UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEXAS ALLIANCE FOR HOME CARE SERVICES, 1126 S. Cedar Ridge Dr., Suite 103, Duncanville, Texas 75137	)	
and	)	
DALLAS OXYGEN CORPATION, 11857 Judd Ct. # 214, Dallas, Texas 75243	)	
Plaintiffs,	)	
vs.	)	**Civil Action No. _____**
KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, 200 Independence Ave., SW Washington, DC 20201	)	
and	)	
MARILYN TAVENNER, in her official capacity as Acting Administrator, Centers for Medicare and Medicaid Services, United States Department of Health and Human Services, 200 Independence Ave., SW, Washington, DC 20201	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Nature of the Suit

1. Plaintiffs bring this suit under the Administrative Procedure Act ("APA") and the Freedom of Information Act ("FOIA") to compel Defendants to (1) comply with the Medicare provisions of the Social Security Act regarding suppliers of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS," or "DME" in short form) by specifying

financial standards that such suppliers must meet, taking into consideration the needs of small providers, (2) to comply with the APA and the Medicare provisions of the Social Security Act by providing proper notice and opportunity for public comment in proposing and specifying such financial standards, and (3) to publish in the *Federal Register*, or otherwise provide to Plaintiffs, the "financial standards" it is applying to qualify such DME suppliers, if in fact they exist. Plaintiffs allege that in fact Defendants have not specified financial standards, even internally andwithout public notice and comment, and are making decisions regarding the financial soundness of prospective DME suppliers on an *ad hoc* basis without the application of specified financial standards, contrary to law.

Jurisdiction and Venue

2. This Court has original subject matter jurisdiction under 28 U.S.C. § 1331 because this suit arises under the laws of the United States. Those laws include 42 U.S.C. § 1395w-3(b)(2)(A)(ii) (Medicare), 5 U.S.C. § 553(b) and (c) (APA), 42 U.S.C. § 1395hh(b) (Medicare), 5 U.S.C. § 701 *et seq*. (APA), 5 U.S. C. § 552(a)(1)(D) (FOIA), and 5 U.S.C. § 552(a)(4)(B) (FOIA).

3. Judicial review and declaratory and injunctive relief are authorized under 5 U.S.C. § 701 *et seq.*, 28 U.S.C. § 2201, and 5 U.S.C. § 552(a)(4)(B).

4. Venue in this Court is proper under 28 U.S.C. § 1391(e) because each Defendant is an officer or employee of the United States and an agency thereof acting in her official capacity whose duties are performed in the District of Columbia.

5. This Court has personal jurisdiction over Defendant Secretary Sebelius. As Secretary of the United States Department of Health and Human Services ("HHS"), her principal office is located in the District of Columbia.

6. This Court has personal jurisdiction over Defendant Tavenner. As Acting Administrator of the Centers for Medicare and Medicaid Services, HHS, one of her principal offices is located in the District of Columbia.

7. Plaintiff Texas Alliance for Home Care Services ("TAHCS") has standing under Article III of the United States Constitution to bring this suit in a representative capacity on behalf of its members who are Medicare DME suppliers, including small suppliers. Plaintiff Dallas Oxygen Corporation ("DOC") has standing under Article III of the United States Constitution to bring this suit as an accredited and bonded Medicare DME small supplier that has applied under MIPPA to be a Medicare contract supplier. Plaintiffs have standing under Article III of the United States Constitution to bring this suit, and prudential standing under the APA, FOIA, and the Social Security Act because, although there is, of necessity, uncertainty as to the effect of Defendants' procedural failures, those failures cause a distinct risk of harm to Plaintiffs' concrete Medicare DME supplier interests.

Plaintiffs

8. Plaintiff Texas Alliance for Home Care Services ("TAHCS") is a non-profit corporation incorporated in the State of Texas that represents the Texas durable medical equipment industry. Many of its members are accredited and bonded Medicare DME suppliers, serving Medicare beneficiaries in a Round 1 Rebid competitive bidding area. Its members include companies that have applied to Defendants for approval as contract suppliers of DME pursuant to the applicable Medicare provisions of the Social Security Act, and have submitted bids and the financial documentation currently required by Defendants and which Defendants are currently reviewing or have reviewed. Many of those members are small providers within the definition promulgated by CMS. TAHCS conducts advocacy on behalf of its members before

HHS and CMS, counsels its members on Medicare government relations matters and legal compliance, and keeps them informed of developments in the DME industry.

9. Plaintiff Dallas Oxygen Corporation ("DOC") is an accredited and bonded Medicare DME provider and is a member of TAHCS. It supplies more than 3,000 customers with many types of DME. DOC has applied to Defendants for approval as a contract supplier of DME under Medicare and has submitted bids and the financial documentation currently required by Defendants and which Defendants are currently reviewing or have reviewed. DOC is also a small business provider of such equipment under the definition of a small business provider in the Defendants' final rule.

Defendants

10. Defendant Sebelius, as Secretary of the United States Department of Health and Human Services ("HHS"), is responsible by statute for implementing the Medicare provisions of the Social Security Act, including the requirement that she specify financial standards that Medicare DME providers must meet, giving due consideration to the needs of small providers. Ms. Sebelius' predecessor as Secretary of HHS, Michael O. Leavitt, approved the May 1, 2006 notice of proposed rulemaking (71 Fed. Reg. 25654), the April 10, 2007 notice of final rulemaking (72 Fed. Reg. 17992), and the interim final regulations of January 16, 2009 (74 Fed. Reg. 2873) that contained provisions supposedly concerning financial standards for DME providers, but which, Plaintiffs allege, did not actually specify proposed standards on which Plaintiffs and others could provide comments or specify the financial standards which they must meet.

11. Defendant Tavenner is Acting Administrator of the Centers for Medicare and Medicaid Services ("CMS"). CMS is the program office within HHS principally responsible for implementation of the Medicare provisions of the Social Security Act. Ms. Tavenner's

predecessors as Administrator or Acting Administrator of CMS, Mark B. McClellan, Leslie Norwalk, and Kerry Weems, approved, respectively, the Medicare DME rulemakings referred to above in paragraph 10.

Facts

12. On December 8, 2003 the President signed into law Public Law 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, commonly known in short form as the Medicare Modernization Act or "MMA." The MMA replaced the previous Medicare fee-schedule pricing system with a competitive bidding program to supply DMEPOS. 42 U.S.C. § 1395w-3. The MMA required, as a prerequisite to qualify for being considered as a Medicare DME contract supplier, that the Secretary must find that a DME applicant meets "financial standards specified by the Secretary, taking into account the needs of small providers." 42 U.S.C. § 1395w-3(b)(2)(A)(ii).

13. On May 1, 2006, Defendants issued a notice of proposed rulemaking to implement the MMA that contained a section in the preamble titled "3. Financial standards (Proposed § 414.414(d))." 71 Fed. Reg. 25654, 25675. That preamble section stated: "We welcome comments on the financial standards, in particular the most appropriate documents that will support these standards." This section also stated: "As we develop our methodology for financial standards, we will further consider which individual measures should be required . . . ." *Id.*

14. Section § 414.414 of the substance of the proposed rule, titled "Conditions for awarding contracts," contained a subsection (d), titled "Financial standards," which stated only that "[a]ll suppliers must meet the applicable financial standards specified in the request for bids." 75 Fed. Reg. at 25700. The proposed rule did not contain any further information on the

substance of the proposed financial standards, and the "request for bids" was not a part of the notice of proposed rulemaking.

15. On April 10, 2007, Defendants issued a notice of final rulemaking. 68 Fed. Reg. 17992. The preamble characterized a number of comments on the proposed rule which requested that Defendants set specific financial standards for DME providers. 68 Fed. Reg. 18037-38. The preamble contained a "Response" to those comments that stated: "We will use appropriate financial ratios to evaluate suppliers. If suppliers do not meet certain ratios, they could be disqualified from the competition. Examples of ratios we might consider include a supplier's debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company. ... We will be reviewing all financial information in the aggregate and will not be basing our decision on one ratio but rather overall financial soundness." *Id*. at 18038. The preamble did not specify the "appropriate financial ratios" to be used and did not otherwise specify the financial standards that would be applied to determine "overall financial soundness." Comments on "financial standards" were further described in the rulemaking preamble at 18072, particularly with regard to small suppliers, and they included comments that HHS should define the financial standards applicable to small suppliers. HHS responded: "We are clarifying in the final rule that the RFB [request for bids] will specify what financial documents will be required (§ 414.414.(d)) so that we can obtain a sufficient amount of information about such supplier while minimizing the burden on both bidding suppliers and the bid evaluation process. This financial information will provide enough information to allow us to determine financial ratios, such as a supplier's debt-to-equity ratio, and credit worthiness, which will allow us to assess a supplier's financial viability. We believe we have balanced the needs of small suppliers and the needs of the beneficiaries in requesting documentation that will provide us with sufficient information to determine the financial soundness of a supplier." *Id*. at 18072.

16. Subsection 414.414(d) in the substantive portion of the above final rule, titled "*Financial standards."* stated only the following: "Each supplier must submit along with its bid the applicable financial documentation specified in the request for bids." *Id*. at 18088. The final rule did not specify financial standards that would be applied to such documentation, and the "request for bids," which was not part of the final rule, did not specify such financial standards.

17. On July 15, 2008, the MMA bidding process for DME was superseded by the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"). Pub.L. No 110-275, § 154. MIPPA effectively negated DME bids submitted under the MMA, reinstated temporarily the fee-schedule system in place before the MMA, and mandated Defendants to conduct a new round of bidding during 2009 similar to that previously conducted under the MMA, with certain modifications not relevant here. MIPPA did not amend the requirement for the Secretary to specify financial standards, taking into consideration the needs of small providers, that was part of the MMA.

18. On January 16, 2009, Defendants issued an "interim final rule," with a 60-day comment period, to implement the re-bid requirements of the MIPPA. 74 Fed. Reg. 2873. The interim final rule altered only very slightly and insignificantly the substantive rules regarding "Financial standards" that were contained in the 2007 final rule. Section 414.414, titled "**Conditions for awarding contracts**," contained a subsection (d)(1), titled "*Financial standards*," that stated: "(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." *Id*. at 2880 (now 42 CFR § 414.414). Subsection (d) also contained a new paragraph (2) that addressed the "*Process for reviewing covered documents."* Subsection (d) did not specify the financial standards that would be used to evaluate the "covered documents." *Id*. at 2880-81. Section 414.402 (titled "Definitions"), referenced in the "*Financial standards"* section, *supra*,

states that "*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 the required financial standards." *Id*. at 2880 (now 42 CFR § 414.402). Nowhere in the interim final rule did Defendants specify the financial standards to be used to evaluate "covered documents."

19. During the Fall of 2009, prospective bidders, including members of TAHCS and DOC, submitted the "covered documents" required by 42 CFR § 414.402 without knowing what financial standards would be used to evaluate them. The bidders, including Plaintiffs and members, also had to formulate their bids while being in the dark about the financial standards that would be applied to their businesses and that would affect what bids they would be willing to submit.

20. Defendants are supposedly using, or have used, the financial standards required to be specified by the MMA, or some other standards or judgments, in order to qualify DME bidders. Plaintiffs and members do not know whether or not they have been determined by Defendants to be qualified bidders under whatever financial standards or judgments are, or have been, applied.

21. Defendants have posted on their Medicare website, on their DMEPOS competitive bidding webpage, a timeline for implementation of the DMEPOS re-bid program mandated in MIPPA. That timeline gives a "target date" of "June 2010" when "CMS announces single payment amounts, begins contracting process," and a "target date" of "Early Fall 2010" when "CMS announces contract suppliers, begins contract supplier education campaign." https://www2.cms.gov/DMEPOSCompetitiveBid/01A0_Timeline.asp#TopOfPage, accessed May 8, 2010.

22. At this time, no DMEPOS supplier contracts have been awarded by Defendants under the DME re-bid provisions of MIPPA.

23. On numerous occasions since issuance of the 2009 interim final rule, interested parties have asked Defendants for the DMEPOS supplier financial standards they are using to evaluate "covered documents" and qualify suppliers, and to allow them to comment on proposed financial standards, but Defendants have not provided any opportunity to comment on formally proposed financial standards, and they have declined to provide such standards to the requesters or publish them in the Federal Register.

24. On information and belief, Defendants are evaluating the financial soundness of DMEPOS bidders without having specified financial standards, taking into consideration the needs of small providers, as required by statute, and are evaluating "covered documents" for the financial soundness of providers on an *ad hoc* basis, without the application of specified financial standards and without any specific means for considering the financial needs of small providers.

I. First Cause of Action

25. Plaintiffs reallege and incorporate by reference paragraphs 1 through 24 of the Complaint as though set forth specifically herein.

26. The "financial standards" that Defendants are statutorily responsible for specifying, "taking into account the needs of small providers," were intended by Congress to be substantive or legislative rules and regulations for which public notice and an opportunity to comment are required by 5 U.S.C. § 553(b) and (c). In its 2006 proposed rule, Defendants purported to provide notice and opportunity to comment on such "financial standards," but the proposed rulemaking did not, in fact, set out proposed "financial standards" that Plaintiffs and other affected parties and the public could reasonably be expected to comment on.

27. Defendants have waived reliance on any exceptions to the notice and comment requirements that are specified in 5 U.S.C. § 553(a).

28. Defendants have failed to comply with the notice and comment requirements of 5 U.S.C. § 553(b) and (c) because they have not provided notice of the proposed DME supplier financial standards to be specified and an opportunity for public comment. Rather than specifying financial standards, Defendants have only required submission of certain financial documents, and have not specified what financial standards they will use to evaluate such documents.

29. Defendants' 2009 interim final rule is final agency action that is reviewable under 5 U.S.C. § 706(2). Defendants have issued a substantive (or legislative) final rule without providing for the required notice and comment.

30. Under 5 U.S.C. § 706(2) this Court may review, and must set aside, the interim final rule as agency action taken "without observance of procedure required by law," namely without public notice of the proposed standards in the *Federal Register*, without meaningful opportunity to comment, without consideration of comments, and without publication of a final rule with an adequate explanation of its basis.

II. Second Cause of Action

31. Plaintiffs reallege and incorporate by reference paragraphs 1 through 23 of the Complaint as though set forth specifically herein.

32. 42 U.S.C. § 1395hh(b) requires Defendants to provide public notice and opportunity for comment "before issuing in final form any regulation under subsection (a) of this section." Subsection (a) of that section covers interim final regulations in subsection (a)(3)(A) and (C).

33. Defendants have failed to comply with the notice and comment requirements of 42 U.S.C. § 1395hh(b) because they did not propose DME supplier financial standards to be specified and did not provide a meaningful opportunity for public comment on those proposed standards. Rather than specifying financial standards, Defendants have only required submission

of certain financial documents, and have not specified what financial standards they will use to evaluate such documents and qualify suppliers. Defendants must provide public, *Federal Register*, notice of its proposed financial standards and a meaningful opportunity for public comment, and then consider those comments and state them in a final rule or interim final rule, before proceeding with selection of contract suppliers using the specified financial standards.

34. Under 5 U.S.C. § 706(2), this Court may review, and must set aside, the 2009 interim final rule as agency action taken "without observance of procedure required by law," namely public notice of the proposed standards in the *Federal Register*, opportunity to comment, consideration of comments, and publication of the final standards with an explanation of their basis.

III. Third Cause of Action

35. Plaintiffs reallege and incorporate by reference paragraphs 1 through 24 of the Complaint as though set forth specifically herein.

36. Defendants are in violation of 5 U.S.C. § 552(a)(1)(D), which requires agencies to "separately state and currently publish in the Federal Register for the guidance of the public ... substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency ...."

37. Defendants are in violation of 5 U.S.C. § 552(a)(1)(C) for failure to publish the specified DME supplier financial standards required by the MMA.

38. Plaintiffs do not have actual knowledge of the specified financial standards applied, or being applied, by Defendants in qualifying and selecting bidders.

39. Under 5 U.S.C. § 552(a)(4)(B) this Court may order Defendants to produce for Plaintiffs any specified financial standards as agency records improperly withheld from them.

IV. Fourth Cause of Action

40. Plaintiffs reallege and incorporate by reference paragraphs 1 through 24 of the Complaint as though set forth specifically herein.

41. Defendants have failed to specify financial standards that DME suppliers must meet, taking into account the needs of small suppliers, as mandated by the MMA, even internally and regardless of public notice and comment requirements, and are failing to apply such standards in evaluating and qualifying DME suppliers. Defendants are therefore acting *ultra vires*, in an arbitrary and capricious manner, abusing their discretion, and acting otherwise not in accordance with law in violation of 5 U.S.C. 706(2). Accordingly, this court must hold unlawful and set aside those actions taken by the Defendants that require the application of the required financial standards, such as qualification of suppliers to be selected as Medicare DME contract suppliers.

Prayer for Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A declaration that Defendants' failure to specify financial standards is "not in accordance with law" under 5 U.S.C. § 706(2);

2. A declaration that in evaluating prospective suppliers without using the required specific financial standards Defendants are acting, or have acted, arbitrarily, capriciously, in abuse of their discretion, and not in accordance with law under 5 U.S.C. § 706(2).

3. A declaration that the Defendants' failure to propose specific financial standards for prospective DME suppliers with adequate Federal Register notice and meaningful opportunity for comment, and then publication of the interim final rule, was final agency action "without observance of procedure required by law" under 5 U.S.C. § 553(b) and (c);

4. A declaration that the Defendants' failure to propose specific financial standards for prospective DME supplier with adequate Federal Register notice and opportunity for comment,

and then publication of the interim final rule, was final agency action "not in accordance with law" and "without observance of procedure required by law" under 42 U.S.C. § 1395hh(b) and 5 U.S.C. 706(2);

5. A declaration that the Defendants' failure to publish the specific financial standards in the *Federal Register* is in continuing violation of 5 U.S.C. § 552(a)(1)(D);

4. An order vacating the Defendant's January 16, 2009 interim final rule, all actions taken by Defendants under that rule that required application of the required specific financial standards, and permanently enjoining the Defendants from proceeding to select DME contract suppliers based on the interim final rule until Defendants specify and publish the required DME financial standards as proposed standards for public comment, consider those comments, and publish the final specific financial standards in the Federal Register in a final rule or interim final rule with an adequate explanation of their basis, and apply those standards.

5. Costs of this suit;

6. All appropriate attorney's fees; and

7. Any other relief that this Court deems just and appropriate.

May 10, 2010

Respectfully submitted,

/s/ William G. Kelly, Jr.
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