IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

NEPHROPATHOLOGY ASSOCIATES, PLC PLAINTIFF

v. NO. 4:12CV00233 JLH

KATHLEEN SEBELIUS, in her official capacity as Secretary of the DEPARTMENT OF HEALTH AND HUMAN SERVICES DEFENDANT

OPINION AND ORDER

Nephropathology Associates, PLC, has appealed the final decision of the Secretary of the Department of Health and Human Services denying payment for renal pathology services. For the following reasons, the Court affirms the Secretary's decision.

I.

Nephropath is an independent pathology laboratory that provides renal pathology services to physicians. The physicians obtain biopsies from patients' kidneys and ship the biopsies to Nephropath for processing and diagnosis. Pinnacle Business Solutions, Inc., a contractor for the Centers for Medicare & Medicaid Services, denied Medicare payment for certain services performed on kidney biopsies by Nephropath from January 3, 2009, through March 31, 2009. The denial of Medicare coverage specifically was for special stains services (when a biopsy tissue is sectioned, the sections are stained, sometimes with special stains in addition to the standard types of stains used) and for electron microscopy services. *See* Record at 4.[1] Nephropath requested a redetermination, and Pinnacle provided an independent review that granted Medicare payment for some but not all of the initial services denied. Nephropath appealed that decision, and qualified independent contractors

[1] The Administrative Record was submitted to the Court in paper form and will be cited in this opinion as "Record."

provided four reconsideration decisions that upheld the denial of Medicare payment for most of the services at issue. The qualified independent contractors' decisions denying payment were based on Nephropath's failure to follow the billing protocol in a coding manual that was not promulgated until after Nephropath had rendered and billed for the services at issue. Nephropath appealed these decisions to the Office of Medicare Hearings and Appeals. An administrative law judge consolidated the four appeals, held a hearing, and decided the appeals. At the hearing, Dr. Patrick Walker, Director of Nephropath, testified that the services were reasonable and necessary. Record at 5850-92.

The ALJ upheld the denials of Medicare coverage for a reason different from the previous determinations. The ALJ agreed with Nephropath that payment could not be denied based on a retroactive application of the coding manual. He found, however, that Nephropath had not met its burden to show that the services were reasonable and necessary. He explained that "to be considered medically necessary clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. 410.32(a)." *Id.* at 340. He further stated, "Medicare rules specifically state that failure to provide independent verification that the test was ordered by the treating physician . . . through documentation in the physician's office may result in denial [of Medicare coverage]." *Id.* The ALJ pointed out that when the order is communicated by telephone, "both the treating physician/practitioner and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records." *Id.* Nephropath had submitted a report generated by Nephropath after the services had been rendered, stating the results of the biopsies, why the services were done, and the date and time a call was placed to or received from "the physician's office." *Id.* at 340; *see id.* at 1331-32, 1782-83, 5205-06, 5423-24.

Nephropath had not, however, submitted "independent verification that the test was ordered by the treating physician." *Id.* at 340. Therefore, the ALJ denied Medicare payment.

Nephropath appealed the ALJ's decision to the Medicare Appeals Council. Before the Medicare Appeals Council made a decision, it sent a letter to Nephropath that gave Nephropath thirty days to submit additional information. The letter explained that if Nephropath did not submit additional information, the Medicare Appeals Council would make a decision "based on the present record." *Id.* at 23. Nephropath submitted a "Summary of Appellant's Position" that was "intended to be a submission of additional information as permitted by the letter." *Id.* at 24. Nephropath did not, however, provide additional evidence. The Medicare Appeals Council upheld the ALJ's decision, concluding that Nephropath's "evidence has not satisfied the Medicare documentation requirements" because Nephropath was required to but did not submit documentation it received from the ordering physician and therefore did not have an "independent demonstration of the underlying bases for the tests." *Id.* at 11-12. The Medicare Appeals Council's decision constitutes the Secretary's final decision.

II.

A. The Medicare Appeals Council's Decision

Medicare, enacted as part of the Social Security Act of 1965, is a federally run health-insurance program for persons aged sixty-five years and older, the disabled, and persons suffering from end stage renal disease. *See* 42 U.S.C. § 1395 *et seq.* The Health and Human Services Secretary prescribes regulations "as may be necessary to carry out the administration" of Medicare. 42 U.S.C. § 1395hh(a)(1). Medicare contains four parts: Part A, which covers hospital insurance benefits, *see* 42 U.S.C. §§ 1395c–1395i-4; Part B, which covers supplemental medical insurance

benefits for some services and products not covered in Part A, *see* 42 U.S.C. §§ 1395j–1395w-4; Part C, which covers Medicare Advantage plans, *see* 42 U.S.C. §§ 1395w-21–1395w-28; and Part D, which covers prescription drug benefits, *see* 42 U.S.C. § 1395hh. Medicare Part B, the part at issue in this action, includes coverage for services such as doctor's visits, diagnostic tests, and certain medical supplies. *See* 42 U.S.C. §§ 1395k(a), 1395x(s).

An individual may seek judicial review of the Secretary's final decision in a Medicare appeal, which here is the Medicare Appeals Council's decision. 42 U.S.C. §§ 405(g), 1395ff(b). The review, however, is deferential: "The findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive . . ." 42 U.S.C. § 405(g); *see* 42 U.S.C. § 1395ff(b). A reviewing court will set aside "agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2); *see Almy v. Sebelius*, 679 F.3d 297, 302 (4th Cir. 2012) (explaining that this is a highly deferential standard). Moreover, an agency's interpretation of its own regulation is entitled to substantial deference. *See Regions Hosp. v. Shalala*, 522 U.S. 448, 457, 118 S. Ct. 909, 915, 139 L. Ed. 2d 895 (1998); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 2387, 129 L. Ed. 2d 405 (1994) (explaining that "[t]his broad deference is all the more warranted" in the Medicare context, as it is "a complex and highly technical regulatory program[]" in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns" (internal quotation marks omitted)); *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-45, 104 S. Ct. 2778, 2781-83, 81 L. Ed. 2d 694 (1984); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414, 65 S. Ct. 1215, 1217, 89 L. Ed. 1700 (1945) (requiring courts to give an agency's interpretation of its own regulation "controlling weight unless it is plainly erroneous

or inconsistent with the regulation"); *Almy*, 679 F.3d at 302-03 (granting this broad deference to the Secretary to determine what is "reasonable and necessary" in the Medicare context).

In general, no payment may be made under Medicare Part B unless the services provided were reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A). Nephropath argues that the Medicare Appeals Council erred in determining that the renal pathology services at issue were not reasonable and necessary. The burden is on the provider of services – here, Nephropath – to furnish sufficient information for the decision maker to determine whether payment should be made and how much should be made. *See* 42 U.S.C. § 1395*l*(e); 42 C.F.R. § 424.5(a)(6); *see also Garcia v. Sebelius*, No. CV 10-8820 PA (RZx), 2011 WL 5434426, at *7 (C.D. Cal. Nov. 8, 2011).

"All . . . diagnostic laboratory tests . . . must be ordered by the physician who is treating the beneficiary," and "[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a). The entity submitting a claim for Medicare payment must maintain "[t]he documentation that it receives from the ordering physician" and "[t]he documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician." *Id.* § 410.32(d)(2)(ii)(A)-(B). The Medicare Benefit Policy Manual defines an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary." Ctrs. for Medicare & Medicaid Servs., *Medicare Benefit Policy Manual* ch. 15, § 80.6.1. An order may be delivered via a signed written document that is hand-delivered, mailed, or faxed; a telephone call; or an email. *Id.* If an order is placed via telephone, "both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records." *Id.*

The Medicare Appeals Council concluded that Nephropath did not submit evidence demonstrating that a physician had ordered the services at issue. To show that the services were reasonable and necessary, Nephropath submitted pathology reports that it generated after rendering the services. *See* Record at 1331-32, 1782-83, 5205-06, 5423-24. These pathology reports identify the beneficiary and the referring physician, and they detail the specimen submitted, the laboratory's diagnosis, the beneficiary's clinical history, a description of the procedure and results, and the date and time of a call to or from a physician's office. *See id.*[2] Nephropath also submitted the testimony of its director, Dr. Patrick Walker, that the services were reasonable and necessary. *Id.* at 5850-92. Nephropath, however, did not provide any documents that it received from an ordering physician, nor did it produce documentation of telephone calls from treating physicians ordering the services in question. It did not provide documentation of what services a physician ordered or even documentation showing that the physician had ordered services. Without such documentation, Nephropath cannot demonstrate that it complied with 42 C.F.R. § 410.32(a)'s requirement that a test must be ordered by a physician for the test to be reasonable and necessary. It therefore cannot overcome 42 U.S.C. § 1395y(a)(1)(A)'s mandate that no Medicare payment may be made for services that are not reasonable and necessary.

Nephropath contends that 42 C.F.R. § 410.32(d)(3) places the burden on the Centers for Medicare & Medicaid Services to request from the entity submitting the claim documentation of the services' orders. 42 C.F.R. § 410.32(d)(3) is titled "Claims review" and provides in relevant part,

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[2] It is unclear whether the date and time of this call refers to the call in which a physician ordered the services or the call in which Nephropath notified the physician or physician's office of the pathology results, but the timing suggests it is the latter, which is what the Medicare Appeals Council concluded. *See* Record at 11, 1332, 1783, 5206, 5424.

(i) Documentation requirements. Upon request by CMS, the entity submitting the claim must provide the following information:

> (A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).
>
> (B) Documentation showing accurate processing of the order and submission of the claim.
>
> (C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

(ii) Services that are not reasonable and necessary. If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

> (A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.
>
> (B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.
>
> (C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

Nephropath interprets this regulation to mean that Nephropath does not have to submit documentation of a physician's order unless and until the Centers for Medicare & Medicaid Services requests such documentation. According to the Secretary, the burden remains on the entity submitting the claim to demonstrate that the services at issue were reasonable and necessary (and therefore to demonstrate that an order was made for the specific services at issue). *See* 42 U.S.C. § 1395*l*(e); 42 C.F.R. § 424.5(a)(6). The Secretary's interpretation is not unreasonable. Placing the burden on the Centers for Medicare & Medicaid Services to request such documentation could render

superfluous 42 C.F.R. § 424.5(a)(6)'s directive that the provider of services must furnish the information necessary to determine whether payment is due and the amount of payment.[3]

Nephropath did not provide the Medicare Appeals Council with any documents that it received from the ordering physicians, nor did it provide documentation showing that orders were made for the services, which means that Nephropath did not document the medical necessity of the tests, as the Medicare Appeals Council found. Record at 12. The Medicare Appeals Council's decision is affirmed.[4]

B. Remand Pursuant to the Sixth Sentence of 42 U.S.C. § 405(g)

Nephropath next argues that, pursuant to the sixth sentence in 42 U.S.C. § 405(g), the Court should remand the action to the Medicare Appeals Council to allow Nephropath to submit the documentation of physician orders for the services at issue. The sixth sentence of 42 U.S.C. § 405(g) states in relevant part, "The court may . . . order additional evidence to be taken before the [Secretary], but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding . . . ." Congress added the good cause and materiality requirements in sentence six "to limit the power of district courts to order remands for 'new evidence.'" *Melkonyan v. Sullivan*, 501 U.S. 89, 100, 111 S. Ct. 2157, 2164, 115 L. Ed. 2d 78 (1991). "New evidence" is "evidence not in existence or available to the claimant at the time of the administrative proceeding." *Sullivan v. Finkelstein*, 496

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[3] If this Court were reviewing the statutes and regulations de novo, it might agree with Nephropath's interpretation that the burden is on the Centers for Medicare & Medicaid Services to request documentation for an order before it can deny a claim for lack of such documentation.

[4] Nephropath also argues that the qualified independent contractors' decisions are wrong, but this Court only has authority to review the Medicare Appeals Council's decision. 42 U.S.C. § 405(g).

U.S. 617, 626, 110 S. Ct. 2658, 2664, 110 L. Ed. 2d 563 (1990).

The evidence that Nephropath wants to submit to the Medicare Appeals Council on remand is not new evidence; it is not evidence that was not in existence or available to Nephropath at the time of the previous administrative proceedings. *See* Document #17-1; Document #17-2; Document #17-3; Document #17-4. Rather, the evidence appears to be documentation that Nephropath possessed when it rendered the services at issue; it is evidence that Nephropath could have submitted during the administrative proceedings.

Even so, Nephropath contends that good cause exists to remand the action because it "was not even put on notice of the alleged defect in the documentation until the [Medicare Appeals Council] opinion" and therefore "it was never provided with an opportunity to supplement the record and present additional evidence on the newly cited theory for denial prior to the instant judicial appeal." Document #17 at 3-4. The record does not support these statements. First, the ALJ's opinion explained the defects in documentation. The ALJ cited section 1833(e) of the Social Security Act, which is codified at 42 U.S.C. § 1395*l*(e), for the proposition that "documentation that coverage criteria are satisfied must be present in the patient's medical record" and that failure to provide documentation of the tests' necessity might result in denial of claims. Record at 340. He also cited chapter 15, sections 80.1 and 80.6.1 of the Medicare Benefits Policy Manual to explain the documentation required when a physician places an order in a telephone call. *Id*. at 340 & nn.2, 6 & 7. The ALJ then explained precisely how Nephropath failed to provide sufficient documentation:

> The beneficiary's medical record submitted by the Appellant in the present appeal consists of only a two-page summary that includes a date and time *a call* was received from "the physician's office." It does not state an order was placed or what tests, if any, were in fact ordered. Medicare has determined that tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. Without

> more, the Appellant failed to satisfy this fundamental requirement for Medicare coverage. Accordingly, the undersigned can not approve payment.

Id. at 340. Thus, Nephropath was on notice of the defects in documentation prior to the Medicare Appeals Council's decision.

Second, the Medicare Appeals Council provided Nephropath with an opportunity to submit additional information before the Council ruled on Nephropath's appeal. On January 5, 2012, the Medicare Appeals Council sent a letter to Nephropath's attorney that gave Nephropath thirty days to submit "anything additional." *Id.* at 23. The letter was an invitation for Nephropath to add to the record, as it explained that if Nephropath chose not to submit additional information, then the Medicare Appeals Council would decide the appeal "based on the present record." *Id*. Nephropath sent a summary of its position to the Medicare Appeals Council, which was "intended to be a submission of additional information as permitted by the [January 5] letter." *Id.* at 24. Nephropath did not submit any new evidence. *Id.* at 24-25. Nephropath contends that it could not present new evidence because, absent good cause, 42 C.F.R. § 405.966 prohibits the presentation of additional evidence past the reconsideration level of appeal. But since the ALJ's opinion was the first to deny Medicare coverage due lack of proper documentation, Nephropath would have had good cause to submit the proper documentation had it attempted to do so, which it did not. More importantly, 42 C.F.R. § 405.1122(a)(1) expressly provides an opportunity for parties to submit additional evidence if the ALJ decides a new issue that the parties did not have an opportunity to address previously: "[I]f the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level, the [Medicare Appeals Council] considers any new evidence related to that issue that is submitted with the request for review." And, despite 42 C.F.R. § 405.966, or perhaps because of

it, the Medicare Appeals Council invited Nephropath to add to "the present record," but Nephropath declined. Nephropath's argument that it did not have an opportunity to produce its additional evidence to the Medicare Appeals Council is incorrect. Nephropath cannot show good cause for failing to incorporate the evidence into the record in a prior proceeding.

Nephropath's additional evidence is not new, and Nephropath has not shown good cause for failing to place the evidence in the record before the Medicare Appeals Council made its decision. Therefore, the Court cannot remand the action pursuant to the sixth sentence of 42 U.S.C. § 405(g).

CONCLUSION

The Medicare Appeals Council held that Nephropath's "claims for Medicare coverage of the laboratory pathology services at issue were not adequately documented and thus cannot be covered by Medicare as they were not medically reasonable and necessary." Record at 13. That decision is supported by substantial evidence and is a reasonable interpretation of the applicable regulations. The Court has no authority to remand the action to the Medicare Appeals Council to give Nephropath an opportunity to provide additional evidence because Nephropath has not shown that the additional evidence is new or that it has good cause for failing to produce the evidence during the administrative proceedings. The decision of the Medicare Appeals Council is affirmed.

IT IS SO ORDERED this 27th day of June, 2013.

J. Leon Holmes

J. LEON HOLMES
UNITED STATES DISTRICT JUDGE