UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, ***ex rel.*** **SHEILA EL-AMIN,** ***et al.*****,**	)	
Plaintiffs/Relators,	)	
v.	)	**Civil Action No. 95-2000 (JGP)**
THE GEORGE WASHINGTON UNIVERSITY,	)	
Defendant.	)	

MEMORANDUM OPINION

INTRODUCTION

This matter came before the Court on Defendant's **Motion for Summary Judgment** [526] and Relators' **Motion for Partial Summary Judgment on Seven Steps Liability** [530]. On October 8, 2004, the Court issued Orders [581, 582] denying both motions because genuine issues of material fact remain as to the claims set forth in the Third Amended Complaint. This memorandum opinion sets forth the reasons for those orders. Additionally, although the Court addressed Defendant's Motion to Dismiss [170] separately, *see* Mar. 25, 2005 Mem. Op., it reserved judgment on one issue raised in that motion as well as in Defendant's Motion for Summary Judgment which it addresses here.

BACKGROUND

Plaintiffs brought suit on behalf of the United States under the *qui tam* provision of the False Claims Act ("FCA"). 31 U.S.C. §§ 3729-3733. The *qui tam* plaintiffs ("relators"), four Certified Registered Nurse Anesthetists ("CRNAs") formerly employed by defendant at its

hospital, allege that from 1989 to 1995, George Washington University ("GWU") violated the FCA by: (1) knowingly presenting, or causing presentation of, false submissions to the Health Care Finance Administration for Medicare reimbursement, *see* 31 U.S.C. § 3729(a)(1); and (2) creating and using, or causing creation or use of, false statements and records in order to ensure payment of the fraudulent Medicare claims, *see* 31 U.S.C. § 3729(a)(2).[1] Third Am. Compl. ¶¶ 62-65. The claims arise from defendant's anesthesiologists' provision of anesthesia services to Medicare patients and the accompanying documentation and billing.

The Third Amended Complaint alleges that GWU knowingly or recklessly submitted claims to Medicare for reasonable charge reimbursement when, in fact, the anesthesiologists failed to satisfy a requirement for reimbursement known as the "Seven Steps" regulation. Third Am. Compl. ¶¶ 27-28, 30-35. Both defendant and relators seek summary judgment on the Seven Steps violation allegations, proffering different legal interpretations of what the regulation required in support of their positions. For purposes of these motions, the disputed issue is who may perform the Seven Steps. Relators argue that the regulation requires anesthesiologists to perform all of the Seven Steps themselves and does not permit delegation of the steps to other qualified medical professionals, such as CRNAs or medical students. *See, e.g.,* Rel.'s Mot. Part. Summ. J. at 2. Defendant argues that the regulation permits anesthesiologists to delegate performance of the Seven Steps to other qualified medical personnel. *See, e.g.,* Def.'s Mem. Summ. Mot. Summ. J. at 7-9.

The Third Amended Complaint also alleges that GWU knowingly or recklessly submitted

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[1]Plaintiff's Third Claim, Third Am. Compl. ¶¶ 66-7, was previously dismissed in United States ex rel. El-Amin v. George Washington University, 26 F. Supp. 2d 162 (D.D.C. 1998) (Flannery, J.)

claims to Medicare for reimbursement at the highest rate, that of "personal performance", when in fact the physician had not met the requirements for billing at that rate. Third Am. Compl. ¶¶ 24-26. Defendant has moved for dismissal of or summary judgment on these claims, arguing that it was required by the regulation to bill procedures known as "one-on-ones", in which a physician was involved in one procedure with assistance from one medical student or CRNA, as personally performed and thus there was no violation. *See, e.g.* Def.'s Mot. Dismiss at 8-12.

ANALYSIS

I. Summary Judgment Standard

Federal Rule of Civil Procedure 56(c) mandates that summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 247, 106 S.Ct. 2505, 2509-10 (1986). The moving party bears the initial burden of identifying evidence it believes demonstrates the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 2553 (1986). In response, "[a]n adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). Summary judgment will be granted "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which the party will bear the burden at trial." *Celotex*, 477 U.S. at 322, 106 S.Ct at 2552.

Whether a fact is material is determined by the substantive law. "Only disputes over facts

that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248, 106 S.Ct. at 2510. A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Id.* "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50, 106 S.Ct. at 2511 (internal citations omitted). In ruling on a motion for summary judgment, the Court assumes the truth of all evidence proffered by the non-moving party and draws all legitimate inferences in its favor. *Id.* at 255, 106 S.Ct. at 2513.

II. False Claims Act

Relators claim liability under the False Claims Act which states that an actor shall be liable if he:

> 1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; [or]
> 2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government

31 U.S.C. § 3729(a) (2000). The FCA defines "'knowingly' to mean that a person . . . (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required. 31 U.S.C. § 3729(b) (2000). "Reckless disregard," for purposes of the FCA, is "an extreme version of ordinary negligence," and "an extension of gross negligence." *United States v. Krizek*, 324 U.S. App. D.C. 175, 183, 111 F.3d 934, 942 (1997).

III. Regulatory Background

The regulation at issue implemented section 1887(a)(1) of the Social Security Act, codified at 42 U.S.C. 1395xx. *See* 48 Fed. Reg. 8902, 8907 (March 2, 1983). That section directed the agency, the Health Care Financing Administration ("HCFA") of the U.S. Department of Health and Human Services,[2] to promulgate a regulation establishing criteria for distinguishing services:

> which constitute professional medical services, which are personally rendered for an individual patient by a physician and which contribute to the diagnosis or treatment of an individual patient, and which may be reimbursed as physicians' services under part B [of Medicare, from those] which constitute professional services which are rendered for the general benefit to patients in a hospital or skilled nursing facility and which may be reimbursed only on a reasonable cost basis . . . .

42 U.S.C. § 1395xx (a)(1). Thus, the regulation distinguished "physicians' services to an individual patient, which are reimbursable on a reasonable charge basis under Part B" of Medicare from "physicians' services to a provider, which are reimbursable only on a reasonable cost basis." 48 Fed. Reg. at 8,907. The regulation set forth criteria for reasonable charge reimbursement of physicians designed to ensure that it was only available for services in which they furnished personal and identifiable service to patients. *See* 42 C.F.R. §§ 405.550, 405.552 (1989-95).[3]

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[2]HCFA was subsequently restructured and has been known as the Centers for Medicare and Medicaid Services since July 1, 2001. *See* http://www.cms.hhs.gov/about/reorg.asp.

[3]Reasonable cost and reasonable charge reimbursement were distinguishable in that they were part of two distinct yet complimentary Medicare programs, "the Hospital Insurance program [Part A] which generally pays for institutionally provided services . . . such as hospital care, and the Supplementary Medical Insurance program [Part B] which pays for physician, diagnostic, and ambulatory services." 48 Fed. Reg. at 8904. Reasonable cost reimbursement was, briefly stated, "the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services". 42 U.S.C. § 1395x (v)(1)(A). Reasonable charge reimbursement was not as concisely defined by statute, but reasonableness of a charge was based on, *inter alia*, "comparison with the physician's customary

While section 405.550 of the regulation set forth requirements applicable to physicians generally, section 405.552 created two requirements particular to physicians furnishing anesthesiology services.[4] The first of these was the Seven Steps regulation which required anesthesiologists to perform seven specific tasks for each individual patient. *Id.* § 405.552(a)(1) (1989-95). The second requirement was the "four concurrency limit" which established that a physician was only eligible for charge reimbursement if he was involved in four or fewer anesthesiology procedures at the same time. *Id.* § 405.552(a)(2), (b).

If an anesthesiologist failed to satisfy the general requirements or the Seven Steps or exceeded the four concurrency limit, his services were deemed "medically supervised" and thus reimbursable only on a reasonable cost basis. 42 C.F.R. §§ 405.550(b), 405.552(b). However, if the general requirements and the Seven Steps were satisfied and the four concurrency limitation not exceeded, the procedure was charge reimbursable. *See id.*

Charge reimbursement was broken down further into two levels, "direct" or "personal" "performance" and "medical direction", based on the physician's level of involvement with the procedures. The direct and personal performance categories described the highest level of

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charges for similar services, as well as with the prevailing charges in the locality for similar services". *See* 48 Fed. Reg. at 8903. As the agency noted, "most providers' charges exceed their costs". *Id.*

It should also be noted that, effective January 1, 1992 the reasonable charge payment mechanism was replaced with a fee schedule. *See* 56 Fed. Reg. 59502, 59625 (Nov. 5, 1991). Because this change does not affect the Court's analysis, in the interest of clarity it has chosen to use the "reasonable charge" language to refer to both reasonable charge and fee schedule reimbursement.

[4]The regulation applied to all physicians furnishing anesthesiology services, not only to anesthesiologists. 48 Fed. Reg. at 8926. Because the conduct giving rise to this suit is that of anesthesiologists and the issue is thus whether the anesthesiologists' conduct violated the regulation, the Court has used the terms "anesthesiologist" and "physician" interchangeably.

physician involvement.[5] Medical direction described lesser physician involvement, while still exceeding that of medical supervision.[6]

IV. Concurrency Rates and Reimbursement Levels

A. Personal or Direct Performance

The regulation stated that direct performance, applicable from 1989 to 1991, described an anesthesiologist's administration of anesthesia to a patient without assistance. 42 C.F.R. § 405.552(a)(2)(1989-91). The term "direct performance" was replaced by "personal performance" on January 1, 1992. In a final rule announcement, the agency clarified that " [its] prior policies on payment for physician . . . services recognize that the anesthesia service may be . . . [p]erformed by a teaching anesthesiologist under an 'attending physician' relationship [or] [p]erformed by an anesthesiologist with assistance provided by an anesthetist [and that under] this circumstance, the anesthesia service is deemed to have been personally performed by the anesthesiologist". 57 Fed. Reg. 33878, 33886-87 (July 1, 1992). Thus, the agency clarified that what was reimbursable in this highest category of performance included not just solo performance by the anesthesiologist, as the rule seemed to state, but also one-on-ones: a single procedure in which the physician was continuously involved with a CRNA or student. *See id.*; 42 C.F.R. § 414.46(c)(2) (1992).

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[5]From 1989 to 1991, the highest level of physician involvement was described as a procedure in which the physician "performs the procedure directly". Beginning in 1992, this became "performs the procedure personally". *See* 42 C.F.R. § 405.552(a)(2).

[6]Some variation in the Medicare rules applied to facilities like GWU which were classified as "teaching hospitals" or "group practices". Nonetheless, the regulation made clear that physicians in teaching hospitals who involved medical students in a patient's care were entitled to charge reimbursement only if they fulfilled the same responsibilities to the patient and conditions for payment. 42 C.F.R. § 405.521(1989-95).

In a similar matter, the agency ratified its existing practice of reimbursing a physician for concurrent involvement in two cases with two medical students (but not CRNAs) at the personal performance level. It made clear that this rule only applied through 1993; beginning in 1994, this practice was considered medical direction. 42 C.F.R. § 414.46(c)(2); *see also* 56 Fed. Reg. 59502, 59563 (Nov. 25, 1991).

B. Medical Direction

Medical direction, a lower level of physician involvement and reimbursement, applied to all procedures which did not qualify as directly or personally performed because the physician was involved in a greater number of concurrent procedures, but where the physician met the Seven Steps requirements and still "direct[ed] no more than four anesthesia procedures concurrently and [did] not perform any other services while he or she [was] directing the concurrent procedures." 42 C.F.R. §405.552(a)(2) (1989-95) (punctuation omitted).

V. Defendant's Personal Performance Argument

Defendant has moved for dismissal or summary judgment on those of Plaintiff's claims, set forth in paragraphs 24-26 of the Third Amended Complaint, which would hold it liable for billing as personally performed procedures in which defendant was involved in a single procedure with one CRNA or student assisting. Def's Mot. Summ. J. at 42-43; Def's Mot. Dismiss at 8-12. Defendant argues that because the agency "deemed" one-on-ones to be personally performed and not medically directed, billing one-on-ones as personally performed was always proper. Thus, the argument goes, the regulation's requirement that the physician be "continuously involved" in a one-on-one procedure, *see* 42 C.F.R. § 414.46(c)(2)(ii) (1992-95) was waived by the language stating that when a physician is involved in one procedure with one

anesthetist "the procedure is deemed to be furnished by the anesthesiologist." 42 C.F.R. § 414.450(d) (1992-95).

Defendant's interpretation of the regulation is incorrect. Defendant has cited no authority for the notion that the term "deem" implies that all other requirements no longer apply. Understood in context, the use of the word "deem" simply clarifies which one of the two professionals involved in a procedure the agency considers to have performed it for billing purposes. Thus, the agency stated "[i]f an anesthesiologist and an anesthetist are involved in a single procedure, the procedure is deemed to be furnished by the anesthesiologist." 42 C.F.R. § 414.450(d) (1992-95). The agency followed by stating that payment for the anesthetist's service may not be made unless shown to be medically necessary. *Id.* Thus, the term is used to clarify who should bill for performance of one-on-ones.

The lack of support for defendant's argument contrasts with the language of the regulation stating when personal performance is applicable:

> HCFA considers an anesthesia procedure to be personally performed by a physician if it meets one of the following circumstances:
>
> (i) The physician personally performs the entire anesthesia procedure.
>
> (ii) The physician is continuously involved in a single case involving a [CRNA or student].
>
> (iii) For services furnished before January 1, 1994, the physician establishes an attending physician relationship in one or two concurrent cases involving a [student] . . . .

42 C.F.R. § 414.46(c)(2) (1992-95). Hence, personal performance includes procedures in which the physician is "continuously involved" in one case with assistance from a CRNA or student. *See id.*

GWU argues finally that the language conflicts and thus its billing was based on a reasonable interpretation of the regulation, negating any possible finding of scienter under the FCA. This argument also fails. As stated above, the Court does not find defendant's reading plausible. Furthermore, the logical extension of defendant's argument is that none of the other regulatory requirements, including the seven steps requirements, would need to be met for one-on-one procedures. There is simply no authority for this proposition.

In *United States ex rel. Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032 (8th Cir. 2002) ("*MANA*"), the Court of Appeals for the Eighth Circuit reversed a district court decision granting defendant summary judgment on claims based on false personal performance billing. The district court had held that the regulations "were susceptible to the interpretation that a physician need not have been continuously physically present in the operating room to bill a case as personally performed" and, accordingly, this ruled out the possibility that the FCA scienter was present. *Id.* at 1052 (internal quotation marks omitted). The Court of Appeals reversed, noting that, even if the regulations were ambiguous, if relators "show[ed] the defendants certified compliance with the regulation knowing that the HCFA interpreted the regulations in a certain way and that their actions did not satisfy the requirements of the regulation as the HCFA interpreted it, any possible ambiguity of the regulations [would be] water under the bridge." *Id.* at 1053. Thus, regardless of arguable ambiguities, scienter could still be established if defendants knew how the agency actually interpreted the regulation. Furthermore, the court noted that an ambiguity regarding what it meant to be "continuously involved" would only permit judgment if this was "the only respect in which the anesthesiologist fell short of fulfilling the personal performance standard". *Id.* at 1054-56.

As in *MANA*, summary judgment is improper. Here, the alleged ambiguity is even less plausible. In *MANA*, the claimed ambiguity dealt with whether continuous involvement required the physician's continuous presence in the operating room. *See id.* at 1053. Here, defendant argues that continuous involvement is not required at all. Def's Mot. Dismiss at 8-12. Even if this were a reasonable interpretation, it is still possible for relators to show that defendant certified compliance with the regulations knowing that the agency did not interpret it the same way. Additionally, here, as in *MANA*, this is not the only alleged violation of the personal performance standard.

VI. The Seven Steps Regulation

The parties advocate different interpretations of the Seven Steps regulation. Relators claim that the regulation requires anesthesiologists to perform all of the Seven Steps themselves, *see, e.g.,* Rel.'s Mot. Part. Summ. J. at 2, while defendant argues that the regulation permits anesthesiologists to delegate performance of the Seven Steps to other qualified medical personnel. *See, e.g.,* Def.'s Mem. Summ. Mot. Summ. J. at 7-9.

Regulatory interpretation begins with the language of the regulation itself. *See Seattle Opera v. NLRB*, 352 U.S. App. D.C. 53, 57, 292 F.3d 757, 761 (2002). Here, the Seven Steps regulation states that a physician performing anesthesia services is eligible for reasonable charge reimbursement, if:

> (1) For each patient, the *physician* –
> (i) Performs a pre-anesthetic examination and evaluation;
> (ii) Prescribes the anesthesia plan;
> (iii) Personally participates in the most demanding procedures in the anesthesia plan, including induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual . . . .;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated [post-anesthesia] care.

42 C.F.R. § 405.552(a)(1)(i)-(vii) (1989-95) (emphasis added).[7] The regulation thus plainly states that the physician must perform the Seven Steps.

Despite this straightforward reading, defendant has offered a theory to support its argument that anesthesiologists were not actually required to perform the Seven Steps themselves. The theory is that medical practices at the time allowed CRNAs and students to perform the tasks included in the Seven Steps regulation and the regulation was intended to codify those existing medical practices. Thus, defendant argues that the language of the regulation cannot be given its plain meaning (which would require doctors to perform those tasks) because it is in fact composed of terms of art which described those existing medical practices (which allegedly permitted non-doctors to perform those tasks). Defendant thus urges the Court to look to its experts to explain those terms of art. *E.g.,* Def.'s Mem. Summ. Mot. Summ. J. at 7-9. Relators argue that the regulation's plain meaning governs and the doctors must perform the Seven Steps. *E.g.,* Rel.'s Mot. Part. Summ. J. at 2.

Defendant's theory is incorrect because it confuses reimbursement standards with medical standards. In brief, the regulation was intended to change reimbursement standards, not to address medical standards. Thus, medical standards were not incorporated as "terms of art" and there is no reason to look to defendant's experts to explain them.

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[7]The physician must meet the other requirements for charge reimbursement as well.

The regulatory history is clear that although the regulation was not intended to change anesthesiology practice by setting quality or care standards, *see* 48 Fed. Reg. 8902, 8928, its purpose was to resolve excessive and duplicate reimbursement in the Medicare system by clarifying what was required for each level of reimbursement. *See* 48 Fed. Reg. 8902, 8904-05, 8928. The then-president of the American Society of Anesthesiologists, Phillip Bridenbaugh, recognized this when he advised in 1997:

> It is imperative that all Medicare providers . . . realize that these federal regulations are legal requirements only for receiving *reimbursement* for services rendered. In spite of an often voiced complaint from many physicians that the government is telling us how to practice medicine, the simple truth is: you can practice as you please; just do not send them the bill for payment."

Phillip O. Bridenbaugh, *"Knowingly?" – Ignorance Is No Excuse!*, ASA Newsletter, Vol. 61, No. 7, President's Page, *at* http://www.asahq.org/Newsletters/1997/07_97/Pres_Pg0797.html. Thus, while not intended to change anesthesiology care generally, the regulation was created to change reimbursement within the Medicare system.

Because the Seven Steps regulation was intended to change reimbursement practices, it was not composed of terms of art which simply codified existing medical standards. Furthermore, although the Seven Steps regulation included terms with medical definitions, such as "pre-anesthesia evaluation and examination", "induction", and "emergence", and although dispute as to these terms' precise definitions may later arise, any such dispute is not currently relevant. That is because the key term, "physician", was neither a term of art nor disputed.

Additionally, the regulatory history of the Seven Steps confirms that the agency intended the term "physician" to be given its plain meaning. For example, the regulatory history of step one, which required the physician to "[perform] a pre-anesthetic examination and evaluation",

confirms that the physician was himself required to perform the exam and evaluation. In the 1983 final rule announcement, a commentator asked whether it was permissible to bill for charge reimbursement when one anesthesiologist in a group practice performed the pre-anesthetic examination and another anesthesiologist in that practice performed or medically directed the actual procedure. The agency responded that this was acceptable so long as the anesthesiologists were in a group practice. The agency noted, however, that "a physician member of the group would have to perform all of the component parts of the anesthesia services; they could not be performed, for example, by an anesthesiology resident." 48 Fed. Reg. 8902, 8928. This clarifies that only an anesthesiologist, not a student or, by extension, a CRNA, could perform step one, or indeed, any step, if the procedure was to be eligible for charge reimbursement. *See id.*

Furthermore, in 1998, subsequent to the time period relevant here, the agency proposed changing step one from requiring the anesthesiologist to perform a pre-anesthesia examination and evaluation to allow an anesthesiologist to review such an examination and evaluation performed by another qualified individual. 63 Fed. Reg. 30818, 30841 (June 5, 1998); 63 Fed. Reg. 58814, 58842 (Nov. 2, 1998). The agency ultimately decided not to adopt this change, retaining the requirement that the physician perform step one himself. 63 Fed. Reg. at 58844-45. This history shows the agency clearly declined to adopt a rule which would have allowed someone other than the physician to perform step one.

The rules regarding teaching hospitals further bolster this interpretation. They provided that, when students were involved in providing care, a physician could satisfy step one by reviewing the patient's history and examination and then performing his own examination. 42 C.F.R. § 405.521(1989-95). Thus, despite this special teaching situation, the physician was still

required to perform step one himself.

The regulatory history of step two likewise confirms that the physician was required to "[prescribe] the anesthesia plan". In 1998, after the period at issue here, the agency chose not to adopt a proposed loosening of step two which would have permitted the physician simply to "[participate] in the development of the anesthesia plan and give final approval to the proposed plan." 63 Fed. Reg. at 58843-44. Noting that "the medical direction requirements specify the activities that the medically directing *physician*, who is usually an anesthesiologist, must perform" to merit reasonable charge reimbursement, the agency ultimately declined to lower the bar. 63 Fed. Reg. at 58843. Thus, step two is clear in its command that the physician himself prescribe the anesthesia plan.

Step seven's history subsequent to the relevant period follows the same trend. Step seven required the physician to "[provide] indicated post-anesthesia care". In 1998, the agency declined to change this to "[provide] indicated post-anesthesia care or [ensure] that it is provided by a qualified individual." 63 Fed. Reg. at 58843. Thus, it is clear that the physician, and not another qualified individual, had to perform step seven.

While all of these examples confirm that the physician had to perform the Seven Steps, defendant offers a further argument to the contrary. Defendant contends that requiring a physician to perform the Seven Steps himself is inconsistent with the general rule, set forth in 42 C.F.R. § 405.550, that only services which "ordinarily require performance by a physician" are reimbursable. Mem. Supp. Def.'s Mot. Summ. J. at 16. Defendant points to evidence that nurse practitioners performs tasks which are included in the Seven Steps. *Id.* The argument is thus that the Seven Steps cannot require physicians to perform services which other individuals also

perform.

This argument is defeated by the regulatory history, which reveals that the agency initially proposed allowing reimbursement only for services which "ordinarily [require] performance by a physician, and [are] not frequently and consistently furnished by nonphysicians". 48 Fed. Reg. 8902, 8905. Ultimately, the proposed requirement that services "not [be] frequently and consistently furnished by nonphysicians" was not adopted. Part of the reason for this was that the agency found that it was "not essential to determine the degree to which a service is performed by nonphysicians in order to decide whether the service requires performance by a physician" and because this would preclude reimbursement for services "when in a relatively few situations or circumstances the particular service is being safely performed by nonphysicians." 48 Fed. Reg. at 8908-09. This history reveals that the agency explicitly contemplated charge reimbursement for physician services which might also be performed by a nonphysician. *See* 48 Fed. Reg. at 8905-09. Thus, there is no conflict created by requiring physicians to perform the Seven Steps when nonphysicians might also on occassion perform some of the tasks. For the above reasons, it is clear that the physicians were required to perform the Seven Steps.[8]

Despite supporting the correct legal position, relators are not entitled to summary judgment because genuine issues of material fact remain as to defendant's physicians' performance of the Seven Steps and the requirements of liability under the FCA. Likewise, having failed in its legal argument, defendant's quest for summary judgment cannot succeed solely on its argument that relators have put forward no competent evidence to create a genuine

[8]The Court notes that the parties raised a number of other issues and proffered additional authorities which were not essential to resolution of these motions.

issue of material fact.

While the record is too extensive to chronicle all factual conflicts, dispute over whether defendant had the requisite FCA intent is sufficient to preclude summary judgment on all Seven Steps violation claims. For example, while relators contend that defendant had knowledge of false billing based on a report prepared by Joseph Locke, *see* Locke Report, Rel.'s Opp'n Def's Mot. Summ. J., Exh. 67, defendant offers evidence of alleged errors in that report which led to it being discounted. *E.g.,* Gehen Dep. at 53*,* Def.'s Opp'n Rel's Mot. Part. Summ. J., Exh. D. Weighing such evidence is not appropriate at the summary judgment stage.

CONCLUSION

Accordingly, for the reasons stated above, the Court has denied both parties' motions for summary judgment.

DATE: August 31, 2005

JOHN GARRETT PENN
United States District Judge