NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 13-1568

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JOHN BALKO & ASSOCIATES, INC.,
doing business as
SENIOR HEALTHCARE ASSOCIATES,

Appellant

v.

SECRETARY U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

_____

On Appeal from the United States District Court
for the Western District of Pennsylvania
(D.C. Civ. No. 2-12-cv-00572)
Honorable Arthur J. Schwab, District Judge

_____

Submitted under Third Circuit LAR 34.1(a)
December 20, 2013

BEFORE: JORDAN, VANASKIE, and GREENBERG, Circuit Judges

(Filed: February 12, 2014)

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OPINION OF THE COURT

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GREENBERG, Circuit Judge.

I. INTRODUCTION

This matter comes on before this Court on an appeal by John Balko and Associates, Inc. ("Balko") from the District Court's order for summary judgment entered on December 28, 2012, in favor of the Secretary of the Department of Health and Human Services (the "Secretary"). Balko is a Medicare provider offering services to elderly patients in nursing homes. SafeGuard Services ("SafeGuard"), a central entity in this case, is a Medicare contractor undertaking auditing services for Medicare on behalf of the Secretary. SafeGuard, after initially finding that Balko had been reimbursed for claims that Medicare did not cover, audited Balko's claims and confirmed that Medicare had paid many of Balko's claims that were ineligible for Medicare payment. In reaching its conclusion SafeGuard used extrapolation—a statistical method which notes patterns in a small sample of data and infers the existence of similar patterns in larger amounts of data—to calculate the amount of overpayment that Balko owed.

Following several levels of review, the Secretary determined that Balko was liable for $641,437 in Medicare overpayments. Balko unsuccessfully appealed from this decision to the District Court and it now appeals from the District Court's order upholding the Secretary's decision. Balko argues that SafeGuard failed to satisfy 42 U.S.C. § 1395ddd(f)(3), which requires an administrative finding that a provider had a sustained or high level of payment error or a determination that documented educational intervention had failed to lead the provider to correct the payment error, before an auditor can use extrapolation to calculate the overpayment that a provider owes to Medicare.

Balko also argues that there was not substantial evidence supporting the Secretary's decision.

We are unpersuaded by Balko's arguments and will affirm the District Court's order upholding the Secretary's decision. We lack jurisdiction under the plain language of 42 U.S.C. § 1395ddd(f)(3) to review the determination that a provider had a sustained or high rate of payment error before an auditor is justified in using extrapolation. We also conclude that there is substantial evidence supporting the Secretary's decision.

II. BACKGROUND

Medicare provides health care benefits to patients who, for the most part, are over 65 years of age. In order to expedite claims processing, Medicare reimburses providers for services before reviewing the medical records associated with the claims and verifying that the claims are valid. Medicare contractors, such as SafeGuard, then review and audit providers to ensure that payments are made properly. See 42 U.S.C. 1395$\underline{1}$(e).

This case centers on a post-payment audit of Balko, a Medicare provider offering certain services to nursing home residents, in particular services pertaining to podiatry, audiology, and optometry.[1] In early 2008, SafeGuard observed that Balko was both the highest-paid provider rendering services to residents at nursing homes in Pennsylvania, and appeared to be providing certain services on a scheduled, periodic basis not eligible for Medicare payment. Consequently, SafeGuard made a further investigation of Balko's

[1] Balko submitted its claims to Highmark Medicare Services, a Medicare fiscal intermediary, but Highmark is not directly involved in this case.

claims, during which its representatives visited Balko's offices and various nursing homes at which Balko serviced residents. Based on its investigation, SafeGuard concluded that Balko was providing services that were not eligible for Medicare payment and, consequently, that Balko must repay Medicare to the extent it had been reimbursed for these ineligible claims.

During the auditing process, SafeGuard followed the procedures laid out in the Medicare Program Integrity Manual ("MPIM"), and used statistical sampling. First, SafeGuard identified a "universe" of 5,445 Medicare beneficiaries associated with particular claims which it then narrowed to a random sample of 81 beneficiaries, encompassing a total of 581 claims. SafeGuard then conducted a detailed review of the medical documentation associated with these claims, and found that 99.85% of these claims had been paid improperly. The Department of Health and Human Services ("HHS"), which oversees the Medicare program and the auditing process, understandably considered 99.85% to be a high error rate and directed SafeGuard to extrapolate an estimate of the amount Balko had been overpaid. After adjusting for potential statistical error, SafeGuard calculated that Medicare had overpaid Balko $857,109.07.

The auditing process includes several levels of administrative appeal, and Balko availed itself of all of them. Balko first requested that Safeguard reconsider its determination, a request that met with partial success as SafeGuard reduced the amount of the overpayment for which Balko was responsible. Then Balko appealed this determination to a Medicare Qualified Independent Contractor. Balko presented evidence that many of the payments contained in SafeGuard's sample had been paid

properly. Following these appeals, the overpayment rate was reduced to 77% and the demand for repayment was reduced to $641,437.

Balko appealed from the determination that it was liable for the reduced amount to an administrative law judge ("ALJ"). Among other contentions, Balko argued that SafeGuard improperly had used statistical extrapolation to calculate its overpayment. Under 42 U.S.C. § 1395ddd(f)(3), Medicare contractors may use extrapolation to determine an overpayment amount in only two circumstances: if (1) there is a finding of "a sustained or high level of payment error," or (2) there is evidence that the provider was informed of the payment error but failed to correct it. Balko regarded SafeGuard's use of extrapolation as inappropriate because SafeGuard failed to find a high error rate "prior to conducting the audit"—essentially, Balko claimed that SafeGuard violated the statute by using the same sample to determine a high error rate and then to extrapolate an overpayment amount. Balko also appealed from the overpayment determinations on specific claims.

The ALJ in an October 20, 2011 decision invalidated SafeGuard's use of statistical sampling and extrapolation, but sustained the overpayment findings on specific claims. The ALJ reasoned that there was no documentation to support a finding either that Balko had a high level of payment error or had been educated regarding any alleged payment errors prior to SafeGuard's extrapolation of an overpayment amount. Accordingly, the ALJ ruled that Balko only should be liable for the specific overpayments identified in SafeGuard's sample without extrapolation.

The Medicare Appeals Council ("MAC") reviewed the ALJ's ruling on its own motion.[2] MAC reversed the ALJ's holding that SafeGuard's statistical sampling and extrapolation were invalid. First, MAC vacated the ALJ's ruling because it found that, under 42 U.S.C. § 1395ddd(f)(3), the ALJ lacked jurisdiction to consider SafeGuard's determination that there had been a high level of payment error. Second, MAC found that the original 99.85% error rate was sufficient to permit extrapolation of overpayments, and explained that the Medicare statute did not require its contractors to determine that there was a high error rate before undertaking audits, which can include statistical sampling. In light of these rulings, MAC sustained SafeGuard's calculations and assessed a $641,437 overpayment against Balko.

Balko appealed MAC's determination to the District Court, which granted summary judgment in favor of the Secretary on December 28, 2012, upholding MAC's determination. The Court concluded that under 42 U.S.C. § 1395ddd(f)(3) it lacked jurisdiction to review the determination that there had been a high rate of error. The Court also held that there was substantial evidence supporting the Secretary's final decision. Balko then timely appealed to this Court.

III. STATEMENT OF JURISDICTION AND STANDARD OF REVIEW

[2] 42 C.F.R. § 405.1110(a) authorizes MAC to review an ALJ's decision on its own motion, and 42 C.F.R. § 405.1110(b) provides that the "[Centers for Medicare and Medicaid Services] or any of its contractors may refer a case to the MAC [to] review the case on its own motion." MAC earlier had vacated a prior decision in this case and had remanded the case to the ALJ for further proceedings. The ALJ incorporated his vacated original decision in his October 20, 2011 opinion.

The District Court had jurisdiction under 42 U.S.C. § 1395ff(b)(1)(A) and 42 U.S.C. § 405(g), and we have jurisdiction under 28 U.S.C. § 1291. We review the District Court's grant of summary judgment de novo, applying the same standards that the District Court used in granting summary judgment. Thus, we may set aside the Secretary's decision "only if it is 'unsupported by substantial evidence,' is 'arbitrary, capricious, an abuse of discretion, or [is] otherwise not in accordance with law.'" Mercy Home Health v. Leavitt, 436 F.3d 370, 377 (3d Cir. 2006) (alteration in original) (quoting 5 U.S.C. § 706(2)(A), (E)). Substantial evidence requires "more than a mere scintilla," and "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Albert Einstein Med. Ctr. v. Sebelius, 566 F.3d 368, 372 (3d Cir. 2009) (citation and quotation marks omitted). If a party contends that we do not have jurisdiction, we apply a de novo standard of review in considering that contention. See In re Caterbone, 640 F.3d 108, 111 (3d Cir. 2011).

IV. DISCUSSION

Balko advances two principal arguments on appeal. It reads Section 1395ddd(f)(3) to require a two-step process for using extrapolation to calculate overpayment amounts: the Medicare contractor first must find a high error rate, and, if it does, then it can move on to use extrapolation in making its determination. In Balko's view, SafeGuard violated this provision by using the same 81-patient sample for the dual purposes of calculating a high error rate and extrapolating the amount of the overpayment. Balko next contends that there is not substantial evidence to support

MAC's decision, and it challenges MAC's credibility findings. The Secretary reads Section 1395ddd(f)(3) differently. She argues that the provision precludes any review of high-error-rate determinations, and further that SafeGuard's use of a single sample for calculating both high error rate and extrapolation was entirely appropriate. The Secretary also argues that there is substantial evidence supporting her decision.

We will affirm the December 28, 2012 order that, by granting the Secretary's motion for summary judgment, upheld MAC's decision. We are satisfied that the plain language of Section 1395ddd(f)(3) precludes judicial review of the Secretary's high-error- rate determination and, accordingly, that, as was true for the adjudicators in the administrative proceedings we have described, we lack jurisdiction to review the substance of Balko's claims. Finally, we find that there is substantial evidence in the record to support MAC's decision.

A. Extrapolation Under 42 U.S.C. § 1395ddd(f)(3)

In 1996, Congress created the Medicare Integrity Program to strengthen the Secretary's ability to deter fraud and abuse. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, §§ 201-02, 110 Stat. 1936, 1992-98 (codified at 42 U.S.C. §§ 1395i(k)(4), 1395ddd). Under this program, Medicare providers must maintain records to support their claims, and Medicare contractors are authorized to audit providers in order to determine what payment is appropriate. 42 U.S.C. § 1395l(e). Providers bear the burden of maintaining and producing information to support their payment claims. 42 U.S.C. § 1395l; 42 C.F.R. § 424.5(a)(6).

In 2003, Congress amended the statutory provisions governing overpayment recovery in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act"), Pub. L. No. 108-173, §§ 911, 935, 117 Stat. 2066, 2378-86, 2407-11 (codified at 42 U.S.C. §§ 1395kk-1, 1395ddd). As relevant to this appeal, the Medicare Modernization Act placed restrictions on the circumstances in which contractors could use extrapolation to calculate the amount a provider had been overpaid:

> (3) Limitation on use of extrapolation
>
> > A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—
> >
> > (A) there is a sustained or high level of payment error; or
> >
> > (B) documented education intervention has failed to correct the payment error.
> >
> > There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

42 U.S.C. §1395ddd(f)(3) (emphasis added).[3] We agree with the Secretary that this provision precludes review of the high-error-rate determination.

[3] Although the statute states that "the Secretary" must find that there is a "sustained or high rate of payment error," the Secretary properly may delegate this authority to Medicare contractors. See 42 U.S.C. § 1395kk(a) (permitting Secretary to perform "any of his functions" directly or through contract); Gentiva Healthcare Corp. v. Sebelius, 723 F.3d 292, 295-97 (D.C. Cir. 2013) (approving Secretary's interpretation that it may delegate determinations of high payment error to contractors).

As we have indicated, we exercise de novo review over challenges to our jurisdiction to adjudicate a particular matter. See Caterbone, 640 F.3d at 111. Here, we conclude—as did MAC and the District Court—that Section 1395ddd(f)(3) unambiguously bars review the of the "high level of payment error" that enabled SafeGuard to use extrapolation to calculate overpayment amounts. The statute clearly states that "[t]here shall be no administrative or judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors." 42 U.S.C. § 1395ddd(f)(3). We agree with a determination of the Court of Appeals for the District of Columbia Circuit that this provision precludes a court of appeals' review of the Secretary's determination that there has been a high level of payment error. Gentiva Healthcare Corp. v. Sebelius, 723 F.3d 292, 297 (D.C. Cir. 2013) ("We read the statute's directive, that '[t]here shall be no administrative or judicial review . . . ,' as clearly precluding our review.").

Balko's attempts to escape the operation of this jurisdictional bar are unavailing. First, Balko refers to legislative history but those references are irrelevant given that the statutory language is unambiguous. See In re Phila. Newspapers, 599 F.3d 298, 304 (3d Cir. 2010) ("Where the statutory language is unambiguous, the court should not consider statutory purpose or legislative history.").[4] Second, Balko argues that a determination that there had been a high level of payment error in this case is reviewable because Balko

[4] Further undermining Balko's argument is the circumstance that the "legislative history" to which it cites is a statement from a witness who was not a member of Congress. Such statements are not entitled to any weight in statutory interpretation. See Circuit City Stores, Inc. v. Adams, 532 U.S. 105, 120, 121 S.Ct. 1302, 1311 (2001).

challenges the procedures used in arriving at the determination rather than the merits of the determination itself. But we reject that argument because the statute precludes judicial and administrative review without the qualification that Balko advances.

B. Substantial Evidence Supports MAC's Decision

Although Balko challenges MAC's reading of the record on two grounds with respect to the sufficiency of the evidence, neither is persuasive. First, Balko claims that MAC unjustifiably "overturned" the ALJ's credibility determinations. Balko misunderstands the review process in these proceedings. Although MAC is limited to considering only the record before it, its review of the ALJ's findings is de novo and MAC "is not obligated to defer to the outcomes of prior decisions below." Almy v. Sebelius, 679 F.3d 297, 310 (4th Cir. 2012), cert. denied, 133 S.Ct. 841 (2013); see also 42 U.S.C. § 1395ff(d)(2)(B) ("In reviewing a decision . . ., [MAC] shall review the case de novo."); 42 C.F.R. § 405.1110(d) (explaining that the MAC "may adopt, modify or reverse the [ALJ's] decision, [or] may remand the case to an ALJ for further proceedings").[5] Therefore even if the ALJ had made credibility findings, MAC justifiably could have reached a different conclusion under its mandate to apply de novo

[5] It is difficult to understand how MAC could have overturned the ALJ's credibility findings because, contrary to what Balko believes, the ALJ did not base his result on credibility findings. Though we recognize that two experts who testified were at odds at the hearing before the ALJ regarding the validity of the statistical sampling and extrapolation methodology, the ALJ based his decision on an evaluation of the record as a whole, and not on either witness's credibility. Although Balko indicates in its brief that "the ALJ's decision was based both on legal principles and on credibility determinations," appellant's br. at 5, arguably it later almost concedes the point that this is not a witness credibility case, for it indicates that the ALJ "had to have implicitly believed Dr. Cox instead of Ms. Bendinsky," id. at 41, but does so without identifying specific credibility findings.

review. Indeed, inasmuch as we are concerned on this appeal, as was the District Court, with a review of MAC's decision, we do not review the ALJ's findings, and Balko's arguments addressing those findings are irrelevant. See International Rehab. Scis. Inc. v. Sebelius, 688 F.3d 994, 1001-02 (9th Cir. 2012) (confining appellate review to whether "the agency decision on direct review" is supported by substantial evidence, not to compare that "decision with other agency decisions not on review").

Second, Balko contends that the MAC ruling was flawed because it did not identify or cite to specific record evidence to support its conclusion that the sampling and extrapolation were valid. Contrary to Balko's assertion, however, MAC's decision is well-reasoned and well-supported by citations to the administrative record, which MAC reviewed in its entirety. Thus, MAC explained that it "reviewed the record that was before the ALJ, including [Balko's] submissions." JA-ADD-77. Further, because SafeGuard complied with applicable Medicare rulings and the MPIM, Balko bore a heavy burden of showing that the sample was statistically invalid, and not merely that "another statistician might construct a different or more precise sample." Id. at 93. MAC concluded that Balko had failed to carry this burden, and Balko does not identify any portion of the record which even hints that this conclusion was erroneous. MAC's decision accordingly was supported by substantial evidence.

V. CONCLUSION

We conclude that 42 U.S.C. § 1395ddd(f)(3) precludes any judicial review of the Secretary's determination that Balko had a high rate of payment error, and the remainder

of the MAC's opinion is supported by substantial evidence in the record. For these reasons, we will affirm the District Court order of December 28, 2012.