PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-1393

CUMBERLAND COUNTY HOSPITAL SYSTEM, INC., d/b/a Cape Fear Valley Health System,

Plaintiff - Appellant,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of Health and Human Services,

Defendant - Appellee.

FUND FOR ACCESS TO INPATIENT REHABILITATION,

Amicus Supporting Appellant.

Appeal from the United States District Court for the Eastern District of North Carolina, at Raleigh. W. Earl Britt, Senior District Judge. (5:14-cv-00508-BR)

Argued: January 26, 2016 Decided: March 7, 2016

Before TRAXLER, Chief Judge, and WILKINSON and NIEMEYER, Circuit Judges.

Affirmed by published opinion. Judge Niemeyer wrote the opinion, in which Chief Judge Traxler and Judge Wilkinson joined.

ARGUED: Kathryn Frances Taylor, K&L GATES LLP, Morrisville, North Carolina, for Appellant. Joshua Marc Salzman, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. **ON BRIEF**: Benjamin C. Mizer, Principal Deputy Assistant Attorney General, Mark B. Stern, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Thomas G. Walker, United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Raleigh, North Carolina; William B. Schultz, General Counsel, Janice L. Hoffman, Associate General Counsel, Susan Maxson Lyons, Deputy Associate General Counsel, Kirsten Friedel Roddy, Attorney, UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, Washington, D.C., for Appellee. Ronald S. Connelly, POWERS PYLES SUTTER & VERVILLE, PC, Washington, D.C., for Amicus Curiae.

NIEMEYER, Circuit Judge:

Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System ("Cape Fear Health System" or "the Hospital System"), commenced this action to obtain a writ of mandamus compelling the Secretary of the Department of Health and Human Services ("HHS") to adjudicate immediately its administrative appeals on claims for Medicare reimbursement. With over 750 of its appeals on such claims awaiting assignment to an Administrative Law Judge ("ALJ") for more than 90 days, the Hospital System asserts that the Secretary's delay violates the congressional mandate that its appeals be heard and decided by ALJs within 90 days. See 42 U.S.C. § 1395ff(d)(1)(A).

The parties agree that, as of February 2014, the Secretary had 480,000 appeals awaiting assignment to an ALJ, and the Secretary conceded in her brief that the number had by then climbed to more than 800,000 appeals, creating a ten-year backlog. While acknowledging the unacceptability of the backlog, the Secretary attributes it to an increased number of appeals within the Medicare system and inadequate funding by Congress to hire additional personnel.

The district court dismissed the Hospital System's complaint, relying on two independent grounds. It held (1) that the Hospital System does not have a clear and indisputable right to an ALJ hearing within a 90-day time frame, as required

for issuance of a mandamus order, and (2) that the political branches, rather than the courts, are best suited to address the backlog in the administrative process. We affirm.

While we agree that the delay in the administrative process for Medicare reimbursement is incontrovertibly grotesque, the Medicare Act does not guarantee a healthcare provider a hearing before an ALJ within 90 days, as the Hospital System claims. Rather, it provides a comprehensive administrative process -- which includes deadlines and consequences for missed deadlines -- that a healthcare provider must exhaust before ultimately obtaining review in a United States district court. Indeed, within that administrative process, a healthcare provider can bypass administrative reviews if such reviews are delayed, "escalating" for review by a United States district court within a relatively expeditious time. The issuance of a judicial order now, however, directing the Secretary to hear the Hospital System's claims in the middle of the administrative process, would unduly interfere with the process and, at a larger scale, the work of the political branches. Moreover, such intervention would invite other healthcare providers suffering similar delays to likewise seek a mandamus order, thereby effectively causing the judicial process to replace and distort the agency process.

I

Cape Fear Health System operates a number of facilities in eastern North Carolina, delivering medical services to, among others, beneficiaries of Medicare. The Medicare Act establishes a federally subsidized health insurance program for the elderly and disabled that is administered by the Secretary. See 42 U.S.C. § 1395 et seq.

In 2012 and 2013, the Secretary denied payment to the Hospital System on over 900 claims for reimbursement for Medicare services that she had initially authorized. By September 2014, the Hospital System had over 750 appeals on these claims that had been pending for more than 90 days before the Office of Medicare Hearings and Appeals ("OMHA") within HHS. Those appeals related to claims for some $12.3 million in reimbursement. The Secretary has not even acknowledged receipt of some of the appeals, and with respect to others, she has reported a delay of over two years in assigning them to an ALJ. Because reimbursement of such a large sum is essential to the Hospital System's operations, the Hospital System commenced this action for a writ of mandamus, ordering the Secretary to docket, assign to an ALJ, and decide its appeals within 90 days, as required by the Medicare Act. See 42 U.S.C. § 1395ff(d)(1)(A). It also seeks a declaratory judgment that the Secretary's "delay in adjudication of Medicare appeals violates federal law."

In its complaint, the Hospital System alleged that the number of appeals to ALJs quintupled during the two years of 2012 and 2013, increasing from 92,000 to 460,000, and that the ALJs' workload increased by almost 300% from fiscal year 2012 to fiscal year 2013. It alleged that, as of February 2014, 480,000 appeals were awaiting assignment to ALJs. The Secretary does not deny the existence of the backlog, nor its size, as the figures alleged by the Hospital System are those published by HHS. Indeed, in her brief, the Secretary acknowledged that the backlog has grown rapidly to more than 800,000 appeals and that, with OMHA's current staffing of ALJs, it would take over ten years for the ALJs to dispose of those appeals. The allegations of the parties do, however, attribute the backlog to different causes.

The Secretary asserts that the backlog is the result of an increased utilization of Medicare-covered services; the additional appeals from audits conducted under the Recovery Audit Program instituted in 2010; and additional Medicaid State Agency appeals of Medicare coverage denials for beneficiaries enrolled in both Medicare and Medicaid. She notes that she has been unable to reduce or even stabilize the backlog because congressional funding has remained relatively stagnant during the last five years and additional ALJs therefore could not and cannot be hired. She states, however, that the President's 2016

budget proposes more than tripling the funding for OMHA and, in addition, proposes new processes that would facilitate the resolution of appeals at earlier stages in the administrative process. Finally, the Secretary points out that Congress has been aware of the existing backlog for some time, has recognized the need for a legislative solution, and, indeed, is working on a solution.

Cape Fear Health System does not disagree completely, but it contends that the backlog is mainly due to the Secretary's mismanagement of HHS resources. The Hospital System points out that, while the agency has proposed pilot programs for alternative dispute resolution with respect to some types of reimbursement, it has not made those programs available for the types of reimbursement being claimed by the Hospital System. Furthermore, the Hospital System contends that the increase in appeals from audits conducted pursuant to the Recovery Audit Program is attributable to the perverse incentives of that program, which pays contractors contingency compensation based on monies they recover in denying improper or excessive claims.

Regardless of the cause, however, the parties agree, and the district court found, that appeals have "skyrocketed" and have "overwhelmed" the Medicare reimbursement process.

The district court granted the Secretary's motion to dismiss the Hospital System's complaint under Federal Rule of

Civil Procedure 12(b)(6), relying on two independent grounds for doing so. First, the court concluded that the Hospital System's complaint failed to state a plausible claim for a mandamus order because (1) it failed to demonstrate a "clear and indisputable right" to relief, as Congress did not grant the Hospital System "an absolute right to an ALJ hearing . . . within the 90-day timeframe," and (2) it failed to demonstrate that the Secretary has "a clear duty to provide such a hearing" within the 90-day time frame. Second, as a matter of discretion, the court concluded that to grant mandamus relief would inappropriately "intermeddle" with the agency's problem-solving efforts and would fail to recognize "HHS's comparative institutional advantage in crafting a solution to the delays in the adjudication of appeals." The court explained that "the political branches are best-suited to alleviate OMHA's crippling delays." The court also noted in this regard that putting the Hospital System "at the head of the queue," where doing so would simply move all others back one space and would produce no net gain, should be avoided as a matter of equity.

The district court also denied the Hospital System's claim for declaratory relief, reasoning that, because the Declaratory Judgment Act does not supply a right of action in the absence of a valid substantive claim, dismissal of the Hospital System's

declaratory judgment must necessarily follow dismissal of its mandamus claim.

Cape Fear Health System filed this appeal.

II

Mandamus is a "drastic" remedy that must be reserved for "extraordinary situations" involving the performance of official acts or duties. Kerr v. U.S. Dist. Court for the N. Dist. of Cal., 426 U.S. 394, 402 (1976). Accordingly, to show that it is entitled to mandamus relief, a plaintiff must show, among other things, that it has a "clear and indisputable right to the relief sought" and that the responding party has a "clear duty to do the specific act requested." United States ex rel. Rahman v. Oncology Assocs., P.C., 198 F.3d 502, 511 (4th Cir. 1999).

In this case, Cape Fear Health System contends that the Medicare Act gives it a clear and indisputable right to have its appeals decided within 90 days and that it imposes on the Secretary a clear duty to accomplish that. In support of this contention, it emphasizes the mandatory language of the Act, which provides that an ALJ "shall conduct and conclude a hearing . . . and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." 42 U.S.C. § 1395ff(d)(1)(A) (emphasis added). It also points to the Chief ALJ's recent

testimony before a congressional committee that the deadlines for ALJs' decisions were set and OMHA was created to "reduce the average . . . waiting time for a hearing decision" that occurred under the prior scheme. It argues that the escalation mechanism in the Medicare Act -- a mechanism whereby healthcare providers can bypass ALJ review if they are delayed and proceed to the Departmental Appeals Board and ultimately to the courts, see id. § 1395ff(d)(3) -- does not diminish its right to an ALJ hearing because escalation is not mandatory but may be employed at the "discretion of the appellant." And, in any event, it maintains that electing to bypass the ALJ hearing would result in its foregoing its right to create an administrative record at the ALJ hearing, thus forcing it to make a "terrible choice": either "waive its right to due process" (i.e., to make a record) or "suffer interminably until the Secretary feels like affording [it] a hearing."

The Secretary, by contrast, maintains that "the Medicare statute does not confer on [the Hospital System] a right to a hearing within 90 days that is enforceable through mandamus," emphasizing that the statute provides that "the consequence of failing to adjudicate an appeal within 90 days is that the provider may escalate that appeal to the [Departmental Appeals Board]." The Secretary argues that, while the statute establishes a time frame for decisions, "it also recognizes that

the time frame may not be satisfied and provides persons seeking review with a specific avenue of relief." Because, as the Secretary argues, such escalation "is the remedy Congress provided," the Hospital System "cannot show indisputable entitlement to any other," regardless of whether escalation adequately ensures the particular administrative review that the Hospital System seeks.

We begin by noting that the process that Congress has provided for obtaining Medicare reimbursement and administrative review of reimbursement decisions is comprehensive and specific -- a "coherent regulatory scheme," Gustafson v. Alloyd Co., 513 U.S. 561, 569 (1995) -- which begins with the submission of a claim for reimbursement, continues through a detailed and multistep administrative process, and concludes with the provision for judicial review. Accordingly, understanding the full process is necessary to address the Hospital System's argument that a court should enforce a specific, discrete element of the process through a writ of mandamus.

To obtain reimbursement for Medicare services, a healthcare provider must, in the first instance, submit a claim to a Medicare Administrative Contractor, a private contractor retained by HHS to make an initial determination regarding whether and in what amount the claim should be paid. See 42 U.S.C. §§ 1395ff(a), 1395kk-1(a). That determination by the

Medicare Administrative Contractor may, under a program that Congress established in 2010, be audited by a different third-party government contractor, known as a Recovery Audit Contractor. See id. § 1395ddd(h)(3). Congress created that audit program to serve "the purpose of . . . recouping overpayments," and it incentivized the Recovery Audit Contractors by paying them "on a contingent basis for collecting overpayments." Id. § 1395ddd(h)(1). Healthcare providers wishing to challenge these initial claim determinations by the Medicare Administrative Contractor or the Recovery Audit Contractor must pursue a comprehensive, four-step administrative review process before seeking review in court.

At the first step, a healthcare provider dissatisfied with either the initial determination or the results of an audit may seek a redetermination from the original Medicare Administrative Contractor. See 42 U.S.C. § 1395ff(a)(3). At the second step, if the healthcare provider is dissatisfied with the redetermination, it may seek reconsideration by a Qualified Independent Contractor ("QIC"), another third-party government contractor retained to independently "review the evidence and findings upon which the [previous determination was] based." 42 C.F.R. § 405.968(a)(1); 42 U.S.C. § 1395ff(c). In doing so, the QIC may receive and consider "any additional evidence the parties submit or that the QIC obtains on its own." 42 C.F.R.

§ 405.968(a)(1). At the third step, the healthcare provider may challenge the QIC's decision by requesting a hearing before an ALJ. See 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. § 405.1000. The ALJ hearing process is administered by OMHA, a division within HHS that is independent of and funded through an appropriation separate from the division that oversees the contractors' review during the first two steps of the administrative review process. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 931, 117 Stat. 2066, 2396-99; Statement of Organization, Functions, and Delegations of Authority, 70 Fed. Reg. 36386-04 (June 23, 2005). At the fourth step, the healthcare provider may appeal the ALJ's decision to the Departmental Appeals Board for de novo review. See 42 U.S.C. § 1395ff(d)(2). The Departmental Appeals Board's decision becomes the final decision of the Secretary, which may then be reviewed in court. See id. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1130.

The Medicare Act establishes deadlines for each step in the administrative review process and specifies the consequences when such deadlines are not met. The Act directs that the first two steps of administrative review be completed by the Medicare Administrative Contractor and the QIC, respectively, within 60 days. 42 U.S.C. §§ 1395ff(a)(3)(C)(ii), 1395ff(c)(3)(C)(i). If the QIC fails to meet this deadline, the healthcare provider may

bypass the QIC determination and "escalate" the process by requesting a hearing before an ALJ, even though a decision by the QIC is ordinarily a prerequisite to such a hearing. Id. § 1395ff(c)(3)(C)(ii). With respect to the adjudication by an ALJ, the Medicare Act provides that an ALJ "shall conduct and conclude a hearing on a decision of a [QIC] . . . and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." Id. § 1395ff(d)(1)(A); see also 42 C.F.R. § 405.1016(c) (providing a 180-day deadline if the appeal had been escalated past the QIC level). If the ALJ does not render a decision before the deadline, the healthcare provider may bypass the ALJ and again escalate the process by "request[ing] a review by the Departmental Appeals Board . . . , notwithstanding any requirements for a hearing for purposes of the party's right to such a review." 42 U.S.C. § 1395ff(d)(3)(A). Finally, if the Departmental Appeals Board does not conclude its review within 90 days, id. § 1395ff(d)(2)(A), or within 180 days if the appeal had been escalated past the ALJ level, 42 C.F.R. § 405.1100(d), the healthcare provider "may seek judicial review [in a United States district court], notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review," 42 U.S.C. § 1395ff(d)(3)(B); see also 42 C.F.R. § 405.1132.

In sum, in order to exhaust the administrative process for reimbursement of Medicare services, a healthcare provider must present the claim in the first instance to a Medicare Administrative Contractor and thereafter engage the process of review and appeal set forth in § 1395ff. While the statute imposes deadlines for completion at each step of the process, it also anticipates that the deadlines may not be met and thus gives the healthcare provider the option of bypassing each step and escalating the claim to the next level, ultimately reaching judicial review by a United States district court within a relatively prompt time.

The order that Cape Fear Health System seeks would have the judiciary enforce an isolated deadline and thereby impose a process not contemplated by the Medicare Act -- indeed, in conflict with it. Instead of having a delayed claim continue by escalation through the steps of the administrative process and ultimately to the courts, the Hospital System would have a court order the Secretary to address its claims without escalation, to the detriment of all other appeals then pending. The precedent established by this judicial intrusion would surely invite every other delayed claimant into the courts, converting the agency process into a hybrid process involving judicial action in medias res. There is no evidence that Congress ever entertained such an idea. More importantly, the Hospital System's argument

that the Secretary must provide an ALJ hearing within 90 days or risk judicial intervention and supervision is grounded in a myopic reading of the Medicare Act.

The Medicare Act directs the Secretary in mandatory terms -- as the Hospital System stresses -- to comply with a 90-day deadline for ALJ decisionmaking:

> Except [when waived], an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) of this section and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.

42 U.S.C. § 1395ff(d)(1)(A) (emphasis added). But the next question is the more important one for addressing the Hospital System's argument -- what consequences follow if the deadline is not met? Congress answered this explicitly, providing:

> In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party's right to such a review.

Id. § 1395ff(d)(3)(A). Consequently, instead of creating a right to go to court to enforce the 90-day deadline, Congress specifically gave the healthcare provider a choice of either waiting for the ALJ hearing beyond the 90-day deadline or continuing within the administrative process by escalation to

the next level of review. The Hospital System's argument focuses on only the provision creating the 90-day time frame and fails to account for its context in the comprehensive administrative process. Our reading of the statute cannot be so restricted. See King v. Burwell, 135 S. Ct. 2480, 2492 (2015) (noting that it is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme" (quoting Util. Air Regulatory Grp. v. EPA, 134 S. Ct. 2427, 2441 (2014) (internal quotation marks omitted))); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000) (noting that "a reviewing court should not confine itself to examining a particular statutory provision in isolation").

Thus, when taken in context, § 1395ff(d) must be understood to provide a 90-day deadline for an ALJ's decision, thereby encouraging the process to proceed expeditiously, and to give the healthcare provider two options if the deadline is not met: bypassing the ALJ hearing and obtaining review by the Departmental Appeals Board, or waiting beyond the 90-day period for the ALJ to conduct a hearing and render a decision. In giving the healthcare provider these options, Congress anticipated that the 90-day deadline might not be met and provided its chosen remedy. But Congress clearly did not authorize healthcare providers to go to court at this stage of

the administrative process. Rather, it required, before going to court, that the healthcare provider obtain a final decision of the Secretary -- the decision of the Departmental Appeals Board. See 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ff(d)(2)(A); see also Heckler v. Ringer, 466 U.S. 602, 605-06 (1984). Only if the Departmental Appeals Board also fails to meet its deadline in reviewing the healthcare provider's claim can the healthcare provider, again in a similar manner, bypass that level of review and proceed to court, all within a relatively expeditious time frame. See id. §§ 1395ff(d)(2)(A), 1395ff(d)(3)(B).

The Hospital System argues that this interpretation of the administrative process is unreasonable as it results in a process that provides it the "terrible choice" of deciding whether to "waive its right to due process" or to "suffer interminably until the Secretary feels like affording [it] a hearing." Its due process argument is based on its presumption that, in bypassing the ALJ hearing, it would be denying itself the opportunity to create a full administrative record at the ALJ hearing, thereby leaving itself without a record for judicial review. See 42 U.S.C. § 1395ff(b)(1)(A) (incorporating 42 U.S.C. § 405(g), which requires that judicial review be conducted on the administrative record).

The Medicare Act, however, does not support the Hospital System's presumptions. The implementing regulations provide

that a healthcare provider may submit "any" evidence it wishes at the QIC redetermination stage, an earlier stage at which the Hospital System has not claimed delay. 42 C.F.R. § 405.968(a)(1); 42 U.S.C. § 1395ff(c). Thus, healthcare providers could, in anticipation of delays at the ALJ stage and beyond, create their record at the QIC stage and thereafter escalate their claims to the courts within a period of months. See 42 U.S.C. § 1395ff(d)(3). Moreover, it is not clear that the Hospital System would have, as it assumes, a right to introduce new evidence during an ALJ hearing even if it had the benefit of the hearing. See id. § 1395ff(b)(3) (providing that healthcare providers "may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the [QIC] . . . unless there is good cause").

Properly understood, therefore, the Medicare Act establishes a multilevel, "coherent regulatory scheme," Gustafson, 513 U.S. at 569, which authorizes a healthcare provider to bypass levels of review that are not completed in accordance with specified time frames and, at the same time, to create a record that it can ultimately use for judicial review. While the Act gives the Hospital System the clear and indisputable right to this administrative process, it does not give it a clear and indisputable right to adjudication of its appeals before an ALJ within 90 days.

Moreover, were we to interfere at the ALJ stage, as the Hospital System would have us do, we would be undermining important separation-of-powers principles, as the district court recognized in denying the Hospital System's request for a mandamus order. In the Medicare Act, Congress required healthcare providers to engage an Executive Branch administrative process in making claims for Medicare reimbursement, thus precluding court suits in the first instance that would bypass the process. But, in doing so, it did not deny healthcare providers judicial review; indeed, it guaranteed such review, but only after the Secretary is given the opportunity to grant or deny the claims in accordance with the specified process.

A writ of mandamus, as requested by the Hospital System, would have courts interrupt the specified administrative process and cross the lines of authority created by statute. Even if the backlog were fully attributable to the Secretary's mismanagement, as the Hospital System maintains, our "respect for the autonomy and comparative institutional advantage of the executive branch" must make us mighty "slow to assume command over an agency's choice of priorities." In re Barr Labs., Inc., 930 F.2d 72, 74 (D.C. Cir. 1991). And if the backlog were attributable to Congress' failure to fund the program more fully

or otherwise to provide a legislative solution, it would likewise be a problem for Congress, not the courts, to address.

Moreover, we have no reason to believe that any judicial intervention into HHS's administrative process, as urged by the Hospital System, would improve anything. The courts surely do not have greater competence to administer the Medicare reimbursement claims process than does HHS. And, in addition, judicial intervention as requested by the Hospital System would simply put each of its claims "at the head of the queue," moving "all others back one space and produc[ing] no net gain." In re Barr Labs., 930 F.2d at 75. We thus share the district court's belief that "the political branches are best-suited to alleviate OMHA's crippling delays."

One can hardly dispute that HHS's procedural arteries are seriously clogged and that its backlog of ten years is risking its procedural vitality. Put simply, its administrative process is in grave condition. While the Secretary laments this and Congress recognizes it, both are presently attempting to revive the process. As bleak as these circumstances appear to be, however, we are unpersuaded that Article III treatment of the ailing Article II patient in the manner the Hospital System urges is the answer or, indeed, even possible or desirable. Despite the legitimacy of the Hospital System's frustration, we

are convinced that the district court acted correctly in leaving treatment to the political branches.

For the reasons given, we affirm the district court's decision to dismiss the Hospital System's claim for a writ of mandamus.

III

Cape Fear Health System also sought "a declaratory judgment in its favor that HHS's delay in adjudication of Medicare appeals violates federal law." Because we affirm the district court's conclusion that the Hospital System failed to state a claim upon which mandamus relief could be granted, it follows that we must also affirm the district court's dismissal of the Hospital System's declaratory judgment claim. See Medtronic Inc. v. Mirowski Family Ventures, LLC, 134 S. Ct. 843, 849 (2014) (recognizing that the Declaratory Judgment Act is only "procedural" and does not create "substantive rights" (internal quotation marks and citations omitted)).

* * *

The judgment of the district court is

AFFIRMED.