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# UNITED STATES COURT OF APPEALS

#### FOR THE SIXTH CIRCUIT

A1 DIABETES & MEDICAL SUPPLY,

Plaintiff-Appellee,

 $\nu$ .

No. 18-6303

ALEX M. AZAR II, Secretary for the United States Department of Health and Human Services; SEEMA VERMA, Administrator for the Centers for Medicare and Medicaid Services.

Defendants-Appellants.

Appeal from the United States District Court for the Western District of Tennessee at Memphis.

No. 2:18-cv-02612—John Thomas Fowlkes, Jr., District Judge.

Argued: August 8, 2019

Decided and Filed: August 22, 2019

Before: GILMAN, SUTTON, and WHITE, Circuit Judges.

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## COUNSEL

**ARGUED:** Joshua M. Salzman, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellants. Jonathan E. Nelson, BASS, BERRY & SIMS PLC, Memphis, Tennessee, for Appellee. **ON BRIEF:** Joshua M. Salzman, Rachel F. Homer, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellants. Jonathan E. Nelson, John S. Golwen, BASS, BERRY & SIMS PLC, Memphis, Tennessee, Parker D. Eastin, NICHOLSON & EASTIN, LLP, Fort Lauderdale, Florida, for Appellee.

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## **OPINION**

SUTTON, Circuit Judge. In 2017, A1 Diabetes & Medical Supply learned that government auditors thought that the company had overcharged a federal agency by several million dollars for services provided to Medicare beneficiaries. A1 challenged the auditors' decisions at two levels of the Medicare appeals process but changed the auditors' minds only in a few minor ways. The government tried to start collecting the money, as the regulatory regime allows. Fearing bankruptcy from the government's recoupment efforts, A1 sought and received a preliminary injunction from a federal district court, barring the government from recouping the money until A1 received a hearing before an administrative law judge.

Even though A1 did not proceed to the third and fourth levels of the administrative appeal, the district court and we have jurisdiction over A1's constitutional claims. At the same time, the appellate briefs and oral argument have identified several factual and legal points on the merits that warrant clarification below. We therefore vacate the district court's order and remand the case for brief proceedings to address these questions.

I.

A federal health insurance program, Medicare makes sure that the elderly and disabled have access to medical care. The program depends on a lot of entities to make sure that beneficiaries get the help they need. One group of entities, medical services companies like A1, provide beneficiaries or their doctors with medical equipment. In exchange for their work, the government reimburses these companies.

Companies submit claims detailing how much they're owed, and the government usually approves them. To make sure it doesn't overpay, the government hires other companies to audit the payments. When an auditor believes that a company has overcharged, it sends a demand letter to the company for the amount owed. Sometimes the company pays. Other times it challenges the decision.

If the provider challenges the decision, it may appeal the decision through four levels of administrative review. At the first two levels of review, called the "redetermination" and "reconsideration" stages of the process, a provider submits written evidence to a new auditor who reviews the original auditor's ruling. The reviewer must explain in writing why it agrees or disagrees with the initial auditor. 42 U.S.C. §§ 1395ff(a)(5), (c)(3)(E). If the reviewers at the redetermination and reconsideration levels both agree that a provider claimed more than it was due, then the government may begin collecting the overpaid amount. *See* 42 U.S.C. § 1395ddd(f). The government recovers the amount due from the money that it would otherwise pay for new reimbursement claims until the provider's debt is paid in full. *See* 42 C.F.R. §§ 405.370(a), 405.371(a)(3).

The statute contains a hardship exception. It permits the government to offer payment plans to providers who demonstrate that repayment within thirty days (the default time period) would pose a challenge. 42 U.S.C. § 1395ddd(f)(1)(A). Most installment plans must be completed within three years, but the government has authority to extend the period up to five years if "unusual circumstances," such as potential insolvency, exist. 42 C.F.R. § 401.607(c).

Even as the government recoups overpayments, a provider may appeal the second-level administrative decision to the third tier of review, where an ALJ holds a hearing on the dispute. 42 U.S.C. § 1395ff(d)(1)(A). Once the provider submits a request for this hearing, the ALJ must hear and decide the case within ninety days. *Id.* If the ALJ agrees with the government auditors, the provider may seek further review with the Medicare Appeals Council. *Id.* A provider's last hope for a safe port of call is federal district court. *Id.* § 1395ff(b)(1)(A); 42 C.F.R. § 405.1136(a)(1). If at the end of this long journey the provider successfully shows the district court that it charged the right amount all along, the government must pay back whatever it collected plus interest. *See* 42 U.S.C. § 1395ddd(f)(2)(B).

One other feature of the administrative review process deserves mention. If the third and fourth layers of review take too long (more than ninety days each), the provider may go directly to district court to challenge the administrative decision on the existing record. *Id.* § 1395ff(d)(1)–(3). (A regulation, it's true, says that if the provider escalates past the ALJ level of review, the Medicare Appeals Council must issue a decision, dismissal order, or remand order

within 180 days from receipt of the party's escalation request, 42 C.F.R. § 405.1100(d). But that regulation appears to concern the timing of the Council's decision, not the timing of escalation to district court.)

According to the auditors, A1 owes the government quite a bit of money. All told, A1 allegedly overcharged the government around \$7 million. After receiving the demand letters, A1 appealed all of them through the first and second levels of administrative review. The reviews reduced in small part the amount A1 had to pay back. In August 2018, A1 submitted requests for an ALJ to review the remaining overpayment decisions but learned that the wait for a hearing would likely be three to five years, not ninety days. A1 felt it could not wait that long. According to A1, 90% of its revenue comes from government reimbursements such as the ones at issue. The government collects most recoupments by deducting the amounts owed to the provider due to new reimbursements based on new services. 42 C.F.R. § 405.373; Appellants' Br. 1. If the government started recouping the millions of dollars that it allegedly overpaid A1 by deducting the amounts from new reimbursements, and if the company could not get a hearing to challenge the recoupment decision, A1 alleged that it would go out of business. A1 sought relief in district court.

Notably, however, A1 did not invoke the escalation procedures allowing it to go to district court to obtain immediate review of the first and second layers of the administrative review process. It instead filed a complaint that this administrative process—particularly the denial of a prompt ALJ hearing and decision—violated its due process rights. A1 sought a preliminary injunction to prevent the government from recovering the amounts A1 owed until A1 could get its ALJ hearing at the third layer of review. The district court issued a preliminary injunction that bars the government from collecting the overcharged amounts until A1 gets a hearing before an ALJ.

II.

We start with a jurisdictional question. Ever since the U.S. Supreme Court's decision in *Arbaugh*, the Court has brought more discipline to delineating the statutory requirements for filing a lawsuit in federal court that amount to non-forfeitable (and non-waivable) jurisdictional

imperatives and those requirements that amount to forfeitable (and waivable) claim-processing rules. *Arbaugh v. Y&H Corp.*, 546 U.S. 500 (2006). The *Arbaugh* test is easy to describe: A statutory requirement goes to the subject matter jurisdiction of the federal courts "[i]f the Legislature clearly" says it does. *Id.* at 515. The test is not always easy to apply.

Seeking federal court review of a Medicare appeal is not for the jurisdictionally faint of heart. District courts typically have jurisdiction to hear cases involving a federal statute, like the Medicare Act, by virtue of 28 U.S.C. § 1331. But the Medicare Act bars federal courts from hearing cases under § 1331. 42 U.S.C. §§ 1395ii, 405(h). The Act permits a federal court to exercise jurisdiction over a party's claim only after the claimant satisfies the requirements of a different provision: *Id.* § 405(g)–(h). *See Shalala v. Ill. Council on Long Term Care*, 529 U.S. 1, 8–10 (2000).

Section 405(g) requires the "Secretary"—the Secretary of Health and Human Services—to make a "final decision" on the claim before a district court has jurisdiction to review any challenge to the administrative decision. 42 U.S.C. § 1395ff(b)(1)(A). As a matter of custom and regulation, the last decision in the administrative process—the decision at the fourth level of review by the Medicare Appeals Council—counts as the final decision. 42 C.F.R. §§ 405.1130, 405.1132. Is going through this fourth level of review a jurisdictional prerequisite or a waivable procedural hurdle? At first blush, one could see it either way. On one side, § 405(g)'s text requires a final decision, and the process is not final until that stage. On the other side, the "final decision" prerequisite looks a lot like an exhaustion rule. *See Ill. Council*, 529 U.S. at 10. We often expect Congress and agencies to decide how much review suffices to give the agency a chance to correct a problem. And in this instance, the statute allows a provider to bypass the third and fourth layers of review if the relevant decision maker at each layer cannot resolve the matter within 90 days. That does not sound like a non-waivable jurisdictional prerequisite, least of all in the context of a constitutional challenge to the process itself.

Cue *Mathews v. Eldridge*, which suggests that § 405(g)'s exhaustion requirement is not a jurisdictional prerequisite for review in federal court. 424 U.S. 319, 331 (1976). The Court assessed a claim that looked like this one in many ways: a constitutional due process challenge to a request for disability benefits lingering in the halls of the agency's appeals process. The

Court held that a district court has jurisdiction under § 405(g) to hear a constitutional challenge related to a claim for benefits as long as the party initially presented the claim to the relevant agency. Section 405(g), the Court explained, "consists of two elements, only one of which is purely 'jurisdictional' in the sense that it cannot be 'waived' . . . . The non-waivable element is that a claim for benefits shall have been presented to the Secretary. Absent such a claim there can be no 'decision' of any type." *Id.* at 328. Because A1 presented a claim for benefits to the Secretary at steps one and two of the review process, this reasoning supports our jurisdiction over the claim.

Two other considerations deserve mention. One is that *Mathews* was decided in 1976, long before the Court (often through the leadership of Justice Ginsburg) began to bring discipline to this area. But that reality does not alter our conclusion. There is no clear statement in the relevant statute that the *Mathews* approach overlooks. If anything, recent decisions have made subject matter jurisdiction limitations *harder* to find.

The other consideration is a qualification—that the administrative review regime at issue in *Mathews* differs from this one. *Mathews* looked at the review process for disability benefits that Social Security provides. At the time, the Social Security Administration had complete authority to decide by regulation what the *Social Security* review process would entail. *See Weinberger v. Salfi*, 422 U.S. 749, 766 n.9 (1975). Congress codified the current four-layer review process for *Medicare* in 2000 through the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act. Even though § 405(g) grants jurisdiction over claims arising under either statutory scheme, the Medicare Act does not grant the Secretary of Health and Human Services the authority to construct an administrative appeals process for Medicare as he or she sees fit. *See* 42 U.S.C. § 1395ff. But that difference doesn't matter here. Far more relevant is a *statute's* grant of authority to the regulated party to go to district court if the administrative process bogs down. Today's statutory provisions—and the escalation authority given to the regulated party after the first and second layers of review—make it difficult to maintain that A1's completion of all four levels of administrative review amounts to a hard and fast limit on the subject matter jurisdiction of the federal courts.

All in all, A1 has complied with § 405(g) and *Arbaugh* and *Mathews*. The company presented its claim for benefits to the relevant agency, and a federal court for the reasons just given may review a due process challenge to the process before a party goes through every stage of agency review. We take some comfort in the reality that the parties agree with our conclusion, and the Fifth Circuit recently reached a similar conclusion. *See Family Rehab.*, *Inc. v. Azar*, 886 F.3d 496 (5th Cir. 2018).

Jurisdiction exists. That leaves the merits.

III.

In gauging requests for a preliminary injunction, district courts look at four factors: (1) the plaintiff's likelihood of success on the merits; (2) the risk of irreparable harm to plaintiffs absent injunctive relief; (3) the risk of harm to others resulting from an injunction; and (4) the broader public interest. *Mich. State AFL-CIO v. Schuette*, 847 F.3d 800, 803 (6th Cir. 2017). In reviewing such decisions, courts of appeals ask two questions: (1) Did the district court rely on clearly erroneous facts in assessing these considerations? And (2) did the court rely on an incorrect legal standard or misapply the governing standard in assessing these considerations? *Id.* This case turns on the law—and A1's likelihood of success on its due process claim.

The Fifth Amendment prohibits the federal government from depriving any person "of life, liberty, or property, without due process of law." U.S. Const. amend. V. To prevail on such a claim, A1 must show that the government deprived it of a "liberty or property" interest and did so without the kind of "process" the Constitution requires.

Let us take for granted that A1 identified a protected "property" interest. Some courts, it's true, have raised doubts about whether a Medicare service provider has any property interest in getting paid for what it provides. *See PHHC, LLC v. Azar*, No. 18-cv-1824, 2018 WL 5754393, at \*8 (N.D. Ohio Nov. 2, 2018); *Alpha Home Health Sols., LLC v. Sec'y of U.S. Dep't of Health & Human Servs.*, 340 F. Supp. 3d 1291, 1303 (M.D. Fla. 2018). Other courts have found a valid property interest. *See Angels of Care Home Health Inc. v. Azar*, No. 3:18-CV-3268-S-BK, 2019 WL 1101286, at \*2 (N.D. Tex. Feb. 13, 2019); *Med-Cert Home Care, LLC v. Azar*, 365 F. Supp. 3d 742, 751 (N.D. Tex. 2019); *Accident, Injury & Rehab., PC v. Azar*, No.

4:18-cv-02173-DCC, 2018 WL 4625791, at \*7 (D.S.C. Sept. 27, 2018). But we need not resolve the point today. We will assume for now that A1 has a property interest in getting paid for its equipment and services.

Mathews v. Eldridge, once again, enters the picture. It tells us to balance four factors in deciding what process A1 deserves: "[1] the private interest that will be affected by the official action; . . . [2] the risk of an erroneous deprivation[;] . . . [3] the probable value, if any, of additional or substitute procedural safeguards; and . . . [4] the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." 424 U.S. at 335.

Two of the *Mathews* factors—the first and fourth—are relatively straightforward to apply here. As to the first one, A1 plainly has a significant "private interest": payment for services rendered. It's difficult for a company to stay in business without fresh revenue. As this case comes to us, the company already has laid off 25 people. And nearly 50 others will lose their jobs if A1 enters bankruptcy—which A1 claims is inevitable if the government may deduct all new reimbursement payments against the \$7 million in recoupment payments now due. The future viability of a company—not to mention (though just mentioned) the jobs it sustains—hinges on whether it gets new reimbursements for new services provided. It's true that *this money* may look less important than other money subject to claims like this one—whether successful claims, *see Goldberg v. Kelly*, 397 U.S. 254, 264 (1970) (identifying government welfare benefits as "the very means by which to live"), or unsuccessful claims, *see Mathews*, 424 U.S. at 340 (recognizing that the private interest in disability benefits is not so significant that a pre-termination hearing is necessary). But we must look at A1's "private interest" in part through its eyes, not exclusively through others' eyes. And there is plenty to appreciate from A1's vantage point.

The fourth factor, by contrast, cuts in favor of the government. It seeks to recover on a timely basis millions of dollars that several government auditors agree it is owed and that two independent layers of administrative review confirm it is owed. This agency, like every federal agency, has ample reason to ensure that it does not waste the people's money. Just as the

people's resources are finite, so are the government's. Delayed recoupment of over-billing puts Medicare at risk, and other government programs too.

Our resolution of the second and third factors is another matter. Both considerations remain clouded by a few questions and the need for a few more answers. Even after the district court's thoughtful decision, admirable appellate briefing, and helpful oral arguments in our court, some details about the administrative scheme and A1's choices under it remain unclear. In view of the centrality of the likelihood-of-success factor to this appeal, and in view of the significance of giving a green light to federal due process claims in this setting, we think it prudent to obtain more information before resolving the point.

The record, for one, remains unclear about A1's choice not to take advantage of the escalation option. By statute, if an ALJ does not provide A1 its hearing and decision in ninety days, A1 may escalate its claim to the fourth and final level of administrative review—and then to district court review if the same problem raises its head. 42 U.S.C. § 1395ff(d)(3)(A)–(B). A1 submitted a timely appeal for an ALJ hearing on August 15, 2018. That started the ninety-day clock. If A1 had submitted a request for escalated review after that period ran, and if it had the same problem at the fourth level of review, it could have made it to district court as early as February 2019. At that point, A1 could have asked for an injunction (on the merits of the recoupment claim rather than on the due process claim) to bar further recoupment while it litigated the auditors' decisions that underlie its claim before this court. At oral argument, A1 represented that it could stave off bankruptcy for ninety days, while waiting for an ALJ decision, but not three to five years. Why was the same not true for the six months it would take to escalate? And how exactly does escalation compromise, as opposed to avoid, due process problems?

Escalation, it's true, requires a party to forgo the right to a live hearing at the third level of the process. Absent the ALJ hearing, it's also true, the district court will be limited to the written administrative record, leaving A1 without the chance to cross-examine the government's statisticians. But these answers, too, leave questions. The Medicare Act generally requires that a provider who challenges an auditor's decision to submit *all* evidence in its favor before it reaches the third layer of review. *See* 42 U.S.C. § 1395ff(b)(3) ("A provider of services or supplier may

not introduce evidence in any appeal under this section that was not presented at the [second level of review] unless there is good cause which precluded the introduction of such evidence ...."). And the first and second levels of administrative review require the decisionmakers to provide detailed, written explanations for their decisions. 42 U.S.C. §§ 1395ff(b)(3), (c)(3)(E). By the third level of review, then, the provider and the government must have submitted all of their supporting evidence, and the decisionmakers must have explained any decision to reject a provider's claim. As for A1's desire to cross-examine the government's auditors, that right is qualified. Although the regulations allow agency officials and the contracted auditors who conducted the extrapolation to participate in the ALJ proceedings, 42 C.F.R. § 405.1010(a)(1), the regulations prohibit ALJs from subpoening agency officials to participate in a hearing. Id. § 405.1010(a) (2). Cross-examination, in other words, is not guaranteed, even at the ALJ hearings, which apparently often are decided by telephone and essentially on the written record. The parties also dispute the extent to which physician testimony on the medical necessity of charges is available at the ALJ hearing. Appellee's Br. 31; Reply Br. 12. What, then, exactly is provided in terms of additional fairness at the ALJ hearing? And relatedly what exactly would A1 give up by not seeking immediate recourse in federal court through escalation?

That leaves the other key question. The parties do not seem to have been aware of a recoupment option that might have allowed A1 to obtain an ALJ hearing before making most or even all of its recoupment payments. Nothing in the statute or regulations seems to prohibit the government from creating an installment-based repayment plan that accounts for a provider's financial distress *and* the government's log jam in resolving appeals at the third and fourth levels of review. For example: It is not clear when or whether the government must demand recoupment—either as a matter of statutory or regulatory authority. (How do we know, to be specific, that the Federal Claims Collection Act applies to Medicare-based claims? The relevant statute, 31 U.S.C. § 3711, does not seem to say.) It is not clear what kind of discretion and how much discretion the government has on timing. *See*, *e.g.*, 42 C.F.R. § 401.607(c)(3); *see also* 42 U.S.C. § 1395ddd(f)(1)(A); 42 C.F.R. § 405.379(h)(2). And it is not clear whether, if the government is statutorily obligated to collect recoupment and if it must do so within a certain time, it may delay the bulk of the recoupment payments until after the ALJ hearing and decision,

keeping in mind that the delays stem from bureaucratic snags in *the government's* appeal process.

Finally, we have unanswered questions regarding the statistics concerning the relief likely to be obtained at the third level of administrative review. In particular, how often does an entity obtain substantial relief at level three over any relief that it obtained at level two? And how should we account for the high rate of dismissals at level three?

To the end of answering these questions, we vacate the district court's order granting A1 a preliminary injunction and remand the case to the district court. On remand, the court is free to maintain the status quo by reissuing a temporary restraining order and other preliminary relief while the parties respond promptly to these (and any other relevant) questions. After obtaining this information, the district court remains free to reach the same or a different conclusion—and to explain how this new information either does or does not alter its initial conclusion. Once the parties and the court promptly complete that process, the losing party may appeal the district court's order on an expedited basis to this panel. At that point, we will decide whether additional briefing and oral argument are necessary.

We vacate the district court's order and remand for proceedings consistent with this opinion.