review" of, *inter alia*, "the awarding of contracts under this section" and "the bidding structure and number of contractors selected under this section."

2. Whether the district court correctly held that the plaintiffs, which do not allege that they or their members were disqualified for failure to meet applicable financial standards, lack standing to challenge the substance of the standards and/or the adequacy of the procedures by which they were adopted.

3. Whether the financial standards promulgated by the Secretary were arbitrary, capricious, or otherwise not in accordance with law.

CONSTITUTIONAL AND STATUTORY PROVISIONS

The relevant statutory provisions are set out in an addendum to this brief.

STATEMENT OF THE CASE

The plaintiffs brought suit against the Secretary of Health and Human Services and the Acting Administrator of the Centers for Medicare and Medicaid Services (collectively, the Secretary), alleging that the Secretary had failed to specify financial standards by which prospective suppliers of medical equipment would be evaluated under the competitive acquisition program mandated by 42 U.S.C. § 1395w-3. JA 5-17. The defendants moved to dismiss the action for lack of subject matter jurisdiction, lack of standing, and failure to state a valid claim. JA 18. The district court granted the motion, holding that it lacked jurisdiction, that the plaintiffs lacked standing, and that the plaintiffs' claims were legally insufficient. JA 114.

STATEMENT OF FACTS

A. Statutory and Regulatory Background.

1. Title XVIII of the Social Security Act, commonly known as Medicare, 42 U.S.C. §§ 1395 *et seq.*, establishes a health insurance program for the elderly and disabled. The program pays for covered medical services and equipment provided to eligible Medicare beneficiaries. *See id.* §§ 1395c, 1395k, 1395m.

Prior to 2003, payments for durable medical equipment provided to Medicare beneficiaries were made based on "a different fee schedule for each class of covered items." H.R. Conf. Rep. 108-391, at 572 (2003). That approach, however, was found to have led to significant and substantial overpayment for durable medical equipment. *See* H.R. Rep. 108-178, Part 2, at 145 (2003) ("The Office of Inspector General has documented that taxpayers and Medicare beneficiaries are paying millions more for durable medical equipment than other programs * * *."). A demonstration project to test competitive acquisition of durable medical equipment showed that both taxpayers and Medicare beneficiaries "saved significantly" and also that "quality standards were higher" with competitive bidding. *Id.* at 192.

Accordingly, Congress amended the Medicare statute in 2003 to provide for competitive bidding for durable medical equipment. *See* Pub. L. No. 108-173, Title III, § 302(b)(1), 117 Stat. 2224 (codified in relevant part at 42 U.S.C. § 1395w-3, as amended). Congress directed the Secretary to "establish and implement programs under which competitive acquisition areas are established throughout the United States for * * * the furnishing under this part of competitively priced items and services." 42 U.S.C. § 1395w-3(a)(1)(A). Congress identified specific regions to be phased in through successive stages of bidding, and also authorized the Secretary to prioritize competitive bidding for "the highest cost or highest volume items and services or those items and services that the Secretary determines have the largest savings potential." *Id.* § 1395w-3(a)(1)(B).

The 2003 statutory amendment set out general requirements for the competitive bidding program. *See* 42 U.S.C. § 1395w-3(b). The Secretary is required to conduct a competition among entities that supply items and services for which competitive bidding has been implemented in a particular region. *Id.* § 1395w-3(b)(1). Before the Secretary can award a contract, she must find that the bidder "meets applicable quality standards specified by the Secretary" and that the bidder has been accredited by a CMS-approved accreditation organization. *Id.*

§§ 1395w-3(b)(2)(A)(I), 1395m(a)(20). In addition, the Secretary must find that the total cost of awards for competitive bidding is less than the amount that would have been paid under the fee schedules, and that "[a]ccess of individuals to a choice of multiple suppliers in the area is maintained." *Id.* § 1395w-3(b)(2)(A)(iii)-(iv). Finally, the Secretary must find that the bidder "meets applicable financial standards specified by the Secretary, taking into account the needs of small providers." *Id.* § 1395w-3(b)(2)(A)(ii). It is this final requirement that is at issue in this litigation.

The Secretary is authorized to set the terms and conditions of contracts with suppliers under the competitive bidding program. *See id.* § 1395w-3(b)(3)(A). The Secretary is also empowered to limit the number of contractors in a particular bidding area and, in making awards, to take into account the ability of the bidder to furnish items or services in sufficient quantities to meet the anticipated need on a timely basis. *Id.* § 1395w-3(b)(4)(A). "[I]n order for a suppliers to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must submit a bid to furnish those items and be awarded a contract * * *." 42 C.F.R. § 414.412(a); *see also* 42 U.S.C. § 1395w-3(b)(6).

Congress established strict limits on administrative or judicial review of the competitive bidding program. Under 42 U.S.C. § 1395w-3(b)(11),

> [t]here shall be no administrative or judicial review under [42 U.S.C. § 1395ff, 42 U.S.C. § 1395*oo*], 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);
>
> (D) the phased-in implementation under subsection (a)(1)(B);
>
> (E) the selection of items and services for competitive acquisition under subsection (a)(2); or
>
> (F) the bidding structure and number of contractors selected under this section.

Finally, Congress directed the Secretary to establish a "Program Advisory and Oversight Committee" to advise her on implementation of competitive bidding, including the "establishment of financial standards" for potential bidders. 42 U.S.C. § 1395w-3(c). The Secretary was also directed to report to Congress on the competitive bidding program. *Id.* § 1395w-3(d).

2. As contemplated by the 2003 enactment, the Secretary established the Program Advisory and Oversight Committee to provide advice on, *inter alia*, financial standards for suppliers in the competitive bidding program. *See* 69 Fed. Reg. 52,723, 52,723 (2004). The Secretary sought public nominations for Committee members, and also invited public participation in Committee meetings.

See ibid. The membership of the Committee included multiple representatives from medical supply companies. *See* 71 Fed. Reg. 25,654, 25,658 (2006). The Committee held a number of meetings between 2005 and 2007 at which the financial standards to be applied to competitive bidders were discussed.[1]

The Secretary also conducted notice-and-comment rulemaking to implement competitive bidding, including the financial standards to be applied to determine bidders' eligibility. As the proposed rule explained, evaluating the "financial standards for suppliers assists [the Secretary] in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the

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[1] *See* 71 Fed. Reg. 25,654, 25,658 (2006); Meeting Summary, Feb. 28-Mar. 2, 2005 Committee Meeting, available at http://www.cms.gov/DMEPOSCompetitiveBid/PAOCMI/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=descending&itemID=CMS028446&intNumPerPage=10; Meeting Summary, Sept. 26-27, 2005 Committee Meeting, available at http://www.cms.gov/DMEPOSCompetitiveBid/PAOCMI/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=descending&itemID=CMS028389&intNumPerPage=10; Meeting Summary, May 22-23, 2006 Committee Meeting, available at http://www.cms.gov/DMEPOSCompetitiveBid/PAOCMI/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=descending&itemID=CMS062292&intNumPerPage=10; Meeting Summary, Oct. 11, 2007 Committee Meeting, available at http://www.cms.gov/DMEPOSCompetitiveBid/PAOCMI/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=descending&itemID=CMS1203655&intNumPerPage=10.

duration of their contracts." 71 Fed. Reg. at 25,675. The proposed rule also noted that, in the demonstration project, the government had found that "general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency, were important considerations for evaluating financial stability" of potential suppliers. *Ibid.*

Accordingly, the proposed rule stated that, as part of the bid selection process, the request for bids would identify the specific information to be used to evaluate suppliers, "which may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency." *Ibid.* The proposed rule also invited comments on the financial standards and, in particular, "the most appropriate documents that will support these standards." *Ibid.* In soliciting comments, the proposed rule also invited commenters to access the presentations, minutes, and updates from the Program Advisory and Oversight Committee, which was also advising the agency on how best to evaluate the financial capabilities of bidders. *See* 71 Fed. Reg. at 25,658.

The Secretary issued the final rule implementing the competitive bidding program in 2007. 72 Fed. Reg. 17,992 (2007). In the preamble to the final rule,

the Secretary responded to comments that the financial documentation described in the proposed rule and accompanying preamble would be too burdensome to obtain and submit, particularly for small suppliers, and that unduly restrictive financial standards could exclude qualified suppliers. *See id.* at 18,037. The Secretary explained that, after further consideration, the Secretary agreed that the proposed financial documentation would be too burdensome, and that a more limited set of materials would be required in the initial round of bidding. *See ibid.* The Secretary explained that this more limited set of materials would allow the agency "to assess a supplier's financial viability." *Ibid.* The Secretary also explained that this same type of information would generally be required in later competitive bidding, but that the Secretary "might choose to add or delete specific document requests as we gain experience on what financial information most accurately predicts whether a supplier is financially stable enough to participate" in the competitive bidding program. *Ibid.*

The Secretary also explained in the final rule that, based on the financial documentation submitted, the agency would "use appropriate financial ratios to evaluate suppliers," giving as examples a supplier's "debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company." *Id.* at 18,038; *accord id.* at 18,037. However, the Secretary declined to accept one

comment that the agency should define "a set ratio, for example, asset ratio should [be no] higher than (X percent) and the asset to liability ratio should be no lower than (X percent)." *Id.* at 18,038. As the Secretary explained, the agency would "review[] all financial information in the aggregate" in evaluating a supplier's financial strength, and would not be basing its "decision on one ratio but rather overall financial soundness." *Ibid.*; *cf.* 18,037 (describing statement by commenter that using debt-to-equity ratio to evaluate privately owned company would be problematic).

The preamble to the final rule accordingly specified the financial documents that would be required to be submitted in the 2007 round of competitive bidding, based on the type of entity:

- Suppliers that file individual tax returns that include business taxes: Schedule C, Profit and Loss Statement, for the most recent three years of 1040 tax returns; a compiled balance sheet, statement of case flow, and statement of income for the most recent three years; and a copy of a current credit report by a major credit reporting agency;

- Limited partnerships and partnerships: Schedule L from 1065, U.S. Return of Partnership Income for the most recent three years; and the other documents required from suppliers that file individual returns;

- Suppliers that file corporate tax returns: Schedule L, Balance Sheet, from past three years' tax returns; a statement of cash flow and statement of operations for the most recent three years; and a copy of a current credit report from a major credit reporting agency.

- Publicly traded companies: In addition to the other materials, 10-K reports filed with the SEC by the company or, if the company is a wholly owned subsidiary, its parent company, for the most recent three years.

72 Fed. Reg. at 18,038-18,039. The final rule also explained that updated information about the requirements for competitive bidding would be available on a website set up by the Secretary for this purpose. *See id.* at 18,061.

Approximately one month after issuance of its final rule, the Secretary issued a request for bids in the first round of competitive bidding under the new program. *See* 74 Fed. Reg. 2,873, 2,875 (2009) (describing history). After several extensions of the bidding deadline, the bidding window closed, and, beginning July 1, 2008, payment for competitively bid items and services in areas for which competitive bidding had been held could only be made to suppliers who had been awarded contracts following the competitive bidding process; to grandfathered suppliers; or to physicians, treating practitioners, or hospitals that furnish certain items directly to beneficiaries. *See* 74 Fed. Reg. at 2,875; 42 C.F.R. § 414.404(b).

3. Following the initial round of competitive bidding, the House Subcommittee on Health, Ways and Means Committee, held a hearing on the competitive bidding program, the nationwide implementation of which was imminent. *See* Hearing on Medicare's DMEPOS Competitive Bidding Program, Serial No. 110-82, House Committee on Ways and Means, 110th Cong., 2d Sess.

(May 6, 2008).[2] Members of Congress and witnesses expressed concern that, in the initial round of bidding, more than 60% of the applicants appeared to have been disqualified for lack of proper documentation. JA 29 (statement of Subcomm. Chairman Stark), 36-37 (Rep. Camp), JA 36-37 (Kerry Weems, Acting Administrator, CMS). The Acting Administrator of CMS was also questioned about the transparency of the bidding process, and testified that bidders had been told "what financial documentation we need" and what financial ratios the agency would consider. JA 48. The only information that had not been disclosed, Administrator Weems explained, was exactly how the financial ratios were used and scored to judge bidders' financial viability. JA 48.

Congress subsequently enacted the Medicare Improvements for Patients and Providers Act, Pub. L. No. 110-275, § 154, 122 Stat. 2494 (July 15, 2008), which delayed the deadlines for nationwide implementation of the competitive bidding program, and also terminated contracts awarded by CMS in the first round of competitive bidding and mandated rebidding of the first round. The statute imposed a new requirement that, in circumstances in which a competitive bidder did not submit all financial, tax, or other documents required to show that the bidder met the applicable financial standards, the Secretary was required to notify

[2] A transcript of the hearing is reprinted in the Joint Appendix at JA 25-61.

the bidder of the deficiency and provide an opportunity to submit missing documents. *See* 42 U.S.C. § 1395w-3(a)(1)(F)(i). Congress made clear, however, that this new requirement did not "prevent the Secretary from rejecting a bid based on any basis" other than an initial failure to submit complete documentation, nor did it bar the Secretary from determining that the submitted materials did not "meet applicable requirements." *Id.* § 1395w-3(a)(1)(F)(iii).

4. To implement the Medicare Improvements for Patients and Providers Act, the Secretary issued a new rule that provided for rebidding of the initial round of competitive bidding and established procedures for notifying bidders of missing documents. 74 Fed. Reg. 2,873 (2009). The Secretary noted that the Act "delayed the Competitive Bidding Program and requires certain changes in subsequent competitions under the program, but it did not alter the fundamental requirements contained in the competitive bidding program statute and regulations, or revise the methodologies used by [the agency] in calculating payment amounts and selecting suppliers under the program." *Id.* at 2,875. Accordingly, the Secretary explained that the agency would require the same categories of financial documents previously requested, and as set out in the request for bids. *Id.* at 2,876. However, the Secretary noted that only one year's worth of financial documentation would be required rather than three years' worth, as the Secretary had determined based

on her experience in the prior round of bidding that one year of documentation was sufficient to evaluate a supplier's financial soundness. *Ibid.*

The Secretary also held public meetings and established an official website for bidders and suppliers that provided additional information to suppliers about how bids would be evaluated, including the evaluation of the financial soundness of bidders. *See* http://www.dmecompetitivebid.com/cbic/cbicrd1.nsf/DocsCat/852573EE00644C008525763B0073EAB3?Open&cat=Suppliers~Bid (posted Mar. 22, 2007). The web site notified bidders that the Secretary determined whether bidders meet the required financial standards by examining, in addition to the bidder's credit report and score, ten different financial ratios: (1) current assets to liabilities; (2) collection period for account receivable; (3) accounts payable to net sales; (4) cash and accounts receivable to current liabilities; (5) current liabilities to net worth; (6) return on sales; (7) sales to inventory; (8) working capital; (9) quality of earnings, *i.e.*, cash flow from operations to net income plus depreciation plus amortization; and (10) operating cash flow to sales.[3]

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[3] The website setting out financial ratios to be considered in the round 1 bidding was posted on March 22, 2007. CMS subsequently posted additional information for the round 2 bidding, including a slightly revised list of financial ratios to be considered in determining bidders' eligibility for contract awards. *See* http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/CBIC~Bidding%20Suppliers%20Round%202%20National%20Mail-Order~Bid%20Evaluation~8P2

(continued...)

On October 21, 2009, CMS opened the bidding window for the first round rebid. *See* http://dmecompetitivebid.com/palmetto/cbic.nsf/docsCat/CBIC~Important%20Dates~Round%201%20Rebid%20Timeline?open&expand=1&navmenu=Important^Dates||. Bidding was closed on December 21, 2009, and contracts were subsequently awarded by CMS. The rebid contracts and prices went into effect on January 1, 2011. *See ibid.*

B. District Court Proceedings.

1. Plaintiff Texas Alliance for Home Care Services is a non-profit organization that represents the Texas durable medical equipment industry. JA 7. Texas Alliance alleges that some of its members submitted bids in the 2009 rebidding of the first-round competitive bidding process. JA 7, 12. Plaintiff Dallas Oxygen Corporation is a supplier of durable medical equipment in Texas; it also alleges that it submitted bids to CMS under the rebidding of the first-round competitive bidding process. JA 8, 12. Before any contracts were awarded in the rebid first-round process, the plaintiffs filed suit in district court against the Secretary and CMS. JA 5, 8-9, 12.

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[3](...continued)
K5N5878?open&navmenu=Bidding^Suppliers^Round^2^National^Mail-Order|||| (last visited 1/24/12; continuously available since 9/2009).

The plaintiffs' complaint notes that the Secretary is required to determine, in evaluating a bidder's eligibility for a contract award under 42 U.S.C. § 1395w-3(b)(2)(A)(ii), that the bidder meets "financial standards specified by the Secretary, taking into account the needs of small providers." JA 9. The plaintiffs allege that the Secretary violated § 553 of the Administrative Procedure Act and § 1395hh of the Medicare Act by failing to make public the specific financial standards used to evaluate bidders' financial soundness and to provide an opportunity for comment on the standards before they were adopted. JA 13-16. The plaintiffs also allege that the Secretary violated the Freedom of Information Act, 5 U.S.C. § 552(a)(1)(C), by failing to publish the applicable standards in the Federal Register. JA 16-17. Finally, the plaintiffs allege that the Secretary acted *ultra vires* by failing to apply specified financial standards to evaluate the financial soundness of bidders. JA 17.

2. The defendants moved to dismiss, arguing that the district court lacks subject matter jurisdiction under the preclusion provision, 42 U.S.C. § 1395w-3(b)(11); that the allegations in the complaint do not establish standing; and that the complaint fails to state a valid legal claim. *See* JA 122-123. The district court granted dismissal, and denied as futile the plaintiffs' motions to amend their complaint. JA 123.

The district court held that judicial review is foreclosed by the plain language of the preclusion provision and the statutory scheme. JA 127. As the district court noted, § 1395w-3(b)(11) bars judicial review of the "awarding of contracts," and the statute "expressly ties the development and application of appropriate financial standards to the Secretary's decision to grant or deny a contract." JA 127. In addition, the statute bars judicial review of challenges to the "bidding structure" of the competitive bidding program, which the district court reasoned includes one of the required components of that bidding structure, *i.e.*, the criteria for eligibility for an award. JA 128-129. The court concluded that it lacks jurisdiction under 5 U.S.C. § 701(a)(1), which withdraws jurisdiction where "statutes preclude judicial review." JA 135-136.

The district court also held that the plaintiffs lack standing to bring suit. JA 138. The district court reasoned that the plaintiffs have not identified a concrete injury that they allegedly suffered as a result of the Secretary's challenged conduct, or that would be redressable in this litigation. JA 138-139. The court noted that any failure to receive a contract was caused by the bidder's inability to meet the underlying financial standards, not the alleged lack of publication of those financial standards. JA 141. Similarly, the court reasoned that a judicial order compelling CMS to publish the financial ratios it applies or to conduct

additional notice-and-comment rulemaking "would not transfer a financially unsound entity into a viable candidate." JA 143.

Finally, the district court held that the plaintiffs' allegations fail to state a valid claim. JA 144-156. The court rejected the plaintiffs' notice-and-comment challenge on the ground that the Secretary "specified what financial documents would be necessary, described the purposes behind the evaluation of financial viability, listed the financial ratios that might be used, and invited comments and suggestions concerning these standards." JA 146. The court held that the Secretary was not required to specify the "*precise* methodology used to calculate financial soundness," but had discretion to "employ broad principles rather than precise formulas." JA 146-148. The court also rejected the plaintiffs' claim that Federal Register publication of financial standards was required under 5 U.S.C. § 552(a)(1), reasoning that the plaintiffs had actual notice of regulatory requirements and had not suffered any adverse effects from the alleged failure to publish. JA 151-153. And the district court dismissed the allegations that the defendants acted *ultra vires* as wholly conclusory and at odds with the public record. JA 153-154. Holding that the plaintiffs' proposed amendments to their complaint did not remedy these defects, the district court also denied their motions to amend as futile. JA 155 n.20.

SUMMARY OF ARGUMENT

I. The district court correctly held that it lacks subject matter jurisdiction because the plaintiffs' claims are barred by 42 U.S.C. § 1395w-3(b)(11). Subsection (b)(11)(B)'s prohibition on judicial review of "the awarding of contracts under [§ 1395w-3]" bars a challenge to a condition on contract awards, *i.e.*, that the Secretary must find that the bidder "meets applicable financial standards specified by the Secretary." Conversely, if subsection (b)(11)(B) is limited to claims contesting an individual contract decision, judicial review is barred under subsection (b)(11)(F), which prohibits review of "the bidding structure" of the competitive bidding program. The statutory reference to "the bidding structure" clearly includes the individual components of the program required by Congress in § 1395w-3(b)(2), including the requirement that the Secretary establish financial standards to determine bidders' eligibility for a contract award. Either one or the other provision applies to bar this lawsuit.

The conclusion that judicial review is barred gains additional support from the structure and history of § 1395w-3. Subsection (b)(11) bars review of virtually every aspect of the Secretary's design and implementation of the competitive bidding program, while permitting certain challenges to post-bid conduct. This is consistent with Congress'sgoal to implement the program quickly in order to

realize enormous financial gains, without the risk of delay by disgruntled suppliers. The clear evidence of congressional intent to foreclose review overcomes the general presumption in favor of judicial review. And the plaintiffs' claims of *ultra vires* agency action are too conclusory and speculative to support federal jurisdiction.

II. The district court also correctly held that the plaintiffs lack standing. The plaintiffs have not shown that the alleged procedural harms that are the basis of their claims resulted in injury to any concrete, particularized interest of the plaintiffs. The plaintiffs allege that the Secretary's failure to promulgate financial standards with greater specificity, or to engage in notice-and-comment rulemaking, created a risk that they would be excluded from bidding. But the plaintiffs do not allege that they were disqualified as bidders on this ground, making any harm purely speculative. The plaintiffs' remaining theories of harm involve highly attenuated and speculative causal chains that cannot sustain a federal court's exercise of Article III jurisdiction.

The plaintiffs have also failed to demonstrate that any injury they suffered was traceable to the Secretary's alleged failure to publish financial standards, rather than to a supplier's underlying financial condition. Similarly, the plaintiffs cannot establish redressability because any requirement that the Secretary publish

the specific financial standards used to determine eligibility would not turn a financially unsound company into a viable bidder.

III. The district court correctly held that the plaintiffs' claims fail to state a valid cause of action. The Secretary's rulemaking process provided ample notice of, and an opportunity to comment on, the financial standards adopted by the Secretary. The proposed rule indicated that bidders would be required to submit financial documentation that would be used to evaluate financial soundness, and it described the documents that were likely to be required and the financial ratios likely to be considered by the Secretary. As shown by the comments on the proposed rule, this notice was sufficient to allow comments on both the requisite financial documentation and the appropriate financial ratios to be used.

The plaintiffs argue that the Secretary has violated the plain terms of statute by failing to specify any financial standards at all. But Section 1395w-3(b)(2)(A)(ii) does not require the Secretary to specify a precise minimum ratio or ratios that a bidder must meet in order to be eligible for a contract award. In the absence of an explicit requirement, the Secretary has broad deference to set the appropriate level of generality for the financial standards. Here, the Secretary has required bidders to submit financial, tax, and other documents, which are used to evaluate the bidders' financial soundness. The Secretary has also described the

specific documents that are likely to be required, and the financial ratios that will generally be used. That rulemaking is a reasonable construction of the statute.

STANDARD OF REVIEW

This Court reviews de novo the district court's dismissal lack of subject matter jurisdiction. *See El Paso Natural Gas Co. v. United States*, 632 F.3d 1272, 1276 (D.C. Cir. 2011). The Court also reviews de novo the district court's ruling that the plaintiffs lack standing and that the allegations in the complaint fail to state a valid claim. *See LaRoque v. Holder*, 650 F.3d 777, 786 (D.C. Cir. 2011).

ARGUMENT

I. THE DISTRICT COURT CORRECTLY HELD THAT 42 U.S.C. § 1395w-3(b)(11) BARS THE PLAINTIFFS' CLAIMS.

A. The Plaintiffs' Claims Are Barred By The Plain Language Of § 1395w-3(b)(11)(B) and (G).

1. As the district court recognized, the statutory requirement that is the basis for the plaintiffs' claims here — the requirement that the Secretary may not award a contract to an entity under the competitive bidding program unless she finds that "[t]he entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers" — is imposed as a statutory "[c]ondition for awarding contract[s]." *See* 42 U.S.C. § 1395w-3(b)(2), (b)(2)(A)(ii). The statutory preclusion provision bars administrative or judicial

review of "the awarding of contracts under this section." 42 U.S.C. § 1395w-3(b)(11). Review of an "award[] of contracts" necessarily encompasses a challenge to the criteria by which eligibility for an award is determined, since otherwise a disgruntled bidder could obtain review of the denial of an award simply by couching its claim as a challenge to the criteria employed in making the award.

The Supreme Court has repeatedly refused to allow litigants to circumvent limits on judicial review of Social Security and Medicare benefit determinations by framing their claims as a challenge to "the lawfulness of a policy, regulation, or statute that *might* later bar recovery" of the benefit. *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 10-15 (2000) (analyzing cases). As the Court recognized in *Illinois Council*, its cases "foreclose distinctions based upon the 'potential future' versus the 'actual present' nature of the claim, [or] the 'general legal' versus the 'fact-specific' nature of the challenge." *Id.* at 13. The district court correctly applied those holdings to conclude that the plaintiffs' claims come within the statutory prohibition on judicial review of "the awarding of contracts under this section." JA 128.

2. Even if the plaintiffs' claims were not barred by the prohibition on judicial review of "the awarding of contracts" under § 1395w-3(b)(11)(B), they

would be precluded by the prohibition on administrative or judicial review of "the bidding structure" of the program developed by the Secretary under § 1395w-3(b)(11)(F). The bidding structure of the program clearly encompasses the specific requirements and criteria established by the Secretary under § 1395w-3(b)(2). Those individual components of the program, such as the quality standards to be applied to determine bidder eligibility under (b)(2)(A)(I), and the financial standards applied under (b)(2)(A)(ii), are what make up the bidding structure of the program. Notably, and as the district court emphasized, the plaintiffs "offer no other part of the [durable medical equipment] Bidding Program to which this language refers." JA 129.

The plaintiffs argue that "bidding structure" refers to how "bid price offers must be submitted and how the agency will evaluate them." Pl. Br. 25. On its face, however, this description includes the agency's evaluation of whether a bidder meets applicable financial standards. The plaintiffs also invoke the Secretary's regulation, which sets out "a detailed, structured process for how bids will be evaluated," Pl. Br. 26, but that very regulation requires a supplier to submit applicable financial documentation to establish that it meets financial standards. 42 C.F.R. § 414.414(d).

The plaintiffs also invoke the statutory canon of construction of *inclusion unius est exclusio alterius* to argue that the preclusion does not apply here because § 1395w-3(b)(11) does not specifically mention financial standards. Pl. Br. 17. The canon that including one item of an associated group excludes another does "not apply to every statutory listing or grouping," however. *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003). The canon "has force only when the items expressed are members of an associated group or series, justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence." *Ibid.* (internal quotation marks and citation omitted). Here, the preclusion provision does not single out individual components of the bidding program that are required under § 1395w-3(b)(2)(A) as being immune from review, but instead refers to all of the components collectively as the "bidding structure" that cannot be challenged. As the district court noted, it is difficult to conceive of a "clearer means of precluding review." JA 129.

Finally, the plaintiffs invoke a vacated district court opinion from another circuit to argue that 42 U.S.C. § 1395w-3(b)(11) does not apply to their challenge. Pl. Br. 27 (discussing *Sharp Healthcare v. Leavitt*, 555 F. Supp.2d 1121 (S.D. Cal.

2008). Apart from the fact that the case has no legal effect,[4] it is also unpersuasive. As the district court recognized, the decision relied on the interpretation of a Medicare provision channeling review in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986), but did not address the critical differences between that statutory provision and § 1395w-3(b)(11). *See* JA 131. Furthermore, the claim in *Sharp Healthcare* did not involve financial standards, but was instead a challenge to the Secretary's decision to include entities in the competitive bidding program that allegedly had been excluded by Congress from the program's scope. *See* 555 F. Supp.2d at 1124. That claim, unlike the plaintiffs' here, arguably might have constituted the type of challenge to *ultra vires* agency action for which review is available notwithstanding a preclusion provision. Significantly, the district court in *Sharp Healthcare* explicitly recognized that the preclusion provision barred it from adjudicating

[4] The plaintiffs assert that the fact the *Sharp Healthcare* decision was vacated should be disregarded because vacatur was the result of settlement. Pl. Br. 27 & n.11. At the time the parties jointly moved for vacatur in *Sharp Healthcare*, the district court had already ruled that the claim over which the district court held it had jurisdiction, a challenge to a demonstration project for competitive bidding, had been rendered moot. *See* No. 08-CV-0170, Order (S.D. Cal. Mar. 25, 2009). The normal rule when "a claim cannot be reviewed on appeal due to mootness" is to vacate the underlying district court judgment. *Maydak v. United States*, 630 F.3d 166, 178 (D.C. Cir. 2010).

some of the plaintiff's challenges to the competitive bidding program. *Id.* at 1124, 1125 n.2.

B. The Conclusion That The Plaintiff's Claims Are Precluded Is Supported By The Structure And History Of 42 U.S.C. § 1395w-3.

The district court also correctly recognized that the conclusion that the plaintiffs' claims are barred by 42 U.S.C. § 1395w-3(b)(11) is buttressed by the statutory scheme and its intended functioning. One of Congress'sprimary goals in enacting the competitive bidding program was to authorize the Secretary to move quickly in order to realize the enormous cost savings expected. The preclusion provision is an integral part of this goal, because it protects from administrative and judicial review all aspects of the design and implementation of the competitive bidding program for durable medical equipment, while permitting certain challenges to post-bid conduct.

Thus, under 42 U.S.C. § 1395w-3(b)(11), there is no review of acceptable payment amounts; facts to be considered by the Secretary in awarding contracts; designation of areas where the Program is to be implemented; the timing of implementation; the choice of which items are included in the program; the structure of the program; or the implementation of any specific rules for particular types of durable medical equipment. "The scope of the other areas of preclusion indicate a scheme to insulate the entire [competitive bidding] program from

review, as does the broad, general language used." *Carolina Med. Sales, Inc. v. Leavitt*, 559 F. Supp.2d 69, 77 (D.D.C. 2008). Permitting the plaintiffs to challenge the financial standards applied by the Secretary to determine eligibility for a contract award would interfere with Congress'sclear intent that Medicare be able to take the initial steps necessary to implement the competitive bidding program without the risk that litigation would block its execution or lead to "inordinate delays" in implementation. *Cardiosom, LLC v. United States*, 656 F.3d 1322, 1326 (Fed. Cir. 2011).

That same broad purpose is evident in other parts of § 1395w-3. In § 1395w-3(b)(2)(B), Congress provided that any delay in the implementation of the required quality standards or the receipt of advice from the program oversight committee (which was charged with advising the Secretary on financial standards) "shall not delay the implementation of the competitive acquisition program under this section." That purpose would be thwarted if a disgruntled supplier could bring suit to enjoin the program on the basis that the Secretary failed to follow the appropriate procedures in setting financial standards.

Indeed, even where Congress itself briefly delayed the implementation of round one of the competitive bidding program, Members expressed significant concern about the loss of cost savings estimated at $3.5 billion for just one year of

delay. JA 57-58. Congress ultimately authorized the delay only in tandem with a "budget neutral offset" that reduced reimbursement rates to suppliers. Pub. L. No. 110-275, § 154(a)(2), 122 Stat. 2494, 2560-2563. In the face of this statutory structure and history, it is utterly implausible that Congress would nevertheless have intended for private suppliers to be able to delay indefinitely the implementation of the program, through litigation challenging the financial standards adopted by the Secretary for the initial round of bidding.

C. The Clear Evidence In The Statutory Text, Structure, And Legislative History Of Congress'sIntent To Bar Review Overcomes Any Presumption In Favor Of Judicial Review.

The clear evidence of congressional intent in the plain language of the preclusion provision, as well as the statutory structure and history, overcomes the general presumption in favor of judicial review. *See Block v. Community Nutrition Institute*, 467 U.S. 340, 347, 349 (1984) (recognizing that the presumption favoring judicial review may be overcome by "inferences of intent drawn from the statutory scheme as a whole"). The plaintiffs assert that the fact they allege non-compliance with a statutory mandate requires an even stronger showing, Pl. Br. 16, but the Supreme Court has applied preclusion in similar circumstances even though the practical consequence was that the plaintiff would

have no right of review at all. *See Heckler v. Ringer*, 466 U.S. 602, 620-624 (1984).

The cases that the plaintiffs rely on to assert a right of judicial review are readily distinguishable; in each case, the evidence of Congress'sintent to cut off was far less clear than is present here. In *Gutierrez v. Lamagno*, 515 U.S. 417 (1995), the argument for preclusion rested on "statutory fog" and Congressional "silence." *Id.* at 425, 426. The holding in *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), as the Supreme Court subsequently recognized, rested on the unique language of the statutory preclusion provision, *see Illinois Council*, 529 U.S. at 14, which is narrower than the language of § 1395w-3(b)(11). *See also General Elec. Co. v. Jackson*, 610 F.3d 110, 126 (D.C. Cir. 2010) (*McNary*'s holding "rested entirely on the Court's analysis of the jurisdictional provision's text"), *cert. denied*, 131 S. Ct. 2959 (2011). In *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), and *Action Alliance of Senior Citizens v. Leavitt*, 483 F.3d 852 (D.C. Cir. 2007), the question was whether Congress had impliedly precluded judicial review through adoption of a channeling-of-review provision, and there was no statutory provision comparable to the express prohibition on review in § 1395w-3(b)(11). *Safe Extensions, Inc. v. FAA*, 509

F.3d 593 (D.C. Cir. 2007), did not even involve an argument that Congress had foreclosed administrative review.

D. The Plaintiffs' Conclusory And Unsupported Claim Of *Ultra Vires* Agency Action Does Not Support Jurisdiction.

The plaintiffs also argue that the district court should review whether the agency acted *ultra vires* by "awarding [durable medical equipment] contracts without having specific financial standards." Pl. Br. 17-18. The district court properly rejected that argument under *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1951 (2009). JA 136-137. As the district court noted, the plaintiffs makes no factual allegations in support of their conclusory assertion that the defendants evaluate the financial soundness of bidders without financial standards and on an *ad hoc* basis. JA 136-137, 142. That conclusory assertion cannot be credited, because it is at odds with the factual allegations in the plaintiffs' own filings and the administrative record, which make clear that the Secretary was applying financial standards to evaluate bids and award contracts. JA 142; JA 12, 72, 88, 106; JA 161-162; 74 Fed. Reg. at 2,875-2,876.

II. THE DISTRICT COURT CORRECTLY HELD THAT THE PLAINTIFFS LACK STANDING.

The district court also correctly held that dismissal of this action is required because the plaintiffs lack standing. The requirement of standing is "an essential

and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). As the parties invoking the jurisdiction of a federal court, the plaintiffs have the burden "clearly to allege facts demonstrating" their standing. *Spencer v. Kemna*, 523 U.S. 1, 11 (1998). In order to meet the "irreducible constitutional minimum of standing," the plaintiffs must demonstrate that Dallas Oxygen Corporation or at least one individual member of Texas Alliance has suffered an "injury in fact" that is fairly traceable to the alleged legal violation challenged in the litigation, and that would likely be alleviated by the relief sought. *Florida Audobon Soc'y v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (en banc); *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002). The plaintiffs have not shown any of these elements.

A. The Plaintiffs Have Not Alleged Any Injury To A Concrete, Particularized Interest.

In order to establish that they have standing to challenge the defendants' alleged failure to publish financial standards, the plaintiffs must show that the procedural violation "resulted in injury to their concrete, particularized interest." *Center for Law & Educ. v. Department of Education*, 396 F.3d 1152, 1157 (D.C. Cir. 2005). This requires more than simply showing that a procedural requirement was violated. *See, e.g., Florida Audobon Soc'y*, 94 F.3d at 664; *Center for Law &*

Educ., 396 F.3d at 1159. The plaintiffs must also "demonstrate how they suffer actual injury" as a result. *Center for Law & Educ.*, 396 F.3d at 1159.

The plaintiffs argue that the Secretary's alleged failure to specify financial standards and the alleged lack of adequate notice of the standards created "the distinct risk" that suppliers of durable medical equipment will not "meet the standards and will lose the opportunity to compete for contracts." Pl. Br. 31. The plaintiffs also suggest that the alleged lack of clarity about financial standards forces suppliers to expend resources to participate in the bidding process even though they might not qualify to be awarded a contract. Pl. Br. 32.

Those harms, however, appear wholly speculative based on the allegations in the plaintiffs' complaint. Although the plaintiffs allege that some members of plaintiff organization Texas Alliance and plaintiff Dallas Oxygen Corporation provide durable medical equipment to Medicare beneficiaries, and that those companies submitted bids under the competitive bidding program established by the Secretary, JA 7-8, the plaintiffs do not allege that any of the bidders were disqualified because they failed to meet financial standards. *Cf. Sierra Club v. EPA*, 292 F.3d at 901 (emphasizing that the facts establishing a plaintiff's standing "are necessarily peculiar to it and are ordinarily within its possession"). Indeed, the plaintiffs' own documents support the contrary conclusion. *See, e.g.,* JA 189.

And although the plaintiffs have moved to amend their complaint on multiple occasions since the first round of competitive bidding was completed, *e.g.,* JA 62-63, 78-79, 94-96, none of the proffered amendments showed that the plaintiffs (or any members of Texas Alliance) were disqualified for failure to meet financial standards.

The plaintiffs also argue that financial standards may impact the bids that suppliers would be willing to submit; that inappropriately lax financial standards may result in financially unsound companies submitting bids; and that inappropriate standards might result in lower quality of service for Medicare beneficiaries. Pl. Br. 33. These harms, however, are far too speculative and attenuated to sustain a federal court's exercise of Article III jurisdiction. The plaintiffs' argument that the Secretary's alleged failure to specify financial standards will create a risk that financial unsound companies will "taint the bidding pool and undercut the Plaintiff suppliers' bids," Pl. Br. 32, for example, requires a court to accept that (1) under the current financial standards certain suppliers would be treated as eligible bidders, but (2) notice-and-comment rulemaking of the specific cut-off ratios to be applied would have resulted in more stringent financial standards, and (3) some of the bidders who were deemed eligible in the competitive bidding program would not have met those stricter

requirements, and (4) the plaintiffs would have submitted bids that were higher than the excluded bidders but low enough to be successful, and (5) as a result, the plaintiffs would have been awarded contracts that they were not awarded in the bidding program or at a higher contract price than they received. Similarly, and as the district court noted, the argument based on harm to individual Medicare beneficiaries is based on the assumptions that "(1) under the current financial standards the Medicare beneficiary would obtain a rate and quality of care that (2) would be altered by new financial standards (whatever they may be) and (3) would lead to higher costs or lower-quality services." JA 140. These theories of injury are insufficient under the decisions of this Court and the Supreme Court. *See, e.g., Center for Law & Educ.*, 396 F.3d at 1160-1161, 1167-1168; *Florida Audubon Soc'y*, 94 F.3d at 669-672; *Allen v. Wright*, 468 U.S. 737, 746-759 (1984); *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 42-46 (1976).

B. The Plaintiffs Have Also Failed To Show That Any Injury Is Fairly Traceable To The Alleged Procedural Violation, Or That It Would Likely Be Alleviated By The Relief They Seek.

The district court also correctly recognized that the plaintiffs failed to show that any injury they suffered was fairly traceable to the Secretary's alleged failure to publish the financial standards applied to determine a bidder's eligibility for a

contract award. To the extent any supplier fails to meet the Secretary's financial standards, that denial will not have anything to do with the specificity of the Secretary's standards, but will instead be a result of the supplier's actual financial condition. JA 141-142. "Nothing about the publication of particular financial standards * * * is capable of altering a supplier's *actual* financial condition." JA 141. The plaintiffs have thus failed to satisfy the requirement of demonstrating that "the defendant caused the particularized injury, and *not just* the alleged procedural violation." *Center for Law*, 396 F.3d at 1159 (emphasis in original; quotation marks and citation omitted); *see also, e.g., Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 663 F.3d 470, 474 (D.C. Cir. 2011).

Conversely, even if the court were to compel the Secretary to submit the financial standards employed to determine eligibility to notice-and-comment rulemaking, that procedural process would not transform a financially unsound company into a viable bidder under the program. *See National Ass'n of Home Builders*, 663 F.3d at 474-475. Accordingly, the plaintiffs are also unable to make the necessary showing of redressability. *Cf. Newdow v. Roberts*, 603 F.3d 1002, 1015 (D.C. Cir. 2010) (recognizing that redressability and traceability typically "overlap as two sides of a causation coin"), *cert. denied*, 131 S. Ct. 2441 (2011).

Finally, the plaintiffs assert that the agency failed to apply financial standards but instead determined suppliers' eligibility "on an *ad hoc* and arbitrary basis." Pl. Br. 31. This allegation is wholly conclusory and not entitled to be credited as true under *Iqbal*. *See also Center for Law*, 396 F.3d at 1159 ("Unadorned speculation will not suffice to invoke the judicial power."). The district court correctly held that the plaintiffs failed to establish Article III standing.

III. THE PLAINTIFFS' ARGUMENTS ALSO FAIL ON THE MERITS.

Finally, the district court was also correct in holding that the plaintiffs' claims fail to state a valid cause of action. Should the court of appeals reach this issue, it should affirm the district court's ruling that the Secretary's rulemaking was neither arbitrary and capricious nor a violation of the statute.

A. The Secretary's Rulemaking Process Provided Ample Notice Of, And An Opportunity To Comment On, Both The Proposed And Final Financial Standards.

As the district court held, "there can be no serious dispute that plaintiffs were given an adequate opportunity to comment on the financial standards." JA 145. As set out in greater detail above (pp. 7-8, *supra*), the Secretary invited public input on the financial standards to be applied to competitive bidders even before the proposed rule was published. In the proposed rule, the Secretary

explained the purposes served by reviewing financial standards, discussed the specific financial documentation that was likely to be requested in requests for bids, and explained that the demonstration project had shown that "general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency, were important considerations for evaluating financial stability" of potential suppliers. 71 Fed. Reg. at 25,675. The notice, which invited comments on the financial standards and "the most appropriate documents that will support these standards," *ibid.* was clearly sufficient to "afford interested parties a reasonable opportunity to participate in the rulemaking process" and "to present relevant information." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008),

The plaintiffs argue that the proposed rule did not identify which financial documents would be required, Pl. Br. 38, but the preamble to the rule did list documents that could be required in specific requests for bids. 71 Fed. Reg. at 25,675. The preamble also gave examples of financial ratios that might be used to evaluate a supplier's soundness. This notice was sufficient to elicit comments both about the financial documentation to be submitted to evaluate a supplier's financial soundness — including the burdens imposed on small providers by the

proposed financial documentation requirements — and the financial ratios that should be applied by the Secretary in evaluating financial soundness. *See* 72 Fed. Reg. at 18,037-18,038; *cf. First Am. Discount Corp. v. CFTC*, 222 F.3d 1008, 1015 (D.C. Cir. 2000) (noting that the existence of comments on a particular issue supported conclusion that notice of the issue was adequate). The fact that notice was provided in the preamble rather than in the text of the proposed rule itself does not render it inadequate. *See, e.g., Edison Elec. Inst. v. OSHA*, 849 F.2d 611, 621 (D.C. Cir. 1988).

The plaintiffs also assert that the Secretary's statement in the notice of proposed rulemaking that the Secretary was developing a "methodology for financial standards" must mean that there is a hidden standard or formula required to be disclosed under cases such as *Connecticut Light & Power Co. v. NRC*, 673 F.2d 525 (D.C. Cir.), *cert. denied*, 459 U.S. 835 (1982), and *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227 (D.C. Cir. 2008). Pl. Br. 37. In those cases, however, the agency "hid[] or disguis[ed] the information that it employ[ed]" in promulgating the rule in a manner that made it impossible for regulated entities to provide "meaningful commentary" on the proposed rule. *American Radio*, 524 F.3d at 236-237 (quoting *Connecticut Light & Power*, 673 F.2d at 530-531). Here, in contrast, the Secretary made clear what financial

information was being considered and also that the Secretary was determining how best to evaluate that financial information to determine a bidder's eligibility.

The plaintiff also claim that the final rule was not a "logical outgrowth" of the proposed rule, Pl. Br. 39-41, but the assertion is meritless. The final rule, like the proposed rule, requires bidders to submit financial documentation specified in the request for bids. That financial documentation will, self-evidently, be used by the Secretary to determine whether the bidder is financially sound enough to be eligible for a contract award. In the preamble to the final rule, CMS describes the types of documents that will typically be required, which is a more limited set of material than had been described in the preamble to the proposed rule. CMS also explained that the materials, and financial ratios calculated based on the materials, will be used by the agency "to assess a supplier's financial viability" and "overall financial soundness." 72 Fed. Reg. at 18,037, 18,038. That approach is fully consistent with the approach in the proposed rule.

B. The Secretary Is Not Required Under 42 U.S.C. § 1395w-3(b) To Publish The Specific Financial Ratio And Numerical Level At Which An Individual Supplier Will Be Found Ineligible To Be Awarded A Contract.

The plaintiffs' principal objection to the Secretary's rulemaking appears to be that the Secretary's rule does not identify a minimum numeric score under a

particular financial ratio or ratios that will make a bidder eligible for a contract award. As we next demonstrate, no such requirement is imposed by the statute.

1. The plaintiffs argue that the Secretary has failed to comply with the plain language of 42 U.S.C. § 1395w-3(b)(2)(A)(ii), which provides that the Secretary may not award a contract to a bidder unless the bidder "meets applicable financial standards specified by the Secretary." But the Secretary has specified financial standards: the rule requires bidders to submit "covered documents," which are defined as "financial, tax, or other document[s] required to be submitted * * * as part of an original bid submission under a competitive acquisition program in order to meet the required financial standards." 42 C.F.R. § 414.402, 414.414(d). Furthermore, the rulemaking describes the financial ratios that will typically be considered in evaluating financial standards. *See* 72 Fed. Reg. at 18,037-18,038. Those standards, even if "vaguely articulated," are sufficient to comply with the statutory requirement to specify applicable financial standards by which bidders will be evaluated. *See Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 218 (D.C. Cir. 2007).

The regulation in this case is quite similar to a regulation challenged in *Cement Kiln*, which implemented a statutory provision requiring that permit applications "contain such information as may be required under regulations

promulgated by EPA." 493 F.3d at 217. The agency's regulation authorized permitting authorities to require information from applicants as "necessary to determine whether additional controls are necessary to ensure protection of human health and the environment." *Id.* at 213-214. The Court rejected the argument that this regulation failed to comply with the statute, holding that the agency had "articulated at least a vague information requirement" and that the general language of the regulatory requirement was "narrowed by the circumstances under which it is triggered." *Id.* at 219-220 (internal quotation and alteration marks omitted). Here, similarly, the agency has articulated a requirement that bidders must submit "financial tax, or other documents," and has also specified the types of documents that are likely to be required and the financial ratios that will be used to determine a bidder's financial soundness.

The plaintiffs also rely on *Oceana, Inc. v. Locke*, No. 10-5299, 2011 WL 2802989 (D.C. Cir. July 19, 2011), but there the agency was required by statute to adopt a standardized reporting methodology yet had "reserve[d] to itself effectively complete discretion to trigger an exemption." *Id.* at *3-*4. *MST Express v. Department of Transportation*, 108 F.3d 401 (D.C. Cir. 1997), which the plaintiffs also rely on, is similarly distinguishable. The statute in that case required the agency to "prescribe regulations establishing a procedure to decide on

the safety fitness of owners and operators of commercial motor vehicles," including "a means of deciding whether the owners, operators, and persons meet the safety fitness requirements," but the regulation merely set out general factors that would be considered and did not allow a motor carrier or operator to determine what safety fitness rating it would receive. *Id.* at 405-406. There is no similar requirement in 42 U.S.C. § 1395w-3(b)(2)(A)(ii) that the Secretary must promulgate "regulations" that allow a bidder to determine whether it meets applicable financial standards before submitting its bid.

2. The plaintiffs explicitly disclaimed any challenge to the reasonableness of the Secretary's financial standards in the district court, so the question whether the Secretary's actions are reasonable under *Chevron*'s step two is not properly before this Court. *See* Plaintiffs' Memorandum In Response To Motion To Dismiss, at 17 n.14, Dkt. 13 ("To be clear, the Complaint here does not allege * * * 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."). In any event, any such challenge would also fail as a matter of law.

Although § 1395w-3(b)(2)(A)(ii) provides that the Secretary may not award a contract to a bidder unless the bidder "meets applicable financial standards

specified by the Secretary," the statute does not impose any additional limits or obligations. In circumstances such as these, where Congress "has 'not specified the level of specificity expected of the agency, * * * the agency [is] entitled to broad deference in picking a suitable level.'" *Cement Kiln*, 493 F.3d at 217 (quoting *Ethyl Corp. v. EPA*, 306 F.3d 1144, 1149 (D.C. Cir. 2002)).

The plaintiffs argue that the use of the statutory term "standards" requires "detailed and uniform criteria" by which bidders' financial soundness is evaluated. Pl. Br. 44-46. As this Court recognized in *State of New Mexico v. EPA*, 114 F.3d 290 (D.C. Cir. 1997), however, terms such as "criteria" and "standard[s]" "are ambiguous as to the level of specificity" they require, and do not necessarily mandate standards that are "detailed or quantitative." *Id.* at 293; *see also, e.g., Public Citizen, Inc. v. FAA*, 988 F.2d 186, 192-193 (D.C. Cir. 1993) (holding that statutory requirement that FAA establish minimum staffing levels does not require agency to "specify the actual number of personnel" or "a formula by which such number can be determined"). The plaintiffs also rely on the statutory instruction that financial standards will be "specified" by the Secretary, Pl. Br. 49, but a "statutory mandate that requirements be 'specific' [does not] illuminate the degree of specificity required." *Am. Trucking Ass'ns, Inc. v. Dep't of Transp.*, 166 F.3d 374, 378-379 (D.C. Cir. 1999). Indeed, if anything, the use of the term "financial

standards" — rather than, for example, "financial standard" — suggests that Congress intended to allow the Secretary the discretion to consider multiple factors and indicia of financial strength in determining a bidder's eligibility.

The challenged rule in this case is quite similar to a rule upheld in *Cement Kiln*, which governed the permitting process for facilities that burn hazardous waste as a fuel. The statute directed the agency to establish such performance standards "as may be necessary to protect human health and the environment," and the challenged rule authorized a permitting authority to require a site-specific risk assessment if it concluded based on a review of several non-exclusive factors "that compliance with [existing standards] alone may not be protective of human health or the environment." 493 F.3d at 213-214. This Court rejected the argument that this regulation was insufficiently specific to comply with the statute, holding that the Secretary was not required to establish "numerically * * * the threshold risk level that will trigger an SSRA or dictate unconditional approval of a permit." *Id.* at 222-223. Here, similarly, the Secretary has identified the relevant documentation that will be reviewed in evaluating the financial soundness of a bidder, and has also identified various financial ratios that may be considered, but has not set out a precise numerical threshold that bidders must meet. That

approach is fully consistent with the statutory text, which grants the Secretary with broad discretion in setting financial standards for eligibility.

The Secretary's approach also serves to effectuate other statutory requirements, including the requirements to take into account the needs of small suppliers, *see* 42 U.S.C. § 1395w-3(b)(2)(A)(ii); to ensure that multiple suppliers in an area remain eligible for and are awarded contracts, *see id.* § 1395w-3(b)(2)(A)(iv), (b)(4)(B); and to take into account the ability of bidders to provide sufficient quantities of items or services to meet the anticipated need in the area, *see id.* § 1395w-3(B)(4)(A). The use of a flexible standard permits the Secretary to make adjustments to financial standards as the competitive bidding program is implemented nationwide, without the risk of delay. The decision not to publish a minimum numerical threshold also serves to further the statutory goal of "combatting waste, fraud, and abuse," Pub. L. 108-173, Title III, by reducing the risk that companies could manipulate their submissions to make it appear falsely that they meet financial standards. JA 148-149.

Subsequent congressional action also supports the conclusion that the Secretary acted reasonably in implementing the statute through the issuance of broadly worded financial standards that permit consideration of a variety of types of information and financial ratios, rather than the specification of a precise

minimum ratio for eligibility cut-off. As noted above (pp. 12-13, *supra*), at the committee hearing following initial implementation of the competitive bidding program, members of Congress expressed concern about the transparency of the process, JA 29, 36-37, and the Acting Administrator acknowledged that bidders had not been told exactly how financial ratios were used and scored to judge bidders' financial viability. JA 48. Although Congress subsequently amended the statute to require the Secretary to notify bidders of missing documentation and give them an opportunity to resubmit, 42 U.S.C. § 1395w-3(a)(1)(F)(I), Congress chose not to require the Secretary to disclose the minimum financial ratio scores used to determine eligibility, and it explicitly affirmed the Secretary's authority to reject a bid on the basis that the submitted materials did not "meet applicable requirements." *Id.* § 1395w-3(a)(1)(F)(ii). Deference to the agency's construction of the statute is particularly appropriate where Congress is aware of public concerns about the agency's construction of the statute but has chosen not to overturn it despite enacting legislation that modifies other aspects of the agency's practice. *See CBS, Inc. v. FCC*, 453 U.S. 367, 383-384 (1981).[5]

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[5] The plaintiffs cite *General American Transportation Corp. v. ICC*, 872 F.2d 1048 (D.C. Cir. 1989), *cert. denied*, 493 U.S. 1069 (1990), and *AFL-CIO v. Brock*, 835 F.2d 912 (D.C. Cir. 1987), for the proposition that the legislative history in this case fails to satisfy the requirements for congressional ratification of an

(continued...)

Finally, the plaintiffs argue that, even if the statute did not require the Secretary to establish a numerical cut-off score for determining financial eligibility, once the Secretary has done so, she must make that score public. Pl. Br. 52-54. The plaintiff does not argue that the use of a cut-off score is inconsistent with the Secretary's rulemaking, and any claimed right of access to internal agency documents under the Freedom of Information Act is not before this Court. The Secretary's final rule is a reasonable construction of the statute, intended to permit consideration of relevant financial documentation and financial ratios in order to determine a bidder's financial soundness.

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[5](...continued)
agency's construction of a statute. Pl. Br. 55-56. Those cases, however, address the distinct question, not presented here, whether Congress has legislatively ratified an agency's interpretation of a statute in a manner that bars the agency from changing course. *See General American Transp.*, 872 F.2d at 1053; *AFL-CIO*, 835 F.2d at 915. The Court explicitly recognized in *General American Transp.* that evidence that Congress is aware of an agency's interpretation of a statute and chooses not to alter it by legislation can demonstrate the reasonableness of the interpretation under *Chevron*'s step two. 872 F.2d at 1053 n.10.

CONCLUSION

For the foregoing reasons, this Court should affirm the district court's order of dismissal.

Respectfully submitted,

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FEBRUARY 2012

CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

I hereby certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 10,689 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared with Word Perfect 12 in a proportional typeface with 14 characters per inch in Times New Roman.

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CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing Brief for Defendants-Appellees were filed with the Court and served on the following counsel through the CM/ECF system on February 22, 2012:

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ADDENDUM

INDEX TO STATUTORY & REGULATORY ADDENDUM

United States Code

Title 42. The Public Health and Welfare
Chapter 7. Social Security
Subchapter XVIII. Health Insurance for Aged and Disabled
Part B. Supplementary Medical Insurance Benefits for Aged and Disabled

§ 1395w-3. Competitive acquisition of certain items and services

(a) Establishment of competitive acquisition programs

(1) Implementation of programs

(A) In general

The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) Phased-in implementation

The programs--

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in--

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

(C) Waiver of certain provisions

In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Changes in competitive acquisition programs

(i) Round 1 of competitive acquisition program

Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section--

(I) the contracts awarded under this section before the date of the enactment of this subparagraph are terminated, no payment shall be made under this subchapter on or after the date of the enactment of this subparagraph based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

(ii) Round 2 of competitive acquisition program

In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)--

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008;

(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs

In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

(E) Verification by OIG

The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal

bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) Supplier feedback on missing financial documentation

(i) In general

In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary--

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) Covered document review date

The covered document review date specified in this clause with respect to a competitive acquisition program is the later of--

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) Limitations of process

The process provided under this subparagraph--

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) Covered document defined

In this subparagraph, the term "covered document" means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(2) Items and services described

The items and services referred to in paragraph (1) are the following:

(A) Durable medical equipment and medical supplies

Covered items (as defined in section 1395m(a)(13)) of this title for which payment would otherwise be made under section 1395m(a) of this title, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs).

(B) Other equipment and supplies

Items and services described in section 1395u(s)(2)(D) of this title, other than parenteral nutrients, equipment, and supplies.

(C) Off-the-shelf orthotics

Orthotics described in section 1395x(s)(9) of this title for which payment would otherwise be made under section 1395m(h) of this title which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) Exception authority

In carrying out the programs under this section, the Secretary may exempt--

(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) Special rule for certain rented items of durable medical equipment and oxygen

In the case of a covered item for which payment is made on a rental basis under section 1395m(a) of this title and in the case of payment for oxygen under section 1395m(a)(5) of this title, the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1395m(a) of this title.

(5) Physician authorization

(A) In general

With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) No effect on payment amount

A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

(6) Application

For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) of this section shall be substituted for the payment basis otherwise applied under section 1395m(a) of this title, section 1395m(h) of this title, or section 1395u(s) of this title, as appropriate.

(7) Exemption from competitive acquisition

The programs under this section shall not apply to the following:

(A) Certain off-the-shelf orthotics

Items and services described in paragraph (2)(C) if furnished--

(i) by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service; or

(ii) by a hospital to the hospital's own patients during an admission or on the date of discharge.

(B) Certain durable medical equipment

Those items and services described in paragraph (2)(A)--

(i) that are furnished by a hospital to the hospital's own patients during an admission or on the date of discharge; and

(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician's own patients as part of the physician's professional service.

(b) Program requirements

(1) In general

The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) of this section for each competitive acquisition area in which the program is implemented under subsection (a) of this section with respect to such items and services.

(2) Conditions for awarding contract

(A) In general

The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1395m(a)(20) of this title.

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(B) Timely implementation of program

Any delay in the implementation of quality standards under section 1395m(a)(20) of this title or delay in the receipt of advice from the program oversight committee established under subsection (c) of this section shall not delay the implementation of the competitive acquisition program under this section.

(3) Contents of contract

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) Term of contracts

The Secretary shall recompete contracts under this section not less often than once every 3 years.

(C) Disclosure of subcontractors

(i) Initial disclosure

Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on--

(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

(II) whether each such subcontractor meets the requirement of section 1395m(a)(20)(F)(i) of this title, if applicable to such subcontractor.

(ii) Subsequent disclosure

Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

(4) Limit on number of contractors

(A) In general

The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

(B) Multiple winners

The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

(5) Payment

(A) In general

Payment under this part for competitively priced items and services described in subsection (a)(2) of this section shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

(B) Reduced beneficiary cost-sharing

(i) Application of coinsurance

Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

(ii) Application of deductible

Before applying clause (i), the individual shall be required to meet the deductible described in section 1395*l*(b) of this title.

(C) Payment on assignment-related basis

Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

(D) Construction

Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

(6) Participating contractors

(A) In general

Except as provided in subsection (a)(4) of this section, payment shall not be made for items and services described in subsection (a)(2) of this section furnished by a contractor and for which competition is conducted under this section unless--

(i) the contractor has submitted a bid for such items and services under this section; and

(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

(B) Bid defined

In this section, the term "bid" means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

(C) Rules for mergers and acquisitions

In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

(D) Protection of small suppliers

In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

(7) Consideration in determining categories for bids

The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

(8) Authority to contract for education, monitoring, outreach, and complaint services

The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

(9) Authority to contract for implementation

The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

(10) Special rule in case of competition for diabetic testing strips

(A) In general

With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

(B) Study of types of testing strip products

Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquistion program described in subparagraph (A).

(11) No administrative or judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* 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 services 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).

(c) Program advisory and oversight committee

(1) Establishment

The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the "Committee").

(2) Membership; terms

The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

(3) Duties

(A) Advice

The Committee shall provide advice to the Secretary with respect to the following functions:

(i) The implementation of the program under this section.

(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii) of this section.

(iii) The establishment of requirements for collection of data for the efficient management of the program.

(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1395x(d) of this title, and individuals.

(v) The establishment of quality standards under section 1395m(a)(20) of this title.

(B) Additional duties

The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

(4) Inapplicability of FACA

The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

(5) Termination

The Committee shall terminate on December 31, 2011.

(d) Report

Not later than July 1, 2011, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

(e) Repealed. Pub.L. 110-275, Title I, § 145(a)(1), July 15, 2008, 122 Stat. 2547

(f) Competitive acquisition ombudsman

The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1395b-9(c) of this title. The ombudsman shall submit to Congress an annual report

on the activities under this subsection, which report shall be coordinated with the report provided under section 1395b-9(c)(2)(C) of this title.

Code of Federal Regulations

Title 42. Public Health
Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter B. Medicare Program
Part 414. Payment for Part B Medical and Other Health Services
Subpart F. Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (Dmepos)

§ 414.414 Conditions for awarding contracts.

(a) General rule. The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) Basic supplier eligibility.

(1) Each supplier must meet the enrollment standards specified in § 424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in § 414.418.

(c) Quality standards and accreditation. Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a

CMS–approved organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) 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.

(2) Process for reviewing covered documents.

(i) Submission of covered documents for CMS review. To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) CMS feedback to a supplier with missing covered documents.

(A) For Round 1 bids. CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) For subsequent Round bids. CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

(iii) Submission of missing covered documents. Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

(e) Evaluation of bids. CMS evaluates bids submitted for items within a product category by--

(1) Calculating the expected beneficiary demand in the CBA for the items in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the items in the product category;

(3) Establishing a composite bid for each supplier and network that submitted a bid for the product category.

(4) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(5) Calculating the pivotal bid for the product category;

(6) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) Expected savings. A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under Subpart C or Subpart D.

(g) Special rules for small suppliers.

(1) Target for small supplier participation. CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under § 414.416 of this subpart.

(h) Sufficient number of suppliers.

(1) Except as provided in paragraph (h)(3) of this section. CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under § 414.410(d)(2) of this subpart.

(i) Selection of new suppliers after bidding.

(1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by--

(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is

willing to become a contract supplier under the same terms and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

[72 FR 18085, 18088, April 10, 2007; 74 FR 2880, Jan. 16, 2009; 74 FR 7653, Feb. 19, 2009; 76 FR 70315, Nov. 10, 2011]