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

DOCTORS TESTING CENTER, LLC II **PLAINTIFF**

v. **Case No. 4:11-cv-00857 KGB**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;
KATHLEEN SEBELIUS, Secretary **DEFENDANTS**

OPINION AND ORDER

Plaintiff Doctors Testing Center, LLC II ("DTC II") brings this action to appeal the final decision of the Secretary of the Department of Health and Human Services (Dkt. No. 1). DTC II filed a motion for summary judgment (Dkt. No. 53), to which defendants filed a cross-motion for summary judgment in response (Dkt. No. 54). DTC II and defendants filed replies (Dkt. Nos. 56, 57). For the following reasons, the Court affirms the Secretary's final decision. DTC II's motion for summary judgment is denied, and defendants' cross-motion for summary judgment is granted. DTC II's motion requesting hearing regarding the cross-motions for summary judgment is denied as moot (Dkt. No. 59).

I. Statutory And Regulatory Framework

Medicare is a federal medical insurance program for the aged and disabled that is governed by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*. In general, Medicare does not cover any services provided unless the services are "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Audiology services (*i.e.*, hearing and balance assessments) can be covered by Medicare as "other diagnostic tests." Cntrs. for Medicare & Medicaid Servs., *Medicare Benefit Policy Manual* ("MBPM"), ch. 15, § 80.3.A; *see* 42 U.S.C. § 1395x(s)(3). "Other diagnostic tests" are "reasonable and necessary" when a physician who is

treating the beneficiary orders such tests. 42 C.F.R. § 410.32(a); Cntrs. for Medicare & Medicaid Servs., MBPM, ch. 15, § 80.3.B. In other words, such tests not ordered by a treating physician are not reasonable and necessary and thus not covered by Medicare.

A treating physician is a physician "who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a)(2). An "order" is a "communication from the treating physician/practitioner requesting that a diagnostic test be performed for the beneficiary." Cntrs. for Medicare & Medicaid Servs., MBPM, ch. 15, § 80.6.1. A physician may make an order by signed written document, documented telephone call, or email. *Id.* The treating physician need not sign an order but "must clearly document, in the medical record, his or her intent that the test be performed." *Id.*

The Centers for Medicare & Medicaid Services ("CMS"), an agency within the Department of Health and Human Services ("DHHS"), administers and oversees the Medicare program. CMS contracts with private entities to carry out the daily administrative functions of Medicare reimbursement, including claims processing and reviewing whether items or services are covered, reasonable, and necessary.

The Secretary of DHHS, through promulgated regulations, has set forth a system of administrative appeals that is available to parties dissatisfied with certain determinations by CMS or its contractors, such as coverage or payment decisions. *See generally* 42 U.S.C. § 1395ff; 42 C.F.R. Ch. IV, Subch. B, Pt. 405, Subpt. I. There are five levels of appeal: (1) a redetermination of the initial claim decision (42 U.S.C. §§ 405.940-405.958); (2) a reconsideration by a Qualified Independent Contractor ("QIC") (*id.* §§ 405.960-405.978); (3) a hearing before an Administrative Law Judge ("ALJ") (*id.* §§ 405.1000-405.1054); (4) a review by the Medicare

Appeals Council (the "MAC") (*id.* §§ 405.1100-405.1140); and (5) judicial review in federal courts (42 U.S.C. §§ 405(g), 1395ff(b); 42 C.F.R. § 405.1136).

II. Factual And Procedural Background

In 2007, DTC II provided diagnostic audiological testing to multiple Medicare beneficiaries (AR 5-6).[1] In January of 2008, a prepayment auditor denied coverage on over 150 claims filed by DTC II for audiological diagnostic testing (AR 815, 1554-58). DTC II appealed through the five steps outlined above. Contractors, including a QIC, conducted a redetermination and reconsideration of the denial of DTC II's claims and found no error (AR 1325-28 (redetermination), 1291-1316 (reconsideration)). DTC II sought review by an ALJ.

On May 27, 2009, an ALJ held a hearing on the matter (AR 6315-67). On June 30, 2009, the ALJ issued a decision partially in favor of DTC II (AR 1253-81). DTC II sought review of the ALJ's decision by the MAC. On August 25, 2010, the MAC vacated and remanded the ALJ's unfavorable decision on claims of 91 beneficiaries, concluding that the ALJ failed to develop properly the record and to consider the applicable Medicare regulations and authority (AR 810-36). On remand, the ALJ issued a decision partially in favor of DTC II on May 9, 2011, finding that claims for 68 beneficiaries met Medicare coverage requirements but that other claims did not (AR 109-117).

CMS referred the ALJ's May 9, 2011, decision to the MAC for its "own motion review," citing legal errors by the ALJ (AR 61-92). The MAC, on its own motion, decided to review the ALJ's decision based on errors of law material to the outcome of the claims (AR 1-4).

On October 5, 2011, the MAC issued a final decision reversing in part the ALJ's decision (AR 4-24). Specifically, the MAC found that the ALJ erred in finding that claims for the 68

[1] The sealed Administrative Record was submitted to the Court and will be cited in this Opinion as "AR."

Medicare beneficiaries qualified for Medicare coverage (AR 24). On December 2, 2011, DTC II filed this action seeking judicial review by this Court of the MAC's decision, which is the Secretary's final decision, pursuant to 42 U.S.C. § 405(g) (Dkt. No. 1).

III. Standard Of Review

Summary judgment is proper if the evidence, when viewed in the light most favorable to the nonmoving party, shows that there is no genuine issue of material fact and that the defendant is entitled to entry of judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The initial burden is on the moving party to demonstrate the absence of a genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 323. The burden then shifts to the nonmoving party to establish that there is a genuine issue to be determined. *Prudential Ins. Co. v. Hinkel*, 121 F.3d 364, 366 (8th Cir. 1997).

The Medicare Act provides for judicial review of the Secretary's final decision in a Medicare appeal. 42 U.S.C. §§ 405(g), 1395ff(b). However, the review is deferential: "[t]he findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." *Id.* § 405(g). "Substantial evidence is less than a preponderance, but is enough that a reasonable mind would find it adequate to support the [Secretary's] conclusion." *McKinney v. Apfel*, 228 F.3d 860, 863 (8th Cir. 2000). "In determining whether existing evidence is substantial, [courts] consider evidence that detracts from the [Secretary's] decision as well as evidence that supports it." *Id.* Further, courts "may not reverse merely because substantial evidence also exists that would support a contrary outcome, or because [it] would have decided the case differently." *Davis v. Apfel*, 239 F.3d 962, 966 (8th Cir. 2001).

When there is an issue of statutory interpretation, the Court must determine whether the Secretary employed the proper legal standards. *Horras v. Leavitt*, 495 F.3d 894, 900 (8th Cir.

2007). If the language of the statute is clear, the Court must enforce its plain meaning. *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004). "If there is ambiguity in a statute that an agency has been entrusted to administer, however, the agency's interpretation is controlling when embodied in a regulation, unless the interpretation is 'arbitrary capricious, or manifestly contrary to the statute.'" *Hennepin Cnty. Med. Ctr. v. Shalala*, 81 F.3d 743, 748 (8th Cir. 1996) (quoting *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984)). Further, "an agency's interpretation of its own regulation is controlling unless plainly erroneous or inconsistent with the regulations being interpreted." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 171 (2007) (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)) (internal quotation marks omitted).

IV. Analysis

DTC II offers four main arguments. First, DTC II argues that the MAC violated its statutorily prescribed scope of review by making its own findings of fact instead of reviewing the ALJ's decision for errors of law only. Second, DTC II claims that, even if the MAC had authority to review the ALJ's decision *de novo*, the MAC erred in finding that, pursuant to DHHS regulations, "a physician's signature is required prior to rendering diagnostic testing and that failure to obtain a signature on the 'front end' results in any services rendered as not being 'reasonable and necessary'" (Dkt. No. 53, at 1-2). Third, DTC II argues that the MAC also erred when it determined that "[DTC II's] patient records were insufficient to show the participation of a physician in approving the diagnostic tests and thereafter using the results of the tests for the benefit of the patients' treatments" (*Id.*). Fourth, DTC II contends that, even if the MAC's substantive conclusions were correct, the MAC should have remanded the limited liability issue

to the ALJ and that this Court should do so now. The Court will consider each of these arguments in turn.

A. The MAC Did Not Exceed Its Authority To Review The ALJ

DTC II alleges that the MAC exceeded its authority by making its own findings of fact and reviewing the ALJ's decision *de novo*, instead of reviewing the ALJ's decision for errors of law only. In support of this argument, DTC II cites 42 C.F.R. § 405.1110(c)(2), which states in relevant part that when CMS refers a matter to the MAC but did not participate in the ALJ proceedings or appear as a party:

> [t]he MAC *will accept review* if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. *In deciding whether to accept review*, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

(emphasis added).

However, § 405.1110(c)(2) applies only to the MAC's determination of whether to review an ALJ decision, not to the MAC's standard of review once that determination has been made. In other words, the Secretary limited the scope of the MAC's own-motion review by allowing it to accept review of cases in which CMS did not participate only if the decision contains an "error of law" or a "broad policy or procedural issue that may affect the general public interest." 42 C.F.R. § 405.1110(c)(2). Such limitation on "the *scope* of the MAC's review" does not alter "the applicable *standard* of review." Medicare Program: Changes to the Medicare Claims Appeal Procedures, 74 Fed. Reg. 65,296-01, 65,328 (Dec. 9, 2009) (emphasis added). Once the MAC decides to review an ALJ decision, different regulations apply: "[w]hen the MAC reviews an ALJ decision, it undertakes a de novo review." 42 C.F.R. § 405.1100(c); *see* 42 U.S.C. § 1395ff(d)(2)(B) (when reviewing a decision of an ALJ, the MAC "shall review the case de novo"); Medicare Program: Changes to the Medicare Claims Appeal Procedures, 70

Fed. Reg. 11,420-01, 11,466 (Mar. 8, 2005); *Almy v. Sebelius*, 679 F.3d 297, 310-11 (4th Cir. 2012) (acknowledging that the Secretary may limit the MAC's scope of review consistent with the statutory requirement that the MAC apply a *de novo* standard of review).

Here, CMS referred the ALJ's May 9, 2011, decision to the MAC because CMS believed the ALJ erred as a matter of law (AR 61-92). Specifically, CMS claimed that the ALJ failed to apply correctly 42 C.F.R. § 410.32 (AR 62). The MAC agreed and decided to review the ALJ's decision because the alleged errors of law were material to the outcome of the claim (AR 4). In deciding to review, the MAC properly limited its consideration to the error of law exceptions raised. *See id.* § 405.1110(c)(2). Once the MAC decided to review the ALJ's decision, however, it was within the MAC's authority to review the ALJ's decision *de novo* and to reverse the ALJ's decision as to all issues properly before it. *Id.* § 405.1100(c); *see id.* § 405.1128(b) ("The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision."). Thus, the MAC did not exceed its authority in deciding to review the ALJ's decision based on errors of law and then in reviewing the decision *de novo*.

B. The MAC's Interpretations Of DHHS's Regulations Were Not Plainly Erroneous Or Inconsistent With The Regulations

DTC II contends that the MAC erred in finding that "a physician's signature is required prior to rendering diagnostic testing and that failure to obtain a signature on the 'front end' results in any services rendered as not being 'reasonable and necessary'" (Dkt. No. 53, at 1-2). However, in applying MBPM, ch. 15, § 80.6.1's requirement that a physician "clearly document, in the medical record, his or her intent that the test be performed," the MAC did not hold that a physician's front-end signature was required for any services rendered to be "reasonable and necessary." Instead, the MAC concluded that a doctor's "*intent*, or knowledge, that certain diagnostic tests were going to be performed" is not documented merely by the doctor's

"signature after the tests were performed," even though other evidence might do so absent a doctor's front-end signature (AR 17). Neither MBPM, ch. 15, § 80.6.1's requirement that a physician "clearly document, in the medical record, his or her intent that the test be performed," nor the MAC's conclusion that a doctor's "signature *after* the tests were performed does not document [the doctor's] *intent*, or knowledge, that certain diagnostic tests were going to be performed" is a "plainly erroneous or inconsistent" interpretation of 42 C.F.R. § 410.32(a) (AR 17). *See Long Island Care at Home, Ltd.*, 551 U.S. at 171 (holding that "an agency's interpretation of its own regulation is controlling unless plainly erroneous or inconsistent with the regulations being interpreted").

DTC II also argues that a physician's signature is not required at all "on orders for clinical diagnostic tests that are paid on the basis of the clinical laboratory fee schedule, the Medicare physician fee schedule, or for physician pathology services" (Dkt. No. 53, at 11). DTC II contends that instead its technicians—who DTC II claims were certified, qualified to perform testing, and properly supervised—could order such tests when "working directly for a physician" (*Id.*). Again, the MAC was not plainly erroneous or inconsistent in its conclusion that "Medicare will not cover tests ordered by technicians" because § 410.32(a) only "permits *the physician who is treating the beneficiar*y, that is the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem, to order tests" (AR 18). The MAC concluded that while DTC II's contractor may not require a physician's signature "on orders for clinical diagnostic tests that are paid on the basis of the clinical laboratory fee schedule, the Medicare physician fee schedule, or for physician pathology services," the physician still "must clearly document in the medical record his or her intent that the test be performed" (AR 22). Further, the MAC

explained that neither technicians' qualifications nor direct supervision by physicians change the requirement of 42 C.F.R. § 410.32(a) that only a treating physician can order diagnostic tests for the technician to perform (AR 22-23). This Court cannot say that the MAC's interpretation is plainly erroneous or inconsistent with the regulation.

C. Substantial Evidence Supports The MAC's Finding That DTC II's Tests Were Not Covered By Medicare

The MAC found that "the diagnostic testing that DTC II is seeking Medicare coverage for was conducted by technicians, without orders or requests from treating physicians, and without treating physicians who used the results in the management of a beneficiary's specific medical problem" (AR 21). Based on this, the MAC ruled that, "according to section 410.32(a), [DTC II's] tests were not reasonable and necessary, and cannot be covered by Medicare" (*Id.*).

DTC II argues that the MAC erred when it determined that "[DTC II's] patient records were insufficient to show the participation of a physician in approving the diagnostic tests and thereafter using the results of the tests for the benefit of the patients' treatments" (Dkt. No. 53, at 1-2). The Court disagrees and determines that substantial evidence supports the MAC's ruling that the diagnostic testing was not ordered by a treating physician, as there was no evidence of the doctors' intent, or knowledge, that certain tests were going to be performed (AR 17). *See* Cntrs. for Medicare & Medicaid Servs., MBPM, ch. 15, § 80.6.1.

Instead, there is substantial evidence that DTC II technicians, not physicians, ordered the diagnostic tests. DTC II asked beneficiaries to fill out a patient profile form and sign a "Company Information and Consent Form" of the "Doctors Hearing/Testing Center Companies," which listed physicians who "may be reviewing your tests or results if necessary" (AR 7; *see*, *e.g.*, AR 3982). Diagnostic technicians then performed a detailed screening of the beneficiary (AR 7, 6334-38; *see*, *e.g.*, AR 3989-98). Based on the results of this screening, the technician

decided which further tests to perform (AR 7, 6334-38). Once a test was complete, the technician would prepare and fax a form to a doctor, who would sign the form, fax it back to DTC II, and sometimes order additional testing (AR 7, 6351-52). There is no evidence of written, electronic, or telephone orders from any physician for the diagnostic tests—or any other evidence, such as physician notes or records of consultation with physicians—to show physicians intended these specific tests to be performed for each beneficiary. Instead of ordering the diagnostic test, therefore, physicians merely signed off on testing forms after the testing had been completed.

D. Remand To The ALJ Is Not Necessary

Lastly, if this Court upholds the MAC's determination that Medicare does not cover the diagnostic testing, DTC II requests that the Court remand to the ALJ for further proceedings to determine whether it is liable for the non-covered services. According to DTC II, remand is required pursuant to 42 U.S.C. § 1395pp(a) and *Meridian Laboratory Corporation v. Sebelius*, No. 3:11-cv-00406-FDW, 2012 WL 3112066 (W.D.N.C. July 31, 2012). Section 1395pp(a) provides a limitation of liability for suppliers such as DTC II when certain requirements are met. Specifically, Medicare will pay for items or services that are denied coverage for not being "reasonable and necessary" when the supplier "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services." 42 U.S.C. § 1395pp(a). In *Meridian*, the district court remanded the case to the MAC—or to the ALJ if the MAC found it proper—because the MAC failed to consider the limited liability issue. *Meridian Lab. Corp.*, 2012 WL 3112066, at *4. DTC II argues that this Court should do the same.

The Court determines that a remand to the ALJ is not necessary because the MAC properly addressed the limited liability issue and substantial evidence supports its determination

that DTC II knew or should have known that a treating physician must order diagnostic tests (AR 23-24). To begin, *Meridian* is not analogous. In *Meridian*, the MAC did not rule on the limited liability issue, and the Secretary conceded in district court that the issue should be remanded to the MAC. *Id.* The district court consented and remanded the issue to the MAC with the instruction that "if the MAC finds that question is not in its . . . jurisdiction, it should request an ALJ decision on the issue." *Id.* Here, finding the issue within its jurisdiction based on its authority to conduct a *de novo* review of the ALJ decision, *see* 42 C.F.R. § 405.1100(c), the MAC addressed and ruled on DTC II's limited liability argument (AR 23-24).

Further, substantial evidence supports the MAC's conclusion that DTC II knew or should have known that a treating physician must order diagnostic tests. A provider has actual or constructive knowledge of non-coverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [a Medicare contractor]" and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." *Id.* §§ 411.406(e)(1), (e)(3). As evidence of DTC II's knowledge, the MAC cited regulations and CMS guidelines, specifically 42 C.F.R. § 410.32(a) ("[Diagnostic] tests not ordered by the physician who is treating the beneficiary are not reasonably and necessary") and the MBPM, ch. 15, § 80.6.1 ("[T]he [treating] physician must clearly document, in the medical record, his or her intent that the test be performed.") (AR 22-23). Moreover, like the MAC (AR 21-23), this Court has considered but finds unpersuasive DTC II's contentions that other guidance justifies its claim of having no actual or constructive knowledge.

* * *

For these reasons, the Secretary's final decision that DTC II's tests were not reasonable and necessary, and cannot be covered by Medicare, is affirmed. DTC II's motion for summary judgment is denied, and defendants' cross-motion for summary judgment is granted. DTC II's motion requesting hearing regarding the cross-motions for summary judgment is denied as moot.

SO ORDERED this 10th day of January, 2014.

Kristine G. Baker
United States District Court