IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
July 31, 2020

Lyle W. Cayce
Clerk.

No. 17-50855

DOMINION AMBULANCE, L.L.C.,

Plaintiff–Appellant,

v.

ALEX M. AZAR, II, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant–Appellee.

Appeal from the United States District Court
for the Western District of Texas
USDC No. 3:16-CV-146

Before OWEN, Chief Judge, and DENNIS and SOUTHWICK, Circuit Judges.

OWEN, Chief Judge:

The Department of Health and Human Services (HHS) concluded that Dominion Ambulance, L.L.C. (Dominion) must return approximately $1.3 million in Medicare payments. After appealing to the agency, Dominion brought suit in district court challenging that determination. The district court granted HHS's motion for summary judgment. We affirm.

I

Dominion is an ambulance service provider in southwest Texas. Qualifying ambulance transportation services are covered by Medicare Part B. Dominion submitted claims to Medicare and was reimbursed. As Secretary of

HHS, Alex M. Azar, II (the Secretary) is responsible for administration of the Medicare program. The Secretary delegates this authority to regional contractors that process and pay reimbursements to providers.

Zone Program Integrity Contractors (ZPICs) audit the regional contractors' payment determinations. ZPICs may reopen otherwise final determinations and identify instances of overpayment.[1] If the ZPIC determines from a sample of a provider's claims that there is a "sustained or high level of payment error," the ZPIC may extrapolate the error rate to determine the total overpayment.[2] The ZPIC then notifies the appropriate regional contractor, who issues a demand letter to the provider.[3] The provider may then engage in four levels of administrative appeals.[4] First, it may seek a redetermination from the regional contractor who initially authorized the reimbursement determination that resulted in an overpayment.[5] Second, it may then seek reconsideration from a Qualified Independent Contractor (QIC).[6] Third, it may request a de novo hearing before an Administrative Law Judge (ALJ).[7] Fourth, it may appeal to the Medicare Appeals Council (MAC).[8] The determination at the conclusion of the administrative appeal process is a "final decision" of the Secretary subject to judicial review under 42 U.S.C. § 405(g).[9]

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[1] 42 C.F.R. § 405.980.

[2] 42 U.S.C. § 1395ddd(f)(3); *see Gentiva Healthcare Corp. v. Sebelius*, 723 F.3d 292, 295-96 (D.C. Cir. 2013) (holding that the Secretary may authorize a contractor to make the high-error-level determination).

[3] *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 499 (5th Cir. 2018).

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Maxmed Healthcare Inc. v. Price*, 860 F.3d 335, 338 (5th Cir. 2017).

On May 11, 2010, a ZPIC notified Dominion that it was reviewing a random sample of forty claims drawn from a group of over twelve thousand for which Dominion had been reimbursed. The earliest of these claims was dated September 1, 2007. On April 25, 2012, the ZPIC found that thirty-eight of the forty claims were improperly paid (a 95% rate of error). It determined that the sample contained a "high level of payment error" and extrapolated from that sample to calculate a total overpayment rate and amount.

Dominion availed itself of the administrative appeal process, during which several of the ZPIC's findings were reversed. HHS ultimately concluded that twenty-six of the forty sampled claims were paid in error (a 65% rate of error). Each of the rejected claims was for nonemergency, scheduled, repetitive ambulance services that HHS determined was not medically necessary despite being supported by a physician certification statement of necessity.

Without making a determination that the revised 65% rate of error constituted a "high level of payment error," HHS re-extrapolated the sample, which reduced the overpayment amount to $1,321,933. Dominion then initiated suit.

Dominion and the Secretary filed cross-motions for summary judgment. Dominion argued that (1) a physician certification statement was sufficient under the applicable regulations to demonstrate medical necessity; (2) the ZPIC improperly reopened seven of the forty claims because the four-year regulatory limitations period had expired; (3) the use of extrapolation was inappropriate given that HHS did not make a high-error-level determination after revising the error rate in the sample; and (4) the use of extrapolation violated Dominion's due process rights because (a) the methodology used was statistically unsound and should not have been applied when the medical necessity of claims was at issue, and (b) it rendered Dominion unable to identify and recoup payment from patients for claims that were disallowed.

The district court granted the Secretary's motion for summary judgment. It agreed with the Secretary that a physician certification statement is not dispositive of medical necessity, and held that the court lacked jurisdiction to consider Dominion's arguments that reopening the claims was barred by limitations and that HHS could not extrapolate in the absence of a finding that the 65% rate of error was a high level. The district court refused to consider Dominion's constitutional claims, reasoning that they should have first been presented to HHS. Dominion has appealed.

II

This court reviews a grant of summary judgment de novo, "applying the same standard to review the agency's decision that the district court used."[10] We have not resolved whether we review factual issues in a Medicare case for substantial evidence or under the Administrative Procedure Act's (APA) arbitrary and capricious standard, but any distinction between the standards "probably makes no difference."[11] We may affirm on any grounds supported by the record.[12]

III

Ambulance transportation is covered under Medicare "where the use of other methods of transportation is contraindicated by the individual's condition, but . . . only to the extent provided in regulations."[13] Services "not reasonable and necessary for the diagnosis or treatment of illness or injury"[14] are not covered by Medicare. Dominion contends that under regulations in

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[10] *Id.* at 340 (quoting *Baylor Cty. Hosp. Dist. v. Price*, 850 F.3d 257, 261 (5th Cir. 2017)).

[11] *Id.* (quoting *Baylor Cty. Hosp.*, 850 F.3d at 261).

[12] *See, e.g.*, *Doctor's Hosp. of Jefferson, Inc. v. Se. Med. All., Inc.*, 123 F.3d 301, 307 (5th Cir. 1997).

[13] 42 U.S.C. § 1395x(s)(7).

[14] *Id.* § 1395y(a)(1)(A).

effect at the time, which have since been amended, a physician's determination that transportation by ambulance is "reasonable and necessary" is not subject to challenge in a Medicare review process.

Congress directed the Secretary to "promulgate regulations and make initial determinations with respect to benefits" under Medicare Part B.[15] The Secretary is responsible for reviewing claims and recovering overpayments.[16] In fulfilling this role, the Secretary is authorized to enter into contracts with "eligible entities."[17] Congress did not, however, authorize the Secretary to delegate his decision-making responsibility to private physicians who may or may not have an interest in Medicare integrity.[18] The statutory scheme does not support Dominion's argument that a private physician can unilaterally bind the Secretary.

Under the regulations in effect at the time Dominion provided the services at issue and as modified in 2012, ambulance transportation is covered by Medicare if "the service meets the medical necessity . . . requirements of" 42 C.F.R. § 410.40(d).[19] Under § 410.40(d), ambulance services are covered only if "other means of transportation are contraindicated."[20] Further, "[n]onemergency transportation by ambulance" is only "appropriate" if the beneficiary is "bed-confined" as defined in the regulation or "if his or her medical condition . . . is such that transportation by ambulance is medically required."[21]

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[15] *Id.* § 1395ff(a)(1).
[16] *See id.* § 1395ddd.
[17] *Id.* § 1395ddd(a).
[18] *See id.* § 1395ddd(c) (describing what constitutes an eligible entity).
[19] 42 C.F.R. § 410.40(a)(1) (2002).
[20] *Id.* § 410.40(d)(1).
[21] *Id.*

Section 410.40(d)(2) creates a "[s]pecial rule for nonemergency, scheduled, repetitive ambulance services."[22] Such "medically necessary" services are covered only if "the ambulance . . . supplier . . . obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1)" are met.[23] In other words, a physician must provide a physician certification statement for nonemergency, scheduled, repetitive ambulance services to be covered by Medicare. The parties dispute that rule's effect. Dominion argues that the physician certification statement conclusively establishes that a service was medically necessary. The Secretary counters that such a statement is required but does not irrefutably establish medical necessity. The agency amended § 410.40(d) in 2012 to clarify the effect of a physician certification statement.[24] The amended regulation states that such a statement "does not alone demonstrate that the ambulance transport was medically necessary."[25] Our task is to determine the meaning of § 410.40(d) at the time Dominion's claims were submitted.

When a regulation is unambiguous, courts owe no deference to the agency's interpretation of it and simply apply the regulation's plain meaning.[26] But when the regulation is ambiguous, courts generally defer to any agency interpretation that is not "plainly erroneous or inconsistent with the regulation."[27] "It is well established that an agency's interpretation need not

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[22] *Id.* § 410.40(d)(2).

[23] *Id.*

[24] 42 C.F.R. § 410.40(d)(2)(ii) (2012).

[25] *Id.*

[26] *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000).

[27] *Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 208 (2011) (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)); *La. Dep't of Health & Hosps. v. CMS*, 346 F.3d 571, 576 (5th Cir. 2003) ("[T]he Secretary's interpretation of Medicare regulations is given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" (quoting *Harris Cty. Hosp. Dist. v. Shalala*, 64 F.3d 220, 221 (5th Cir. 1995))).

be the only possible reading of a regulation—or even the best one—to prevail."[28] Deference is inappropriate, however, if "there is reason to suspect that the agency's interpretation 'does not reflect the agency's fair and considered judgment on the matter in question.'"[29] "This might occur when the agency's interpretation conflicts with a prior interpretation or when it appears that the interpretation is nothing more than a 'convenient litigating position'. . . ."[30] However, "novelty alone is not a reason to refuse deference."[31]

Section 410.40(d)(2), under the 2002 version and the current version, provides that a physician's statement certifying that the medical necessity criteria were met is *necessary* for nonemergency, scheduled, repetitive ambulance transportation.[32] But that provision has never explicitly stated that a physician certification statement conclusively establishes medical necessity. This court cannot say that the regulation unambiguously states that a such a statement establishes medical necessity. And as explained below, the Secretary's interpretation is not plainly erroneous. Accordingly, we will apply the agency's interpretation.[33]

The Secretary argues that a physician certification statement is necessary but not sufficient to establish that nonemergency, scheduled, repetitive ambulance transportation is covered by Medicare, as the contrary interpretation would render the phrase "medically necessary" in § 410.40(d)(2) superfluous. In the regulation, "medically necessary" modifies "nonemergency,

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[28] *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 613 (2013).

[29] *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012) (quoting *Auer*, 519 U.S. at 462).

[30] *Id.* (internal citation omitted) (quoting *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988)).

[31] *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 564 U.S. 50, 64 (2011).

[32] 42 C.F.R. § 410.40(d)(2).

[33] *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000) (the court applies the plain meaning of an unambiguous regulation); *Auer*, 519 U.S. at 461 (the Secretary's interpretation of an ambiguous regulation is controlling unless it is plainly erroneous).

scheduled, repetitive ambulance services."[34] That modifier would be unnecessary if the physician certification statement were dispositive.[35] The Secretary further submits that deeming a physician certification statement to be dispositive would allow disinterested, third-party physicians to determine ambulance services' coverage status, in violation of the statutory scheme that requires the Secretary to determine medical necessity.

At least in the criminal fraud context, this court and the Sixth Circuit have agreed with the Secretary's interpretation.[36] Other circuits have also held that a physician certification is not sufficient to establish the medical necessity of other healthcare services covered by Medicare.[37] The Secretary's interpretation is neither plainly erroneous nor inconsistent with the regulation.

Dominion's arguments to the contrary are unavailing. It first argues that the Secretary's interpretation violates the disparate exclusion/inclusion canon of construction. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."[38] Dominion argues that this canon should apply equally to agencies writing regulations. In 2002, HHS amended the

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[34] 42 C.F.R. § 410.40(d)(2) (2002).

[35] *See, e.g.*, *Exelon Wind 1, LLC v. Nelson*, 766 F.3d 380, 399 (5th Cir. 2014) ("When presented with two plausible readings of a regulatory text, this court common-sensically . . . prefers the reading that does not render portions of that text superfluous."); *see also United States v. Advantage Med. Transp. Inc.*, 698 F. App'x 680, 692-93 (3d Cir. 2017) (Jordan, J., dissenting).

[36] *See United States v. Read*, 710 F.3d 219, 222-23 (5th Cir. 2012) (per curiam); *United States v. Medlock*, 792 F.3d 700, 709 (6th Cir. 2015).

[37] *See Maximum Comfort Inc. v. Sec'y of Health & Human Servs.*, 512 F.3d 1081, 1083 (9th Cir. 2007) (holding that physician certification is not conclusive as to medical necessity for durable medical equipment); *MacKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 347-48 (4th Cir. 2007) (same); *Gulfcoast Med. Supply, Inc. v. Sec'y, Dep't of Health & Human Servs.*, 468 F.3d 1347, 1351-52 (11th Cir. 2006) (same).

[38] *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972).

regulations in § 410.40(d)(3) to provide that, for "nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis," supporting documentation from the healthcare provider "does not alone demonstrate that the ambulance transport was medically necessary."[39] The agency's failure to add a similar disclaimer to § 410.40(d)(2), according to Dominion, indicates that it did not intend for one to apply. It also argues that § 410.40(d)(2) and (d)(3) are special rules whose provisions should not apply to one another.

Even if Dominion's interpretation is reasonable, it fails to show that the Secretary's interpretation is plainly erroneous. Dominion's invocation of the disparate inclusion/exclusion canon does not render its interpretation unambiguously correct.[40] Nor would Dominion's interpretation be the only reasonable interpretation. The mere fact that another plausible reading—or even a better reading—of the regulation is possible does not render the agency's interpretation unreasonable.[41]

Deference is appropriate unless there is reason to suspect that the interpretation proffered by the agency does not represent its considered judgment on the issue.[42] Such may be the case when the agency's interpretation conflicts with a prior interpretation,[43] but there is no indication that HHS has ever interpreted the regulation differently. Since at least 1993, HHS's internal position has been that "no presumptive weight should be assigned to the treating physician's medical opinion in determining the

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[39] 42 C.F.R. § 410.40(d)(3)(v) (2002).
[40] *See U.S. Dep't of Justice v. FLRA*, 727 F.2d 481, 491 (5th Cir. 1984).
[41] *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 613 (2013).
[42] *Auer v. Robbins*, 519 U.S. 452, 462 (1997).
[43] *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012).

medical necessity" of services covered under Medicare Part A.[44] The ambulance services at issue here are covered by Medicare Part B,[45] but the agency has invoked the Part A rule to broadly assert that "the Secretary is the final arbiter of whether a service is reasonable and necessary and qualifies for Medicare coverage."[46]

In promulgating § 410.40(d)(2), the agency stated that it believed "[t]he physician certification requirement will *help* to ensure that the claims submitted for ambulance services are reasonable and necessary."[47] And in the context of a bed-confined beneficiary, the agency said that the physician certification statement requirement does not "relieve the [ambulance] supplier of his or her responsibility to submit adequate information supporting the reason for a bed-confinement determination."[48] These statements suggest that HHS did not consider a physician certification statement conclusive.

HHS's clearest statement came in 2012 when it amended the regulation to state that "[t]he presence of the signed physician certification statement does not alone demonstrate that the ambulance transport was medically necessary."[49] The agency asserted that its amendment only "clarif[ied]" the prior regulation's proper interpretation.[50] Even if HHS did not announce this interpretation prior to 2012, it is clear that HHS has never explicitly

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[44] HCFA Ruling No. 93-1, at 13 (Dep't of Health and Human Servs. May 18, 1993), https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/HCFAR931v508.pdf.

[45] *See* 42 U.S.C. § 1395k.

[46] Final Rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013, 77 Fed. Reg. 68,892, 69,161 (Nov. 16, 2012).

[47] Final Rule, Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements, 64 Fed. Reg. 3,637, 3,641 (Jan. 25, 1999) (emphasis added).

[48] *Id.* at 3,640.

[49] 42 C.F.R. § 410.40(d)(2)(ii) (2012).

[50] 77 Fed. Reg. at 69,161.

considered a physician certification statement conclusive. There is no conflict between the interpretation the Secretary advances now and any prior interpretation of § 410.40(d)(2).

Nor has Dominion shown that the Secretary is advancing this interpretation merely as a "convenient litigating position."[51] The agency announced its interpretation at least six years ago and codified it into a regulation.[52] The Secretary has not advanced a new interpretation as a means of winning this case. Accordingly, the district court properly deferred to the agency's reasonable interpretation.

B

Dominion contests the timeliness of the agency's decision to reopen Dominion's claims. Under 42 C.F.R. § 405.980(b), "[a] contractor may reopen an initial determination or redetermination on its own motion . . . [w]ithin 1 year from the date of the initial determination or redetermination for any reason," "[w]ithin 4 years . . . for good cause," or "[a]t any time if there exists reliable evidence . . . that the initial determination was procured by fraud or similar fault."[53] The "decision on whether to reopen is binding and not subject to appeal."[54]

Because the "decision on whether to reopen is binding and not subject to appeal," the district court held that the regulation "flatly bars review of the decision to reopen the initial determination on appeal." The court also held that even if it had jurisdiction, "the regulations provide for reopening of an initial determination at any time when evidence of fraud or 'similar fault'

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[51] *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012) (quoting *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988)) (noting that interpretation advanced for litigation convenience may not represent agency's considered judgment on the matter).

[52] 77 Fed. Reg. at 69,161.

[53] 42 C.F.R. § 405.980(b).

[54] *Id.* § 405.980(a)(5).

exists." We assume, without deciding, that the district court had jurisdiction to review the timeliness of the decision to reopen the initial determination, and we conclude that the decision to reopen was timely.

In the district court, Dominion argued that HHS erred in retroactively applying the 2010 version of 42 C.F.R. § 405.980(b) to the ZPIC's decision to reopen and revise its determinations. It argued that the ALJ and MAC should have applied the 2005 regulation. The 2005 regulation required the agency to "reopen and revise" determinations within four years.[55] The 2010 regulation imposes a four-year time limit on "reopen[ing]" only.[56]

On appeal, Dominion changed its approach. It now argues that regardless of whether the 2005 or 2010 regulation applied to the reopening decision, the reopening was untimely as to seven claims because they were not "reopened" until April 25, 2012. As a result, it has abandoned any argument that the *revision* of those seven claims was untimely.[57] Because the parties agree that both the 2005 and 2010 versions of the regulation impose the same time limits for the *reopening* of determinations, we need not decide which version of the regulation applies.

As discussed above, an agency's interpretation of its own regulation is generally entitled to deference unless it is "plainly erroneous or inconsistent with the regulation."[58] Under 42 C.F.R. § 405.980(b), the Secretary may not reopen a final benefits determination after four years has passed, absent some indicia of fraud.[59] The regulatory definition of "reopening" is "a remedial action taken to change a binding determination or decision that resulted in either an

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[55] 42 C.F.R. § 405.980(b) (2005).
[56] 42 C.F.R. § 405.980(b) (2010).
[57] *See, e.g.*, *In re Southmark Corp.*, 163 F.3d 925, 934 n.12 (5th Cir. 1999).
[58] *Auer v. Robbins*, 519 U.S. 452, 461 (1997).
[59] 42 C.F.R. § 405.980(b) (2010).

overpayment or underpayment."[60] Dominion argues that the regulation is unambiguous and that "reopening" does not occur until the ZPIC issues a revised determination. The Secretary argues that the reopening must occur before the revision and that a claim is reopened when the ZPIC's review begins. The Secretary proffers a reasonable interpretation, and thus the regulation cannot unambiguously support Dominion's interpretation.[61] Even if Dominion's interpretation is also reasonable and the regulation is ambiguous, the Secretary's interpretation is entitled to deference.[62]

Under the Secretary's interpretation of the regulation, all reopenings were timely. The ZPIC reviewed claims dating from as early as September 1, 2007, and began its review of Dominion's claims on May 11, 2010. That is within the four-year window. Dominion does not argue that the agency lacked "good cause" to reopen these claims.[63] Accordingly, the agency did not improperly reopen Dominion's claims.

C

As an alternate holding, the district court noted that the fraud exception justified any untimeliness in reopening the determinations. Because the reopenings were timely, we need not consider whether the record contains indications of fraud.

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[60] *Id.* § 405.980(a)(1); 42 C.F.R. § 405.980(a)(1) (2005) (defining a reopening as "a remedial action taken to change a *final* determination or decision that resulted in either an overpayment or underpayment") (emphasis added).

[61] *United States v. Kaluza*, 780 F.3d 647, 658 (5th Cir. 2015) (statutory language is ambiguous if it is "susceptible to more than one reasonable interpretation" (quoting *Carrieri v. Jobs.com Inc.*, 393 F.3d 508, 518-19 (5th Cir. 2004))).

[62] *See Auer*, 519 U.S. at 461.

[63] *See* 42 C.F.R. § 405.980(b)(2) (providing that claims may only be reopened after one year for good cause).

D

By statute, the Secretary must determine that "there is a sustained or high level of payment error" before using "extrapolation to determine overpayment amounts."[64] "There shall be no . . . judicial review" of such a determination.[65] The ZPIC initially identified thirty-eight improperly paid claims in the forty-claim sample and determined that there was a high level of payment error.[66] Because the ZPIC's decision on twelve of these claims was reversed during the administrative appeal process, Dominion argues that the Secretary was required to make a second high-error-level determination in order to continue using extrapolation. The district court held that it did not have jurisdiction to consider whether the Secretary should have made a second finding of a high rate of error.

Dominion argues that the district court erred because it had jurisdiction and "should have disallowed the extrapolation because the Agency failed to make a determination that the final error rate was high enough to justify extrapolation." The Secretary argues that a high-error-rate determination is "insulated . . . from *administrative* as well as judicial review," and even if the agency made a subsequent determination, extrapolation would still be appropriate. According to the Secretary, twenty-six out of forty claims—a 65% error rate—is still a high error rate that justifies extrapolation.[67]

Because the Secretary would find that a 65% error rate constitutes a "high level of payment error," we need not decide if a second determination is required. The record makes clear that the QIC, ALJ, and MAC approved the continued use of extrapolation, even after several of the claims were reversed.

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[64] 42 U.S.C. § 1395ddd(f)(3).

[65] *Id.*

[66] *See Gentiva Healthcare Corp. v. Sebelius*, 723 F.3d 292, 296 (D.C. Cir. 2013) (holding that the Secretary may authorize a contractor to make the high-error-level determination).

[67] *Id.*

The Secretary's position is that "[w]hether the error rate is 65% or 95%, . . . extrapolation remains valid." Dominion does not challenge that point. At oral argument, Dominion did not contest that the Secretary would find a 65% error rate high. Instead, it argued, without any relevant authority, that the court should simply reverse the decision without giving the Secretary the opportunity to make that finding.

It is clear from the record and briefing that if the court remanded the case for the Secretary to make a second determination—the act which Dominion argues the Secretary was required to do—the result would not change. Dominion has provided no authority or support that extrapolation is inappropriate when a 65% error rate exists, and the Secretary makes clear that his position is that such a rate is high. Assuming Dominion is correct that the Secretary had to make a second determination, we will not vacate and remand because Dominion fails to show that a 65% error rate is not high and that extrapolation is inappropriate in this case.

E

Dominion raises two Fifth Amendment challenges to the overpayment determination. The district court did not consider Dominion's constitutional claims. The court ruled that Dominion waived its arguments by failing to raise them during the administrative appeal proceedings. In its opening brief, Dominion argues that it was not required to exhaust its constitutional claims in the administrative appeal process and asked the court to remand the case to the district court. In response, the Secretary argues that Dominion failed to exhaust its claims and that the claims fail on the merits regardless. We assume, without deciding, that Dominion did not waive its constitutional

arguments by failing to raise them during the administrative appeal. Both claims fail on the merits.[68]

The Fifth Amendment provides that "[n]o person shall . . . be deprived of . . . property, without due process of law."[69] In evaluating property-based procedural due process claims like Dominion's, we first determine whether the plaintiff "has been deprived of a protected interest in property."[70] If so, we balance (1) "the private interest that will be affected;" (2) "the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards;" and (3) "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail."[71]

1

The nature of Dominion's first claim is unclear. In its complaint, Dominion alleged that despite "properly raised concerns over the use of stratification," the ALJ ruled that "the sampling methodology was sufficient." Dominion then alleged that the "calculation does not have a constitutionally valid level of certainty." In its summary judgment briefing to the district court, Dominion argued that "there are medical judgments that must be made on an individual patient basis, and therefore the extrapolation should be dismissed" and indicated that it was challenging "the appropriateness of statistical sampling in medical necessity cases."

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[68] *See Doctor's Hosp. of Jefferson, Inc. v. Se. Med. All., Inc.*, 123 F.3d 301, 307 (5th Cir. 1997) ("A district court's grant of summary judgment may be affirmed on grounds supported by the record other than those relied on by the court.").

[69] U.S. CONST. amend. V.

[70] *Edionwe v. Bailey*, 860 F.3d 287, 292 (5th Cir. 2017).

[71] *Bowlby v. City of Aberdeen*, 681 F.3d 215, 221 (5th Cir. 2012) (quoting *Meza v. Livingston*, 607 F.3d 392, 402 (5th Cir. 2010)).

To the extent that Dominion raises a constitutional objection to the ZPIC's sampling and extrapolation methodology in this case, it has provided neither facts nor argument, even in the district court, as to why this method is constitutionally infirm. This bare allegation of a due process violation does not provide this court with any basis to grant relief.[72]

To the extent that Dominion raises a broader claim that extrapolation is inappropriate where medical necessity is at issue, that claim also fails. As numerous courts have held, extrapolating from a randomly selected sample of paid claims presents a "fairly low risk of error" in calculating the ultimate overpayment amount.[73] Other courts have concluded that "statistical sampling is the only feasible method available" for HHS to effectively audit waste and fraud in the Medicare and Medicaid programs.[74] Dominion's proposed alternative—that HHS individually audit over twelve thousand claims—would likely make it impossible for HHS to audit the program in a meaningful way, especially when applied to all Medicare providers nationwide.

Dominion cited several class action cases to the district court in support of its position. These cases all emphasize that "a defendant in a class action has a due process right to raise individual challenges and defenses to claims."[75] But those decisions are inapposite here; Dominion was afforded four layers of administrative review to raise specific defenses regarding the medical

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[72] *See N.W. Enters., Inc. v. City of Hous.*, 352 F.3d 162, 183 n.24 (5th Cir. 2003) (holding that failure to adequately brief an issue constitutes its waiver); *cf. Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2007) (holding that a "'naked assertion[]' devoid of 'further factual enhancement'" does not adequately state a claim on which relief can be granted (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007))).

[73] *Chaves Cty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 922 (D.C. Cir. 1991); *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 90 (2d Cir. 1991).

[74] *Ill. Physicians Union v. Miller*, 675 F.2d 151, 157 (7th Cir. 1982); *see Ratanasen v. State of Cal., Dep't of Health Servs.*, 11 F.3d 1467, 1471 (9th Cir. 1993); *Chaves*, 931 F.2d at 922; *Yorktown*, 948 F.2d at 90.

[75] *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013).

necessity of the claims included in the sample. Dominion provides no argument in support of its attempt to import class action certification doctrine into an administrative adjudication. Dominion's first constitutional claim fails on the merits.

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Dominion argues that the use of extrapolation, as opposed to a case-by-case determination, deprived it of the right to identify and collect payment from patients whose claims were disallowed, in violation of the Fifth Amendment. The use of extrapolation deprives Dominion of a protected property interest in collecting from the unnamed beneficiaries whose claims were disallowed. The Supreme Court has held that the Fifth Amendment Due Process Clause protects even disputed interests in property.[76] Dominion presumably has a remedy under state law to collect payment from these beneficiaries.[77] Indeed, the Secretary argues that Dominion has not been deprived of a property right because "it remains free to seek reimbursement from patients." Its interest in those payments is therefore a protected property interest under the Due Process Clause.[78]

The Secretary argues that the agency has not interfered with Dominion's ability to collect payment from the Medicare beneficiaries who used its ambulance services. In response, Dominion argues it cannot pursue payment from those beneficiaries because the agency has failed, with the exception of those in the sample, to identify whose claims were disallowed. Dominion then

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[76] *Fuentes v. Shevin*, 407 U.S. 67, 86-87 (1972) (holding that disputed possessory interest in personal property is a protected property interest).

[77] *See Purselley v. Lockheed Martin Corp.*, 322 F. App'x 399, 403 (5th Cir. 2009) (per curiam) (unpublished) (describing the intersection of contract law, unjust enrichment, and quantum meruit under Texas law).

[78] *See Bryan v. City of Madison*, 213 F.3d 267, 274-75 (5th Cir. 2000) (showing of "constitutionally protected property right" "must be made by reference to state law").

argues it lacks any meaningful way to exercise its right to collect and has been deprived of a protected interest in repayment from the beneficiaries who were not included in the sample. We need not decide whether Dominion is prevented from recouping any meaningful portion of the disallowed payments from the individuals themselves. Certainly, though, pursuing such collections would be fraught with problems.

Nonetheless, weighing the private and public interest factors, extrapolation withstands scrutiny under the Due Process Clause. On the one hand, Dominion's interest affected here is substantial. It argues that it has no way to collect approximately $1.3 million in service charges from its patients. Second, although the risk of deprivation is considerable, Dominion has not articulated feasible alternative procedures, barring case-by-case review, that the Secretary could implement to avoid the deprivation. However, Dominion is in a position to determine, in many if not most cases, whether the patient it is transporting meets the Medicare criteria. Finally, the government's interest in functional audits to protect Medicare funds is compelling. The ultimate question here is whether the cost of erroneously paid-out Medicare funds should be borne by Medicare service providers or the taxpayers. Because Dominion was never entitled to such funds in the first place[79] and "statistical sampling is the only feasible method available" for HHS to effectively audit waste and fraud,[80] the due process balance weighs heavily in favor of protecting the public even if Dominion may bear the costs.

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For these reasons, we AFFIRM the judgment of the district court.

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[79] *Cf. Chaves*, 931 F.2d at 922-23 ("HHS emphasizes that providers have no legitimate expectation of retaining payments for services they knew or should have known were not covered . . . .").

[80] *Ill. Physicians Union v. Miller*, 675 F.2d 151, 157 (7th Cir. 1982).