UNITED STATES DISTRICT COURT DISTRICT OF CONNECTICUT

----X YALE-NEW HAVEN HOSPITAL, INC.,: et al.,

Plaintiffs, :

-against- : No. 3:99CV2546(GLG)

RULING ON MOTION TO STRIKE

TOMMY G. THOMPSON,

Secretary of Health and

Human Services,

Defendant. :

The background of this administrative appeal is described at length in the Court's Opinion of August 31, 2001, in which the Court denied the Secretary's motion to dismiss this appeal on collateral estoppel grounds. See Yale-New Haven Hospital, Inc. v. Thompson, 162 F. Supp. 2d 54 (D. Conn. 2001)(hereinafter "Yale-New Haven"). Following that ruling, the parties submitted cross-motions for summary judgment [Doc. ## 33, 40]. Plaintiff Yale-New Haven Hospital ("Yale"), on behalf of itself and 48 Medicare beneficiaries, now moves this Court to strike Defendant's Motion for Summary Judgment, Defendant's Combined Memorandum of Law in Support of Defendant's Motion and in Opposition to Plaintiff's Motion for Summary Judgment, Defendant's Local Rule 9(c)1
Statement, and the Declaration of Robert A. Streimer and the two additional declarations attached thereto. [Doc. # 46]. For the reasons set forth below, Yale's motion to strike will be granted.

Discussion

Yale argues that the three declarations at issue were not part of the administrative record and, therefore, are not properly before this Court in this appeal of a final adverse decision of the Secretary. Defendant responds that these declarations should be considered because they address new legal arguments raised by Yale for the first time on appeal. Because this Court adjudicates questions of law de novo, defendant argues that these declarations are judicially cognizable apart from the administrative record. Further, defendant states that the declarations do not address facts presented during the administrative hearings nor do they attempt to support the Secretary's findings of fact. Yale retorts that the arguments raised herein are not new and that the declarations are merely an attempt by the Secretary to bolster evidence already in the record.

We agree with Yale that the three declarations submitted by defendant, which are not part of the administrative record on appeal, must be stricken. A more problematic question, however, is whether defendant's briefs and statement of facts must also be stricken in their entirety, thus significantly delaying resolution of this administrative appeal.

This appeal of a final adverse decision of the Secretary of Health and Human Services is brought pursuant the Medicare Act,

42 U.S.C. § 1395ff(b), which provides:

Any individual dissatisfied with any determination under subsection (a) of this section . . . shall be entitled . . . to judicial review of the Secretary's final decision after such hearing <u>as is provided in section 405(g)</u> of this title.¹

42 U.S.C. § 1395ff(b)(1) (emphasis added); see Am. Comp. ¶¶ 40, 54. The cross-referenced § $405(g)^2$ provides in relevant part that a reviewing court

shall have the power to enter, <u>upon the</u> <u>pleadings and transcript of the record</u>, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the cause for a rehearing. The findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive. . .

42 U.S.C. § 405(g) (emphasis added). Thus, the scope of this Court's review is limited to the pleadings and transcripts from the administrative proceedings, including all evidence considered by the Administrative Law Judge ("ALJ"). See Mathews v. Weber, 423 U.S. 261, 270-71 (1976); Stein v. Secretary of HHS, 924 F.2d 431, 433 (2d Cir. 1991); Bodnar v. Secretary of HHS, 903 F.2d 122, 126 & n.2 (2d Cir. 1990) (holding that the court reviews the record as a whole, including the ALJ's findings, to determine if

This standard of review is distinguishable from that applicable to provider appeals brought under 42 U.S.C. § 139500(f)(1), which incorporates the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(a). See Estate of Morris v. Shalala, 207 F.3d 744, 745 (5th Cir. 2000).

² All section numbers used in this opinion are those used in the United States Code, Title 42, rather than the original section numbers of the Medicare Act.

the Secretary's decision is supported by substantial evidence);

Hurley v. Bowen, 857 F.2d 907, 912 (2d Cir. 1988); Goodrich v.

Heckler, 628 F. Supp. 187, 189 (D. Conn. 1986). The reason for this limited review is obvious. "Resolution of Medicare reimbursement issues requires an understanding of complicated and technical facts, and Congress has delegated these difficult decisions to the agency that has specialized knowledge in the area." Stein, 924 F.2d at 433.

It is undisputed in the instant case that the three declarations at issue were never submitted to the ALJ or to the Appeals Council and are not part of the administrative record before this Court for purposes of this appeal. Therefore, these declarations cannot be considered by this Court in its review of the record as a whole. Simply put, they are not part of the record.

The only evidence not presented to the ALJ or Appeals

Council below, which this Court may consider, is "material
evidence" that for "good cause" shown was not presented at the
administrative level. 42 U.S.C. § 405(g); Goodrich, 628 F. Supp.
at 190. Such additional evidence may be the basis for the
district court's remanding a case to the Secretary for
reconsideration in light of the new evidence. 42 U.S.C. §
405(g); Goodrich, 628 F. Supp. at 190. However, a remand is
appropriate only where three criteria have been met: (1) there is
new, non-cumulative evidence; (2) the evidence is material, that

is, relevant and probative so there is a reasonable possibility that it would change the administrative result; and (3) there is good cause for the failure to submit the evidence at the administrative level. <u>Jones v. Sullivan</u>, 949 F.2d 57, 60 (2d Cir. 1991); <u>Vega v. Commissioner of Social Security</u>, 265 F.3d 1214, 1218 (11th Cir. 2001).

Assuming <u>arguendo</u> that the information set forth in these declarations is new, non-cumulative, and material, the Court finds that defendant has not demonstrated good cause for its failure to submit these declarations at the administrative level.

The 2001 Streimer Declaration

The declaration of Robert A. Streimer, Deputy Director of the Office of Clinical Standards and Quality in the Centers for Medicare and Medicaid Services, formerly the Health Care Financing Administration ("HCFA"), within the Department of Health and Human Services ("HHS"), is dated December 19, 2001, long after the Secretary's final decision in these cases. Streimer states that he has been employed by HHS in the Medicare program since 1967 and that he was the person responsible for the development of the Medicare provider payment and coverage rules for the agency. Defendant does not claim that Streimer was somehow unavailable to the agency during the administrative proceedings. In fact, defendant offers no explanation for not presenting this testimony during the administrative process,

other than its claim that Yale has raised new legal issues on appeal which were not considered during the administrative proceedings.

Defendant's own papers protesting the ALJ's decision, however, belie this assertion. For example, in its protest filed July 18, 1996, defendant argued that the Manual provision was a valid interpretive rule that did not effect a change in Medicare's long-standing policy of not covering procedures or items that were experimental or investigational. 1 A.R. 163, 167 (Protest at 2, 6). This argument addressed by defendant in its 1996 protest raises many of the same issues as the Streimer declaration. The Court is not persuaded by defendant's argument that the legal issues raised by Yale are so new that defendant should not have anticipated the need to file this declaration at the administrative level. Further, this Court holds that good cause has not been shown for not presenting this declaration

³ This was in response to the ALJ's finding persuasive the holding of District Judge Davies in <u>Cedars-Sinai Medical Center v. Shalala</u>, 939 F. Supp. 1457 (C.D. Cal. 1996)(later affirmed in part and remanded in part, 125 F.3d 765 (9th Cir. 1997), and appeal after remand, 177 F.3d 1126 (9th Cir. 1999)), that the Manual provision was void <u>ab initio</u> as an impermissible attempt to engage in rule-making without complying with the requirements of the APA.

The Administrative Record ("A.R."), which contains 50 volumes, will be referenced by volume and page number. The entire Administrative Record was sealed by agreement of the parties [Doc. # 32] to protect the confidentiality of the patients' medical records. No references are made to the individual patients or their medical records in this decision, and, therefore, this decision is not being sealed.

during the administrative proceedings so as to warrant a remand to the agency for reconsideration.

Although this Court grants Yale's motion to strike the Streimer declaration, the Court would note that this does not necessarily preclude consideration of the issues addressed by Many of the "statements" by Streimer, ostensibly Streimer. based on his personal knowledge, are not statements of fact at Rather, they are legal arguments based on the legislative history of the Medicare Act, regulatory history taken from the Federal Register, and conclusions drawn from Intermediary Letters which are referenced in defendant's protest of the ALJ's decision. Although defendant may not rely on facts that are not part of the record, defendant may certainly cite to the Act's legislative history, the regulations, the Federal Register, and other matters of which this Court may take judicial notice, without the need to resort to personal affidavits and declarations.

The 1995 Hoyer Declaration

In paragraph 3 of his declaration, Streimer adopts and reaffirms the declaration of Thomas E. Hoyer, Director, Office of Chronic Care and Insurance Policy, Bureau of Policy Development, Health Care Financing Administration dated October 30, 1995, which was offered in the Cedars-Sinai, litigation and referenced by Judge Davies in his summary judgment opinion. Cedars-Sinai,

939 F. Supp. 1457. This declaration suffers from the same infirmities as the Streimer declaration.

As of 1995, Hoyer had been employed by HCFA for 23 years. No explanation is offered for defendant's failing to present his testimony during the administrative proceedings, except that, as noted above, Yale has allegedly raised new legal arguments on appeal, and the fact that Yale was a party to the <u>Cedars-Sinai</u> litigation.

The first argument has already been addressed. As to the second point, the fact that Yale was a party to other federal court litigation in which this affidavit was offered is irrelevant to this Court's review of the findings of the ALJ and Appeals Council with respect to these specific 49 cases. Indeed, to take defendant's argument to its logical extreme would allow the parties to introduce any and all evidence from the Cedars—Sinai litigation, in effect, allowing the parties to relitigate the issues that were already decided by that Court. That is not the proper role of this Court with respect to this appeal.

Had defendant determined that the 1995 Hoyer declaration was necessary to protest the ALJ's findings, which relied on Judge Davies' decision, defendant could have offered this affidavit and it would have become part of the administrative record. This it did not do. Because the Hoyer affidavit is not part of the administrative record on appeal, it will not be considered by this Court.

However, like Streimer, Hoyer attests to Congressional intent in enacting the Medicare Act, he raises legal arguments based upon the language of the Act, and he refers to notices in the Federal Register. Many of the matters addressed by his affidavit are legal arguments or matters as to which the Court may take judicial notice and do not require testimony by an agency official.

The 1998 Ruiz Declaration

The Streimer declaration, paragraph 3, also adopts the declaration of Linda A. Ruiz, Director of the Program Integrity Group within HCFA, dated May 1, 1998, which was also filed in the Cedars-Sinai litigation, presumably on remand. Her declaration addresses the manner in which fiscal intermediaries process Medicare claims. Again, this affidavit was never presented to the ALJ or the Appeals Council for their consideration during the administrative hearings and will not be considered by this Court for the first time on appeal. No good cause has been shown which would warrant a remand. Accordingly, this declaration will also be stricken.

As noted above, a more problematic aspect of Yale's motion is whether it is necessary for this Court to strike defendant's brief and statements of fact. After a careful review of the parties' submissions, the Court reluctantly concludes that rebriefing is necessary because of the extensive references to

these affidavits throughout defendant's brief and statements of fact. Thus, Defendant's Combined Memorandum of Law in Support of Defendant's Motion for Summary Judgment, and in Opposition to Plaintiffs' Motion for Summary Judgment [Doc. #41], the Declaration of Robert Streimer (including the two attached declarations) [Doc. # 43], Defendant's Local Rule 9(c)1 Statement [Doc. # 45], and Defendant's Local Rule 9(c)2 Statement and Response to Plaintiffs' Local Rule 9(c)1 Statement [Doc. # 44] are stricken. Defendant's Motion for Summary Judgment [Doc. # 40] need not be stricken.

Defendant shall have 45 days from the date of this ruling to file an amended brief in support of its motion for summary judgment and in opposition to plaintiffs' motion for summary judgment. Plaintiffs shall then have 30 days to respond.

Defendant will then have 20 days to file a reply brief to plaintiffs' opposition.

Accordingly, Yale's Motion to Strike [Doc. # 46] is GRANTED such that Documents ## 41, 43, 44, and 45 are stricken. Document # 40, however, is not stricken. The parties shall submit new briefs in accordance with the schedule set forth above.

SO ORDERED.

Date: April 12, 2002.
Waterbury, Connecticut.

____/s/____

GERARD L. GOETTEL, United States District Judge