UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

FIRST CALL AMBULANCE SERVICE, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 3:10-0247**
	)	**Judge Sharp**
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, and KATHLEEN SEBELIUS, in her official capacity as Secretary of HHS,	)	
	)	
Defendants.	)	

MEMORANDUM

This is an administrative appeal from the final decision of the Secretary of the Department of Health and Human Services (HHS) denying certain Medicare payments for ambulance services. The parties have filed cross Motions for Summary Judgment (Docket Nos. 31 & 33) based upon the administrative record. For the following reasons, the motions will be granted in part, and denied in part.

I. FACTUAL BACKGROUND[1]

Plaintiff First Call Ambulance Service, LLC, is a Nashville, Tennessee based ambulance service provider. Defendants are HHS, and its Cabinet Secretary, Kathleen Sebelius. HHS is

[1] The following factual recitation is drawn primarily from Defendant's Statement of Facts (Docket No. 35). Plaintiff incorporated its facts in its Memorandum in support of its Motion For Summary Judgment, instead of in a separate filing as contemplated by Local Rule 56.01(b). Moreover, Plaintiff did not respond to the statement of facts submitted by Defendant, and, under Local Rule 56.01, that failure "indicate[s] that the asserted facts are not disputed for purposes of summary judgment." In any event, and based upon the record, the specific facts set forth in this Court's summary appear to be a fair characterization of the facts relevant to the issues presented by the Motions for Summary Judgment.

responsible for oversight of the Medicare Act.

The Centers for Medicare & Medicaid Services ("CMS") is a component of HHS, charged with administering Medicare. To process the high volume of claims, CMS contracts out many of Medicare's audit and payment functions to private Medicare contractors. Those contractors are called fiscal intermediaries ("FIs") or carriers.

Typically, Medicare carriers are private insurance companies. They perform a variety of functions, including making payment determinations in accordance with the Medicare Act, applicable regulations, and certain manuals, such as the Medicare Benefit Policy Manual and the Medicare Claims Processing Manual.

Ambulance service providers, such as Plaintiff, submit claims for services rendered to the appropriate Medicare carrier. That carrier, in turn, pays the provider based on an assignment of benefits by the Medicare beneficiary.

To streamline the process, claims for services (including ambulance services) under Medicare are paid based upon the claim when first presented, unless the claim contains glaring irregularities. Carriers then conduct post-payment audits to ensure that payments are made in accordance with applicable Medicare payment criteria. When a payment is erroneously made, an "overpayment" is assessed and "recouped" from subsequent payments otherwise due the supplier of the medical goods or services.

If a Medicare provider is unsatisfied with the resolution of a claim, it must present its grievance through the designated administrative appeals process and exhaust the administrative remedies available to it. See, 42 U.S.C. § 1395u(b)(3)(C); 42 U.S.C. § 395ff(b). Generally speaking, and with certain exceptions, if the service provider is dissatisfied with the initial determination, it

may seek a "redetermination" by the carrier, 42 C.F.R. § 405.940, and, if still dissatisfied, may seek a "reconsideration" from a different Medicare contractor called a Qualified Independent Contractor ("QIC"). 42 C.F.R. §§ 405.902, 405.968. If the provider is not satisfied with the reconsideration results, it may then request a hearing before an Administrative Law Judge ("ALJ"). If the provider is dissatisfied with the ALJ's decision, it may then appeal to the Medicare Appeals Council ("MAC" or "Council") and that body's decision is the final decision of the Secretary of HHS. 42 C.F.R. § 405.1130.

Turning to the facts of this case, from January 2005 to September 2006, Plaintiff submitted claims for ambulance transport services that were provided to different Medicare beneficiaries. CIGNA Government Services, the Medicare contractor, initially paid the claims in full. A Medicare Program Safeguard Contractor, AdvanceMed, then conducted a post-payment audit review of a random sample of Plaintiff's claims for reimbursement and discovered what it believed to be a "high level of payment error" in the reimbursements Plaintiff received.

Specifically, AdvanceMed reviewed a 90-claim sample involving medical records of 76 Medicare beneficiaries and 181 billed line items. Using that sample of claims, AdvanceMed found an error rate of 56.67% which yielded an overpayment of $10,763.84. AdvanceMed also projected the total amount of overpayment that Medicare made to Plaintiff and, with the error rate of 56.67%, AdvanceMed "extrapolated" an overpayment of $2,645,585.00. It then notified Plaintiff of the overpayment on March 18, 2008, and CIGNA issued a formal notice of overpayment on March 24, 2008.

Plaintiff appealed the decision, prompting CIGNA in June 2008 to issue a redetermination decision in which it upheld the entire overpayment. Plaintiff then appealed the decision to

Q2Administrators, LLC, the QIC, which issued a partially favorable reconsideration decision to Plaintiff, finding that a number of the claims should have been reimbursed, some claims should have been reimbursed at a lower amount, and upholding 34 claims that were appealed.

The QIC's decision was next appealed to an ALJ. During proceedings before the ALJ, Plaintiff abandoned many of its claim, presenting 23 claims for consideration by the ALJ. After a hearing, the ALJ found in favor of reimbursement on 12 claims, and against reimbursement on 11 claims. Those 11 claims were then presented to the Council.

Before the Council, Plaintiff did not challenge the specific medical necessity decisions made by the ALJ. Rather, it asserted that a physician's certification alone is sufficient to prove medical necessity and merit Medicare payment for nonemergency, scheduled, repetitive ambulance services. Plaintiff also argued it was denied due process, the QIC and ALJ should have recalculated the error rate, and there was no showing that good cause to reopen the claim for a reimbursement decision.

In an opinion dated January 10, 2010, the Council rejected Plaintiff's argument. So far as relevant to the present litigation, the Council found that physicians' certifications were insufficient to establish medical necessity, but rather medical necessity must be proven by the beneficiaries' conditions. On that basis, the Council reviewed the Medicare beneficiaries' medical documentation and found that "the vital signs of the non-emergency transports were essentially stable" and that "the record does not support that other means of transportation were contraindicated." (Admin. R. at 13). The Council ultimately concluded that "the ambulance services provided were not medically necessary and are not covered by Medicare." (Id.).

The Council's decision was the final decision of the Secretary. This appeal followed.

II. STANDARD OF REVIEW

"The standard of review for cross-motions for summary judgment does not differ from the standard applied when a motion is filed by only one party to the litigation." Ferro Corp. v. Cookson Group, PLC, 585 F.3d 946, 949 (6th Cir. 2009). A party may obtain summary judgment if the evidence establishes there are no genuine issues of material fact for trial and the moving party is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Covington v. Knox County School Sys., 205 F.3d 912, 914 (6th Cir. 2000). A genuine issue exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986). In ruling on a motion for summary judgment, the Court must construe the evidence in the light most favorable to the nonmoving party, drawing all justifiable inferences in his or her favor. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

III. LEGAL DISCUSSION

Plaintiff invokes this Court's jurisdiction under 42 U.S.C. § 1395ff(b) which entitles an individual or entity to judicial review of the final decision of the Secretary under 42 U.S.C. § 405(g). See, Heckler v. Ringer, 466 U.S. 602, 615 (1984) (Section 405(g) provides the "sole avenue for judicial review for 'all claims arising under' the Medicare Act"). Judicial review of the Secretary's decision is limited in significant respects.

First, it "'is limited to determining whether the Secretary's findings are supported by substantial evidence[2] and whether the Secretary employed the proper legal standards in reaching her conclusion.'" Besaw v. Sec. of Health & Human Serv's., 966 F.2d 1028, 1030 (6th Cir. 1992) (footnote added, citation omitted). Second, "'[t]he scope of review is limited to an examination of

[2] "Substantial evidence is more than a scintilla of evidence but less than a preponderance and is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Id.

the record,'" meaning that the Court does "'not review the evidence *de novo*, make credibility determinations nor weigh the evidence.'" Id. With those standards in mind, the Court turns to the arguments raised by the parties.

The cross-motions for summary judgment essentially present four issues for this Court's consideration: (1) Is Medicare responsible for paying non-emergency, scheduled, repetitive ambulance services where the need for such services is expressed in a physician's certification without more?; (2) Was Plaintiff deprived of due process?; (3) Can the Court consider whether the the QIC and the ALJ should have determined whether there was a high rate of payment error (as determined by AdvanceMed), so as to justify utilizing "extrapolation"?; and (4) can the Court determine whether there was good cause to reopen Plaintiff's requests for reimbursement?

This is not the first time that this Court has been presented with these very same issues. In MoreCare Ambulance Service, LLC v. Dept. of Health and Human Serv's, 2011 WL 839502 (M.D. Tenn. March 4, 2011) (MoreCare II), Judge Trauger was presented with an appeal of a final decision of the Secretary which denied claims for ambulance services which were undertaken by MoreCare Ambulance Service based upon a physician's certification of medical necessity.[3]

With respect to the last three issues presented for review in this case, Judge Trauger rejected the very same arguments, writing:

> The plaintiff makes a series of unavailing arguments. The plaintiff argues that he was denied "due process" because CIGNA "did not in fact make a new and independent decision on the claims at issue" but simply adopted AdvanceMed's findings. . . . Plaintiff has pointed to no recognized, protected property interest that it was deprived of nor has it provided any clear evidence that it has been denied "notice and a meaningful opportunity to be heard," which is the "core of due process." LaChance v. Erickson, 522 U.S. 262, 266, 118 S.Ct. 753, 139 L.Ed.2d 695

[3] Counsel for present Plaintiff also represented the plaintiff in MoreCare.

> (1998). Additionally, the limited purpose of this proceeding is to consider the MAC's decision, not CIGNA's conduct. The plaintiff also argues that the claims never should have been reopened by AdvanceMed in the first place. The initial determination to re-open claims, however, is not reviewable. 42 C.F.R. § 405.926(l). . . . The plaintiff also argues that there is no continuing basis for extrapolation, because the "high rate of error," initially used to justify extrapolation under the relevant regulations, no longer exists. . . . The court's view is that the proper calculation of the amount that Medicare was overbilled should await the court's determination of how many of the sample claims were actually valid. As discussed below, this stage has not yet been reached.

MoreCare II, 2011 WL 839502 at *2 n.2 (citations to record omitted).

It is true, as the Government points out, the undersigned is not bound by Judge Trauger decision. But that is not to say that the Court cannot follow that opinion if it is correct under the law. Having considered Judge Trauger's opinion in relation to the pending motions for summary judgment and the arguments by the parties in this case, the undersigned finds that Judge Trauger reached the right result and, for the reasons expressed in MoreCare, the Court reaches the same conclusion in this case with respect to the last three issues presented for review.

Turning to what is really the heart of this case (just as it was in MoreCare), at issue is whether the Secretary applied the relevant regulations in accordance with the law.

"[F]ederal courts 'do not write on a blank slate' when interpreting agency regulations." Covenant Me. Ctr, Inc. v. Sebelius, 424 Fed. Appx. 434, 436 (6th Cir. 2011) (quoting, Rosen v. Goetz, 410 F.3d 919, 927 (6th Cir.2005)). As already noted, the Secretary's decision is entitled to substantial deference, including "an agency's interpretation of its own regulations." St. Francis Health Care Ctr. v. Shalala, 205 F.3d 937, 943 (6th Cir. 2000).

"In reviewing the Secretary's interpretation of [the] regulations, courts may overturn the Secretary's decision only if it is 'arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law.'" Clairborne-Hughes Health Ct. v. Sebelius, 609 F.3d 839, 844 *6th Cir.

2010) (citations omitted). The Court's "task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 511 (1994) (citation omitted). "In sum, if 'it is a reasonable regulatory interpretation ... [a court] must defer to it.'" Id. at 944 (citation omitted).

As Judge Trauger observed, the regulations in question, 42 C.F.R. § 410.40, begin with the "basic rule" in subsection (a) that the ambulance "service meets the medical necessity . . . requirement of paragraph[] (d)." 42 C.F.R. § 410.40(a). Paragraph (d) in turn, sets forth a "general rule" and a "special rule" for the medical necessity rule requirement.

The "general rule" as set forth in subsection (d)(1) provides:

> (1) General rule. Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Nonemergency transportation by ambulance is appropriate if either: the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation. It is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, the following criteria must be met:
>
> (I) The beneficiary is unable to get up from bed without assistance.
> (ii) The beneficiary is unable to ambulate.
> (iii) The beneficiary is unable to sit in a chair or wheelchair.

42 U.S.C. § 410-40(d)(1). The "special rule" is set forth in subsection (d)(2) which provides:

> (2) Special rule for nonemergency, scheduled, repetitive ambulance services. Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending

> physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met. The physician's order must be dated no earlier than 60 days before the date the service is furnished.

42 U.S.C. § 410-40(d)(2).

This case indisputably involves nonemergency, scheduled, repetitive ambulance services for which physician certificates were provided.[4] The Secretary contends a physician's certificate is not enough to cause payment, arguing that "a doctor's note is *necessary, but not sufficient* to merit coverage for nonemergency, scheduled, repetitive ambulance services." (Docket No. 38 at 15, italics in original). Instead, she argues that such "ambulance services are reimbursable *only if*: 1. the patient's condition must demonstrate that other means of transportation would jeopardize his health; 2. the ambulance service provider must tender a note from the beneficiary's attending physician certifying that the ambulance transport is required; and 3. the expenses incurred must be reasonable and necessary for the diagnosis or treatment of illness or injury." (Id., italics in original). In the Court's opinion the Secretary's reading simply does not accord with the plain wording of the regulations.

"Regulations promulgated to effect the purpose of a statute are to be construed in accordance with the well-established principles of statutory construction[.]" In Re Arctic Exp. Inc., 636 F.3d 781, 792 (6th Cir. 2011). A court "'look[s] first to the plain and unambiguous meaning of the regulation, if any,'" and "'with an eye to [its] straightforward and commonsense meaning.'" Id. (citations omitted). If "'the regulation's language reveals an unambiguous and plain meaning,'" the Court's "'task is at an end.'" Id. If, however, the regulation is ambiguous, the Court "'look[s] to the regulatory scheme, reading the regulation in its entirety to glean its meaning.'" Id.

[4] The Court notes, however, that some of the physician certificates were undated and/or unsigned.

Here, the Court need go no further than subsection (d)(2) – the "special rule" – to determine what the regulation requires in terms of the showing of "medical necessity" for nonemergency, scheduled, repetitive ambulance services. In plain and unambiguous language, the regulation states that the ambulance service provider need only provide "a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met." It does not state, as the Secretary argues, that the doctor's note is insufficient in and of itself. Nor does it state, as the Secretary also submits, that, apart from the physician's certificate, the provider must show that the "patient's condition must demonstrate that other means of transportation would jeopardize his or her health." As Judge Trauger observed:

> Clearly, the C.F.R. establishes a "special rule" for certain kinds of repetitive services, whereby a sufficiently detailed and timely "doctor's note" demonstrates medical necessity. Therefore, where the service is "scheduled" and "repetitive" and the "doctor's note" is sufficient, additional review of the record to determine medical necessity is not called for under the regulations.

MoreCare Ambulance Service, LLC v. Dept. of Health and Human Serv's, Case No. 1:09-00078 Docket No. 24 at 6 (M.D. Tenn. Mar. 4, 2010 (MoreCare I). Thus, the Secretary plainly erred in looking beyond the physician's certificate to such things as whether the logs of the ambulance runs showed that the patient had normal vital signs. See, MoreCare II, 2011 WL 2682987 at *3 ("where the service is 'scheduled' and 'repetitive' and the doctor's note is sufficient, additional review of the record to determine medical necessity is not called for under the regulations").

Although the Court finds the regulations require that there be a physician's certificate establishing medical necessity, the Court is not in a position to determine whether there was a

timely, signed and sufficiently detailed physician's certificate for each of the claims appealed.[5] The same sorts of infirmities were presented in the summary judgment record before Judge Trauger and to address the deficiencies Judge Trauger set forth a supplemental briefing schedule as follows:

> [T]he first step in supplemental briefing will be for the plaintiff to clearly identify the portions of the record that demonstrate that a specific claim was for a "scheduled" and "repetitive" service. Once the plaintiff does that, it should, as a matter of completeness, point to where in the record a timely PCS exists that "certif[ies] that the medical necessity requirements" are met. Additionally, where evidence on the "scheduled" and "repetitive" nature of the service is lacking, the plaintiff should proceed under the general rule and, for each claim, demonstrate that the MAC erred in finding that the ambulance service was contraindicated. In short, a claim-by-claim analysis, with specific and precise citation to the record, is required for the court to have any chance at fairly determining where the MAC erred.

MoreCare I, Case No. 1:9-00078, Docket No. 23 at 8.

The undersigned is of the opinion that the same sort of briefing scheduled may be appropriate in this case. However, prior to implementing such a briefing schedule, the Court will provide the parties with an opportunity to consider this Court's interpretation of the regulations to determine whether some agreement can be reached on the sufficiency of the physician's certificate with respect to each matter appealed, and (more optimistically) to determine whether this entire matter can be resolved amicably. Accordingly, the Court will set a status conference, at which time the parties can inform the Court as to whether more briefing is necessary and, if so, what issues should be addressed and the time frame for such briefing.

IV. CONCLUSION

[5] Defendants repeatedly note that Plaintiff does not challenge the "medical necessity" determination of the ALJ and, in fact, in the Complaint before this, Court Plaintiff concedes that it "did not raise the determination of medical necessity for the individual patients" before the ALJ or the MAC. (Docket No. 1, Complaint ¶ 14). However, the Court does not understand this concession to mean that Plaintiff agrees with the ALJ's determination of the patient's condition as set forth in the record (including logs of the ambulance runs). Rather, Plaintiff's position appears to be simply that the ALJ should have considered nothing more than the sufficiency of the physician's certificate in determining medical necessity.

On the basis of the foregoing, the parties' Motions for Summary Judgment will be granted in part, and denied in part. The Court will grant Plaintiff summary judgment and deny Defendant summary judgment on Plaintiff's claim under 42 U.S.C. § 410-40(d)(2) that medical necessity for nonemergency, scheduled, repetitive ambulance services can be established based upon a sufficient physician's certificate alone. The Court will grant Defendant summary judgment and deny Plaintiff summary judgment on Plaintiff's claims that it was deprived of due process, and that good cause did not exist to reopen its claims for reimbursements. The Court will defer ruling on whether sufficient medical necessity existed for each of the claims appealed and the propriety of extrapolation. Finally, the Court will hold a status conference with the parties to discuss further briefing should the parties be unable to resolve the individual claims or settle this case.

An appropriate Order will be entered.

Kevin H. Sharp

Kevin H. Sharp
United States District Judge