United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 18, 2012 Decided June 1, 2012

No. 11-5265

TEXAS ALLIANCE FOR HOME CARE SERVICES AND DALLAS OXYGEN CORPORATION,
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,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:10-cv-00747)

William G. Kelly Jr. argued the cause for the appellants. *Brendan J. Klaproth* was on brief.

Sharon Swingle, Attorney, United States Department of Justice, argued the cause for the appellees. *Tony West*, Assistant Attorney General, *Ronald C. Machen, Jr.*, United States Attorney, and *Michael S. Raab*, Attorney, were on brief. *R. Craig Lawrence*, Assistant United States Attorney, entered an appearance.

Before: HENDERSON, TATEL and KAVANAUGH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* HENDERSON.

KAREN LECRAFT HENDERSON, *Circuit Judge*: The Texas Alliance for Home Care Services, a trade association representing suppliers of durable medical equipment,[1] prosthetics, orthotics and supplies (DMEPOS), and the Dallas Oxygen Corporation, an individual DMEPOS supplier, (collectively, Suppliers) appeal the district court's dismissal of their action against the Secretary of the United States Department of Health and Human Services (Secretary) and the Administrator of the Centers for Medicare and Medicaid Services (CMS).[2] The Suppliers challenge a regulation addressing the "applicable financial standards" that a DMEPOS supplier must meet to be eligible for a Medicare contract under the competitive bidding process established in 42 U.S.C. § 1395w-3 (DMEPOS Statute). The district court dismissed the complaint on three grounds: (1) it is precluded by subsection (b)(11) of the DMEPOS Statute, 42 U.S.C. § 1395w-3(b)(11); (2) the Suppliers lack constitutional standing and (3) the regulation is authorized and otherwise valid. *Texas Alliance for Home Care Servs. v. Sebelius*, 811 F. Supp. 2d 76 (D.D.C. 2011). Because we agree that subsection (b)(11) expressly

[1]"The term 'durable medical equipment' includes iron lungs, oxygen tents, hospital beds, and wheelchairs . . . and includes blood-testing strips and blood glucose monitors for individuals with diabetes." 42 U.S.C. § 1395x(n).

[2]CMS administers the Medicare program on behalf of the Secretary. *St. Luke's Hosp. v. Sebelius*, 611 F.3d 900, 901 (D.C. Cir. 2010).

precludes judicial review of the challenged regulation, we affirm the district court's dismissal on this ground.[3]

I.

In 1965, the Congress enacted the Medicare Act as Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, to establish a federally funded health insurance program for the elderly and disabled. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 506 (1994). The Medicare Act authorizes the Secretary to issue regulations "defining reimbursable costs and otherwise giving content to the broad outlines of the Medicare statute." *Id*. at 506-07 (citing 42 U.S.C. § 1395x(v)(1)(A)).

Before 2003, Medicare reimbursed the cost of DMEPOS pursuant to a fixed fee schedule for each class of covered items. In 1997, the Congress authorized the Secretary to conduct up to five demonstration projects to test competitive bidding (in lieu of the fixed schedules) to price and award contracts for Medicare Part B services, including the provision of DMEPOS.[4] Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4319, 111 Stat. 251, 392 (codified at 42 U.S.C. § 1395w-3 (1998)). The subsequent demonstration projects, conducted in Polk County, Florida and San Antonio, Texas, proved successful; competitive bidding significantly reduced DMEPOS costs, while maintaining quality standards and beneficiary satisfaction. *See* H.R. Rep. No. 108-178(II), at 192 (July 15, 2003). Accordingly, in 2003, the Congress instituted a competitive bidding process

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[3]Accordingly, we do not reach the Suppliers' standing vel non or the regulation's validity.

[4]Medicare Part B covers "outpatient items and services, including durable medical equipment and certain prescription medications." *Hays v. Sebelius*, 589 F.3d 1279, 1280 (D.C. Cir. 2009).

for DMEPOS purchases by enacting the DMEPOS Statute as part of the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, title III, § 302(b)(1), 117 Stat. 2224 (2003) (codified in relevant part at 42 U.S.C. § 1395w-3, as amended). The DMEPOS Statute directed the Secretary to "establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing . . . of competitively priced items and services." 42 U.S.C. § 1395w-3(a)(1)(A) (2004). The Secretary was to implement the programs in three phases, beginning in 2007 with the 10 largest metropolitan areas in the United States. *Id*. § 1395w-3(a)(1)(B)(i)(I).[5]

Under the DMEPOS Statute, no payment may be made for a covered item unless the contractor submits a bid "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" and the Secretary awards a contract to the supplier for such item or service. *Id*. § 1395w-3(b)(6)(A)-(B). In addition, the Secretary "may not award a contract to any entity under the competition conducted in a competitive acquisition area . . . to furnish such items or services unless the Secretary finds," inter alia, that "[t]he entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers." *Id*. § 1395w-3(b)(2)(A)(ii).[6] The Secretary is further directed to form a

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[5]The second and third phases extended the program, respectively, to 80 of the largest metropolitan statistical areas in 2009 and to "additional areas" after 2009. 42 U.S.C. § 1395w-3(a)(1)(B)(i)(II)-(III) (2004).

[6]The Secretary must also find that (1) the entity "meets applicable quality standards specified by the Secretary," (2) total payments to area contractors will decrease and (3) beneficiaries will retain access

"Program Advisory and Oversight Committee" (PAOC) to "provide advice" on several enumerated functions, including the "establishment of financial standards for purposes of subsection (b)(2)(A)(ii)." *Id*. § 1395w-3(c)(A)(i)-(iii).

In August 2004, the Secretary published in the Federal Register a notice of a public meeting of PAOC on October 6, 2004 "to consider issues related to competitive bidding for DMEPOS items and to furnish advice to the Secretary regarding these issues." Medicare Program; Public Meeting of the Program Advisory and Oversight Committee (PAOC) for Quality Standards and Competitive Acquisition of Certain [DMEPOS], 69 Fed. Reg. 52,723, 52,723 (Aug. 27, 2004). The notice solicited written comments "addressing topics discussed at the meeting" to be submitted no later than October 13, 2004. *Id*. During the October 6, 2004 meeting and two subsequent ones, CMS presented to the public and to PAOC material on topics that included the "[f]inancial capabilities of bidding suppliers" before publishing a proposed DMEPOS rule in May 2006. Medicare Program; Competitive Acquisition for Certain [DMEPOS] and Other Issues, 71 Fed. Reg. 25,654, 25,658 (May 1, 2006).

The proposed DMEPOS rule included the following provision regarding financial standards:

> (d) Financial standards. All suppliers must meet the applicable financial standards *specified in the request for bids*.

71 Fed. Reg. at 25,700 (emphasis added). The proposed rule's preamble elaborated:

> [A]s part of the bid selection process, the [Request for Bids] will identify the specific information we will

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to multiple suppliers. *Id*. § 1395w-3(b)(2)(A)(i), (iii)-(iv).

> require 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. We welcome comments on the financial standards, in particular the most appropriate documents that will support these standards.
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> We found that in the demonstration, 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.
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> As we develop our methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process.

Id. at 25,675. In addition, the preamble announced that CMS had created a website "specifically for the public to have access to all PAOC presentations, minutes, and updates for the Medicare DMEPOS Competitive Bidding Program." *Id*. at 25,658.

The Secretary published the final rule in April 2007. Medicare Program; Competitive Acquisition for Certain [DMEPOS] and Other Issues, 72 Fed. Reg. 17,992 (Apr. 10, 2007). Its financial standards provision stated:

> (d) Financial standards. Each supplier must submit along with its bid the applicable financial documentation specified in the request for bids.

Id. at 18,088 (42 C.F.R. § 414.414(d) (2008)). The final rule's preamble, responding to comments, clarified the proposed rule in two respects. First, it explained that "in order to obtain a sufficient amount of information about each supplier while minimizing the burden on both bidding suppliers and the bid evaluation process," CMS intended to require for the initial round of competition that suppliers submit only "certain schedules from their tax returns, a copy of the 10K filing report from the immediate 3 years . . . [,] certain specified financial statement reports, such as cash flow statements, and a copy of their current credit report." *Id*. at 18,037. These documents, the preamble explained, would enable CMS to "determine financial ratios, such as a supplier's debt-to-equity ratio, and credit worthiness" and, from those determinations, "to assess a supplier's financial viability." *Id*. Second, the preamble explained that CMS planned to "review[] all financial information in the aggregate and [] not [] bas[e its] decision on one ratio but rather overall financial soundness." *Id*. at 18,038. On March 22, 2007, CMS posted on the DMEPOS website the ten financial ratios it intended to use, along with a supplier's credit history, in evaluating the supplier's financial health.[7] After evaluating the bids, CMS awarded over 329 contracts to implement the program beginning July 1, 2008.

Meanwhile, the Ways and Means Committee of the United States House of Representatives convened a hearing on the bidding process culminating in the Medicare Improvements for

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[7]Initially, the ten ratios were: (1) current ratio, (2) collection period, (3) accounts payable to sales, (4) quick ratio, (5) current liabilities to net worth, (6) return on sales, (7) sales to inventory, (8) working capital, (9) quality of earnings and (10) operating cash flow to sales. *Tex. Alliance for Home Care Servs.*, 811 F. Supp. 2d at 83; *see* CMS Announces Financial Measures for the [DMEPOS] Competitive Bidding Program, June 1, 2007 (available at http://www.medicarenhic.com/dme/articles/060107_comp_bid.pdf).

Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008) (MIPPA). MIPPA amended the DMEPOS Statute, inter alia, to terminate all contracts awarded pursuant to the 2007 bid and mandate they be rebid in 2009 (postponing the second bidding round to 2011), thereby effectively reinstating the previous Medicare fee schedule for DMEPOS. 42 U.S.C. § 1395w–3(a)(1)(D).

In January 2009, in order to implement MIPPA, the Secretary published a new "interim final rule," which amended 42 C.F.R. § 414.414(d) to read in relevant part:

> (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.

Medicare Program; Changes to the Competitive Acquisition of Certain [DMEPOS] by Certain Provisions of [MIPPA], 74 Fed. Reg. 2873, 2880 (Jan. 16, 2009). Section 414.402 defines "covered documents" broadly as "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." 42 C.F.R. § 414.402.

The Secretary opened the round 1 rebidding on October, 21, 2009 and closed it on December 21, 2009. The resulting contracts, announced in November 2010, went into effect on January 1, 2011.[8] Unsuccessful bidders were so notified by letter, with a chart attached indicating by check marks the reasons for their rejection—financial ineligibility, high bid, lack of accreditation or licensure, etc. *See, e.g.*, Letter from Competitive Bidding Implementation Contractor Palmetto GBA

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[8]CMS issued a final rule in November 2011 which did not change or even address 42 C.F.R. § 414.414(d), the regulation the Suppliers now challenge. 76 Fed. Reg. 70,228 (Nov. 10, 2011).

to Bidder Dallas Oxygen Corp. (dated Nov. 3, 2010) (Dallas Oxygen Corp. Rejection Letter).

Meanwhile, the plaintiffs filed this action on May 10, 2010, alleging that the Secretary's evaluation of bidders' financial eligibility without first "specify[ing]" by regulation the "applicable financial standards" (1) violated the notice and comment requirement of the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)-(c); the separate Medicare notice and comment requirement, 42 U.S.C. § 1395hh(b), and the APA's Federal Register publication requirement, 5 U.S.C. § 552(a)(1)(D); and (2) should be set aside under the APA as ultra vires, arbitrary and capricious, an abuse of discretion and otherwise not in accordance with law, 5 U.S.C. § 706(2).

The Secretary and CMS moved to dismiss the complaint on three alternative grounds: (1) subsection (b)(11) of the DMEPOS Statute precludes judicial review; (2) the Suppliers lacked constitutional standing to initiate the action; and (3) the complaint fails to state a claim. The district court granted the motion to dismiss on all three grounds and the Suppliers timely appealed.

II.

We review the district court's dismissal de novo. *Kim v. United States*, 632 F.3d 713, 715 (D.C. Cir. 2011). The Suppliers invoked the district court's federal question jurisdiction under 28 U.S.C. § 1331 and sought review under the APA. The APA generally "establishes a cause of action for those 'suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action.' " *Koretoff v. Vilsack*, 614 F.3d 532, 536 (D.C. Cir. 2010) (quoting 5 U.S.C. § 702). The APA does not apply, however, "to the extent that . . . statutes preclude judicial review." 5 U.S.C. § 701(a). The district court concluded that subsection (b)(11) of the DMEPOS Statute precludes judicial review of the Secretary's regulation on

financial standards and therefore deprived the district court of jurisdiction. *See Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004) (court lacks jurisdiction over complaint precluded by 42 U.S.C. § 1395*l*(t)(12)(A)). We agree.

"In determining whether a statute precludes judicial review, the court must heed the APA's 'basic presumption of judicial review' that 'will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress.' " *Banzhaf v. Smith*, 737 F.2d 1167, 1168-69 (D.C. Cir. 1984) (en banc) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967)). "The presumption favoring judicial review of administrative action," however, "is just that—a presumption" and, "like all presumptions used in interpreting statutes, may be overcome by specific language or specific legislative history that is a reliable indicator of congressional intent." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984). The presumption of reviewability here is overcome by the specific and emphatic statutory language prohibiting judicial review of the competitive bidding procedure.

Subsection (b)(11) of the DMEPOS Statute sweepingly states:

> There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of—
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> (A) the establishment of payment amounts under paragraph (5);
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> (B) the awarding of contracts under this section;
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> (C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);

> (D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);
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> (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section;
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> (F) the bidding structure and number of contractors selected under this section; or
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> (G) the implementation of the special rule described in paragraph (10).

42 U.S.C. § 1395w-3(b)(11). The mandate that there be "*no* administrative or judicial review" under the two cited statutes "*or otherwise*" unequivocally precludes review of the Secretary's actions addressing the seven aspects of the competitive bidding program enumerated in subsections (b)(11)(A)-(G) (emphases added). *See Amgen*, 357 F.3d at 111 (virtually identical preclusive language in 42 U.S.C. § 1395*l*(t)(12)(A) precluded review of Medicare payment classification system adjustments); *cf. Banzhaf*, 737 F.2d at 1168-69 (statutory language "shall not be reviewable in any court" effectively precluded review of Attorney General's decision not to investigate particular allegations or seek appointment of independent counsel). This language, combined with the broad range of subjects expressly immunized from review, manifest the Congress's intent to "proceed with these initial administrative processes without risk of litigation blocking the execution of the program." *Cardiosom, LLC v. United States*, 656 F.3d 1322, 1326 (Fed. Cir. 2011) (noting "purpose of withholding judicial review in these instances is to insulate these management decisions by the Medicare Administration from the potential of inordinate delays that would transpire if every such management decision were open to an upfront challenge by some disappointed group"); *see also*

Carolina Med. Sales, Inc. v. Leavitt, 559 F. Supp. 2d 69 (D.D.C. 2008) ("The scope of the other areas of preclusion indicate a scheme to insulate the entire program from review, as does the broad, general language used."). Moreover, as we explain below, two of the enumerated subject areas encompass the Secretary's specification of "applicable financial standards" pursuant to subsection (b)(2)(A)(ii) so as to insulate the Secretary's challenged regulation from any judicial review. *See Amgen*, 357 F.3d at 113 ("If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is of the sort shielded from review.")

First, the financial standards regulation is unreviewable under subsection (b)(11)(B), which states that there is to be "no administrative or judicial review . . . of . . . the awarding of contracts under [section 1395w-3]." As the district court observed, the DMEPOS Statute itself "ties the development and application of appropriate financial standards to the Secretary's decision to grant or deny a contract" because the financial standards requirement "is found in the section entitled 'Conditions for awarding contracts,' " 42 U.S.C. § 1395w-3(b). *Texas Alliance*, 811 F. Supp. 2d at 88. Indeed, under the DMEPOS Statute, financial standards are indispensable to "the awarding of contracts" as such standards determine whether or not a contract may be awarded to a bidder based on the financial documents submitted with its bid. If a bidder is found financially ineligible, its bid is rejected in a notice advising that CMS "is unable to offer [the bidder] a contract." Dallas Oxygen Corp. Rejection Letter at 1.

The Suppliers claim the statutory language was meant to preclude only review of "individual contracts." Appellants' Br. 18. The statutory language, however, is not so narrow. By its terms, subsection (b)(11)(B) applies not to the awarding of a

single contract but to "the awarding of contracts" generally, which, under the DMEPOS Statute, requires the formulation and application of financial standards. Nor does it make sense that the Congress would intend to preclude a bidder deemed financially ineligible from challenging the disqualifying financial standards and yet allow a non-bidder to seek review of the same standards. In either case, permitting review would delay the costs savings the Congress sought to realize through DMEPOS competitive bidding. Moreover, the United States Supreme Court has rejected just the sort of distinction the Suppliers seek to draw.

In *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), the Court considered the preclusive effect of a statutory channeling scheme, which prohibits direct review of Medicare claim determinations under 28 U.S.C. § 1331 and requires instead that a challenge proceed initially through a statutory "special Medicare review route, [] set forth in a complex set of statutory provisions," with judicial review available only afterward under the Medicare Act. 529 U.S. at 7-8; *see* 42 U.S.C. § 1395ii (incorporating 42 U.S.C. § 405(h) ("The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. . . . No action . . . shall be brought under section 1331 . . . to recover on any claim arising under [Medicare].")). There, as here, a trade association mounted a direct attack in the district court under 28 U.S.C. § 1331, challenging Medicare regulations governing "how to impose remedies after inspectors find that a nursing home has violated substantive standards." 529 U.S. at 6. The Court concluded that the section 1331 bar applies not only to review of the denial of monetary benefits but also to review of "a policy, regulation, or statute that might later bar recovery of that benefit." *Id*. at 10. The Court explained that it could not "accept a distinction that limits the scope of [the statutory bar] to claims for monetary benefits":

> Claims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions. There is no reason to distinguish among them in terms of the language or in terms of the purposes of [the bar].

Id. at 14. Likewise here, we do not distinguish between an up-front attack on the financial standards by suppliers not yet injured by them and a challenge brought after-the-fact by a frustrated bidder who has been found to be financially ineligible.[9] Under *Illinois Council*, review is precluded in both cases.

The Secretary's financial standard is also immune from review under subsection (b)(11)(F)'s ban on any challenge to "the bidding structure and number of contractors selected." The financial standards, as eligibility criteria, are integral to the

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[9]The Suppliers argue that *Illinois Council* in fact supports reviewability because the Court there acknowledged that in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), the Court concluded the channeling provision did not apply because the result would be no review at all—the same result that will occur, they claim, if section 1395w-3(b)(11)(B) is applied to preclude their challenge here. *See* Appellants' Br. 20-21. In *Michigan Academy*, however, the Court found "persuasive evidence of legislative intent" to foreclose review only of "amount determinations" and therefore concluded the presumption of reviewability had not been "surmounted." 476 U.S. at 680-81. As explained *supra*, here the presumption *is* surmounted—by the broad and unequivocally preclusive language of section § 1395w-3(b)(11), which manifests the Congress's intent to foreclose all review of the listed subjects.

bidding structure the Secretary has erected. The standards are identified in each individual Request for Bids, which lists the financial documentation to be submitted; the bidder submits the financial documents to CMS along with its bid; and the bidder learns if it fails the standards in the notice of rejection of the bid. Financial eligibility under the applicable standards, then, is inextricably intertwined with the bidding structure and review thereof is therefore expressly precluded by subsection (b)(11)(F).

For the foregoing reasons, we conclude that subsection (b)(11) of the DMEPOS Statute precludes judicial review of the Secretary's financial standards regulation and that the district court therefore lacked subject matter jurisdiction. Accordingly, we affirm the district court's judgment of dismissal under Federal Rule of Civil Procedure 12(b)(1).

So ordered.