Case No. 04-15283-G

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

UNITED STATES OF AMERICA *ex. rel.*
KARYN L. WALKER,

Plaintiff/Appellant/Cross-Appellee,

v.

R & F PROPERTIES OF LAKE COUNTY, INC.,
f/k/a LEESBURG FAMILY MEDICINE,

Defendant/Appellee/Cross-Appellant.

On Appeal From a Final Judgment of
the United States District Court
for the Middle District of Florida

BRIEF OF *AMICUS CURIAE* AMERICAN MEDICAL ASSOCIATION IN SUPPORT OF DEFENDANT/APPELLEE/CROSS-APPELLANT AND FOR AFFIRMANCE OF SUMMARY JUDGMENT

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to 11th Circuit Rule 26.1-1, *Amicus Curiae*, the American Medical Association (AMA), certifies that the following persons, firms, partnerships, or corporations might have an interest in the outcome of this litigation:

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10. Gurney & Handley, P.A., Counsel for Appellee/Cross-Appellant.
11. The Honorable William Terrell Hodges, Senior U.S. District Judge.
12. Nancy A. Johnson, Counsel for Appellant/Cross-Appellee.
13. The Honorable Gary R. Jones, U.S. Magistrate Judge.
14. Leonard A. Nelson, Counsel for *Amicus Curiae.*
15. Paul I. Perez, United States Attorney.
16. Francis E. Pierce, III, Counsel for Appellee/Cross-Appellant.

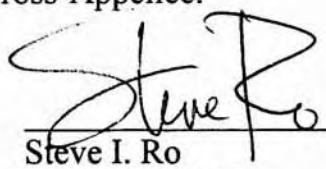
17. R & F Properties of Lake County, Inc., f/k/a Leesburg Family Medicine, Appellee/Cross-Appellant.

18. Steve I. Ro, Counsel for *Amicus Curiae*.

19. Jeffrey Robinson, M.D., Shareholder of Appellee/Cross-Appellant.

20. The United States of America, Party in Interest.

21. Karyn L. Walker, Appellant/Cross-Appellee.



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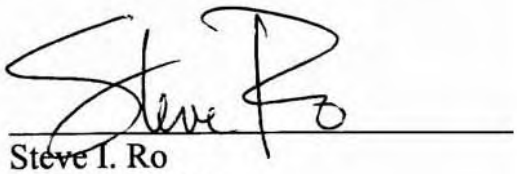
CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(c), *Amicus Curiae*, the AMA, states that it is a not-for-profit corporation, has no parent corporations, and has issued no stock.



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STATEMENT OF INTEREST

Amicus Curiae, the American Medical Association (AMA), is a private, voluntary, not-for-profit corporation of approximately 250,000 physicians, residents, and medical students. Its members practice in all fields of medical specialization and in every state. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health. The AMA submits this Brief of *Amicus Curiae* on its own behalf and as a member of the Litigation Center of the AMA and the State Medical Societies, a coalition of the AMA and the state medical societies of every state and the District of Columbia.

The AMA respectfully submits this brief to present its opinions concerning the proper scope and application of the False Claims Act (FCA). 31 U.S.C. § 3729 *et seq.* (2005). While the AMA opposes fraudulent billing practices, the present case does not involve such a circumstance. Defendant complied fully with the letter and the spirit of all binding laws and contracts at the time of the alleged incidents. The ruling that Plaintiff invites, which the district court rightly rejected, would compel this Court to venture beyond the plain language of the FCA and penalize Defendant for conduct that Congress never intended to punish.

The AMA seeks to file this brief under Federal Rule of Appellate Procedure 29(b). A Motion for Leave to File *Amicus Curiae* Brief accompanies this brief.

STATEMENT OF ISSUE

1. Are informal Medicare billing guidelines, such as those contained in the Medicare Carriers Manual, legally enforceable under the FCA?

SUMMARY OF ARGUMENT

The district court properly granted summary judgment in favor of Defendant, R & F Properties of Lake County, Inc., f/k/a Leesburg Family Medicine (LFM), because informal Medicare billing guidelines, such as those contained in the Medicare Carriers Manual, are not enforceable under the FCA.

This *qui tam* action is based entirely on the proposition that certain Medicare claims submitted by LFM were "legally false" for being inconsistent with the informal requirements of the Medicare Carriers Manual. An action based on a "legally false" claim can *only* subsist if the claim violates a binding law, regulation, or contract. The only law, regulation, or contract that was supposedly violated in the present case, however, is an informal guideline in the Medicare Carriers Manual. This manual was not promulgated in accordance with federal rulemaking standards and lacked the benefit of public notice and comment.

If informal guidelines were to be enforced under the FCA, physicians would be forced to abide by thousands of letters, opinions, and bulletins representing various viewpoints, often contradictory, of Medicare policy. Given the severity of FCA penalties and the strong incentives for employees, especially those recently terminated, to file *qui tam* actions, broadening the scope of the FCA would discourage physicians from participating in Medicare and diminish the quality of federally sponsored health care.

ARGUMENT

Introduction

The FCA is a Civil War era statute that was originally designed to prevent "widespread corruption and fraud in the sale of supplies and provisions to the union government." 132 Cong. Rec. 22,235 (1986). The purpose of the FCA is to punish those who knowingly submit "false or fraudulent claims" for payment to the federal government. *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 692-695 (2d Cir. 2001).

Prior to 1986, the FCA languished in relative disuse. *See* S. Rep. No. 99-345 at 4 n. 10, *reprinted in* 1986 U.S.C.C.A.N. at 5269 (pointing out that in fiscal year 1984 the Department of Justice had filed only 21 FCA complaints). In 1986, Congress modernized the FCA penalty provisions and scienter standard in response to allegations of gross overbilling to the Department of Defense.

Recent *qui tam* actions, however, have sought to expand the scope of the FCA to include matters entirely unrelated to the statute's purpose of confronting fraud by government defense contractors. These claims assert FCA violations based on allegations of failure to comply with anti-kickback statutes, failure to comply with regulatory requirements, or lack of adherence to applicable standards of care. These cases have regularly been rejected as inappropriate or misguided. *See, e.g., Mikes v. Straus*, 274 F.3d at 692-695; *Swafford v. Borgess Med. Ctr.*, 98

F. Supp. 2d 822 (W.D. Mich. 2002), aff'd, 2001 U.S. App. LEXIS 26669 (6th Cir. 2001), *cert. denied*, 535 U.S. 1096 (2002); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034 (N.D. Ill. 1998). This is especially so when the claim is based on the relator's personal disagreement with the manner in which the challenged services were provided, even though such manner of services has not been defined by federal and state regulations. Under such circumstances, *qui tam* actions are neither legally tenable, nor, from a policy perspective, socially desirable. The present case is no exception and should be resolved consistently with these other decisions.

In relating this action, Plaintiff, Karyn L. Walker (Walker), would compel physicians to abide by informal standards and guidelines that were not promulgated with the formalities needed to make them legally binding. Unlike the events which prompted passage of the FCA, Walker does not contend that LFM submitted claims to the government for services that were not performed. Rather, this case arises from Walker's subjective belief that LFM's billing of non-physician services as those "incident to a physician's professional services" was "knowingly false," since such services were rendered with a physician available by telephone or pager rather than with a physician physically on the premises. The AMA urges this Court to affirm the judgment of the district court and reject Walker's attempt to enlarge the scope of the FCA.

I. INFORMAL MEDICARE BILLING GUIDELINES, SUCH AS THE MEDICARE CARRIERS MANUAL, ARE NOT LEGALLY ENFORCEABLE UNDER THE FCA.

The dispositive issue in this appeal is whether the informal guidelines contained in the Medicare Carriers Manual can be legally enforced under the FCA.[1] The FCA imposes penalties on any individual who:

> (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;
> (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; [or]
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid...

31 U.S.C. § 3729(a)(1)-(3).

Thus, to establish liability under the FCA, three elements must be shown: (1) the submission of a claim for payment or approval; (2) the falsity of the claim; and (3) knowledge that the claim was false. With respect to the second element, there are two kinds of "falsity." *Mikes*, 274 F.3d at 695. The first kind, "legal falsity," is based on allegations of a false representation of compliance with a federal statute or regulation or a prescribed contractual term. *Id.* The second kind, "factual

[1] In addition to this issue, Walker raises several procedural grounds for appeal. Walker argues that the district court erred in refusing to consider an expert affidavit that was submitted well after her deadline for responding to the motion for summary judgment. Walker also argues that the district court erred in overruling her objections to the Magistrate Judge's order of August 23, 2004, based on the order's proscription of the relevant time period for purpose of discovery. (Appellant's Brief at 2.) *Amicus* makes no argument regarding these more narrowly focused points.

falsity," involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided. *Id.* at 697.

The present case deals with "legal falsity." The allegedly "false or fraudulent claim" upon which Walker bases her allegation is a form submitted to the government containing a Unique Provider Identification Number (UPIN) of a physician. Walker contends that LFM's use of this UPIN for non-physician services was improper because it failed to conform with the Medicare Carriers Manual's criteria for the billing of such services.

Walker does *not* contend that the use of this UPIN number was "intrinsically" false or that the language of the claim, in and of itself, was false, irrespective of 42 U.S.C § 1395 (1999) (the "'incident to' provision") and the Medicare Carriers Manual—i.e. factually false. *See* Robert Fabrikant and Glenn E. Solomon, *Application of the False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 Ala. L. Rev. 105, 106 (1999) (explaining the "intrinsic" nature of factual falsity and the "extrinsic" nature of legal falsity). Rather, Walker argues that the use of the UPIN was improper because it supposedly violated federal regulations that were "extrinsic" to the language of the claim itself—the "incident to" provision and the Medicare Carriers Manual. (Appellant's Brief at 9.) In other words, Walker alleges that LFM's use of a physician's UPIN was legally false.

To be actionable under the FCA, legally false claims must violate binding laws, regulations, or contracts. *Mikes*, 274 F.3d at 692-695. Walker, however, has failed to identify a single binding law, regulation, or contractual term that required "incident to" billing to be used only when a physician was on the premises while non-physician services were rendered. During Walker's employment, Medicare benefits were defined as "services and supplies...furnished as an ***incident to*** a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills." (Emphasis added.) 42 U.S.C. § 1395x(s)(2)(A) (1999). The relevant Medicare regulations, however, were completely silent with respect to the meaning of "incident to," for purposes of billing (42 C.F.R. § 410.10(b) (1999) and 42 C.F.R. § 410.26(a) (1999)), and Walker fails to cite any other authority to support her theory of falsity.

Numerous cases indicate that if a physician's practice fails to violate any specific law, regulation, or contract term, "falsity" cannot exist as a matter of law. *United States ex rel. Swafford*, 98 F. Supp. 2d at 831-32; *Luckey*, 2 F. Supp. 2d at 1052; *Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998).

For instance, in *Swafford*, the relator argued that in order to bill for "personally furnished" interpretations or readings of ultrasound test results, physicians must do more than merely rely upon the findings of a technician.

According to the relator, the Medicare Carriers Manual required physicians to independently review the supporting data from which the technician arrived at her conclusions. *Swafford*, 98 F. Supp. 2d at 831-32. The court rejected the argument because it found that the regulations pertaining to ultrasound tests were undefined and ambiguous. It stated that the relator's position "devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physicians services." Such a "legal dispute" is insufficient to establish FCA liability. *Id.* The court specifically rejected the standards promulgated under the Medicare Carriers Manual, because they were not controlling law or binding guidelines for physicians.

In *Luckey*, defendant certified that it would utilize certain testing methods to provide accurate and reliable results. 2 F. Supp. 2d at 1037-38. The relator contended that the company's testing procedures were scientifically unsound. The court ruled that the relator could not demonstrate that the defendant's certification was false because he could not point to any contract or regulation that required a specific type of testing and because courts "have consistently declined to find that a contractor's exercise of scientific or ***professional*** judgment as to an applicable standard of care falls within the scope of the FCA." (Emphasis added.) *Id.* at 1047.

Similarly, *Hochman* held that although there may have been a "legal" dispute as to whether a particular billing guideline was applicable, taking an advantageous position on a disputed legal question is not tantamount to filing a knowingly false claim. 145 F.3d at 1073. Likewise, in the present case, there were competing standards of physician supervision (*see infra* at 20), and LFM should not be held to a disputed standard.

Other courts have ruled similarly. *See Glass v. Medtronic, Inc.*, 957 F.2d 605, 608 (8th Cir. 1992) (a statement cannot be false or fraudulent when it is consistent with governing regulations); *United States ex rel. Bidani v. Lewis*, 2001 U.S. Dist. LEXIS 9204, *14 (N.D. Ill. June 29, 2001) (relator's claim was rejected because he failed to point to any governing regulation that had been violated); *United States ex rel. Ben-Shlush*, 2000 U.S. Dist. LEXIS 3039, *9 (S.D.N.Y. Mar. 10, 2000) (relator failed to cite any specific governing regulations).

Walker cites various regulations which purportedly mandated that "incident to" billing required the presence of a physician on the premises. (Appellant's Brief at 10.) These provisions, however, were not in effect during the period of her employment with LFM. Rather, they became effective on January 1, 2002, two years after the period in which the actions giving rise to this suit occurred.

Until the amendment of the applicable regulation, the "incident to" provision was vague and indefinite. Imprecise statements or differences in interpretation

growing out of a "disputed legal question," however, are not "false" within the meaning of the FCA. *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999). "Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000); *United States ex rel. Milam v. Regents of the University of California*, 912 F. Supp. 868, 886 (D. Md. 1995).

II. THE FCA SHOULD NOT BE CONSTRUED AS A DEVICE TO COMPEL PHYSICIANS TO CONFORM WITH INFORMAL FEDERAL GUIDELINES.

The Medicare Carriers Manual is an *informal* guideline for Medicare carriers and intermediaries. *Swafford* states, "the Carriers Manual is merely a guide for fiscal intermediaries between Medicare and physicians, and lacks 'the binding effect of law or regulation.' Moreover, the Medicare Carriers Manual is intended to instruct carriers as to whether to pay a claim and is not routinely provided to physicians." *Swafford*, 98 F. Supp. 2d at 828.

The Medicare Carriers Manual was not meant to bind physicians to standards that are not promulgated in accordance with federal rulemaking guidelines. *See Shalala v. Guernsey Memorial Hosp.*, 514 U.S. 87, 99 (1995). The Medicare Carriers Manual is prepared without the benefit of public notice and comment. Consequently, it does not embody a position of broad public support,

and it does not protect against arbitrariness. The Medicare Carriers Manual is also of questionable substantive validity, since it may include requirements beyond those set forth in the statutes and regulations it purports to interpret. *See* Linda A. Baumann, *Health Care Fraud and Abuse: Practical Perspectives*, 221 (BNA Books 2002).

If the Medicare Carriers Manual were to be deemed binding, it would raise an unworkable question of legal line drawing. The Centers for Medicare and Medicaid Services (CMS) publish thousands of Medicare intermediary letters and program memoranda. The Medicare intermediaries and carriers, in turn, issue their own bulletins and local medical review policies. Numerous opinions concerning Medicare policy are also written by other private groups. The Office of Inspector General (OIG) of the Department of Health and Human Services issues fraud alerts, model compliance programs, and other pronouncements that merely represent the viewpoints of various government enforcement agencies. *See id.* at 221. It is impractical to expect physicians and their attorneys to know and abide by such a vast, amorphous, and sometimes contradictory body of Medicare literature. *Id.*

Medicare's official rules, policies, and regulations consist of more than 110,000 pages. *Rethinking Medicare: Solutions for Medicine's Short- and Long-Term Problems*, 2 (2002), *at* http://www.ama-assn.org/go/medicare. There is no

shortage of adequate means for defining the proper billing of physician and non-physician services. To expand these formal requirements through FCA enforcement of unofficial guidelines would make an already complicated bureaucratic process unmanageable.

III. THE PROPER LEVEL OF SUPERVISION BY PHYSICIANS OF SUBORDINATE EMPLOYEES IS A MATTER OF LEGISLATIVE REGULATION, NOT FEDERAL ADJUDICATION.

Walker's claim is based on a subjective opinion that a physician should be on the premises in order for a service provided by the physician's assistant to be considered "incident to" This policy may or may not be desirable, but, it is not the role of the FCA or the judiciary to make such a "rule."

In accordance with the requirements of the Administrative Procedures Act, federal regulations were ultimately passed in 2002 mandating that "incident to" billing be made only when a physician is on the premises. 42 C.F.R. § 410.26 (2005) and 42 C.F.R. § 410.32 (2005). Thus, the appropriate approach was taken to institute new policy in conformance with standard federal rulemaking guidelines. Prior to these rules, however, there was no fair basis for assuming that a physician must be present on the premises in order to allow such billing.

Save for the guidelines in the Medicare Carriers Manual, Walker asserts no basis for deeming LFM's interpretation of the "incident to" provision to have been false. Walker even admitted in her deposition that LFM had met the requirements

of non-physician supervision under the practice protocol agreements she had signed.

> Q. So under the definition of supervision set forth in the practice protocol agreements, the physicians always had that level of supervision?
>
> A. Yes, sir.
>
> ...
>
> Q. Did any LFM patient ever suffer damage or injury from your services as a result of general supervision?
>
> A. Not that I'm aware of, no.

(Doc. 81 at 52-53.) Moreover, under applicable state law physicians are permitted to provide immediate personal supervision of a non-physician without being on the premises. The only requirement is that they be available by telephone. Fla. Stat. 458.347(2)(f) (1997); Fla. Admin. Code Ann. r. 64B8-30.001 (3)-(5) (Physician Assistant) (2005); Fla. Stat. 464.012(3) (1997); Fla. Admin. Code Ann. r. 64B9-4.001(14) (Advanced Registered Nurse Practitioners) (2005). It is unreasonable to interpret the FCA as superceding the standards clearly defined by state law, absent adoption of a clear regulation otherwise.

CONCLUSION

The finding of a FCA violation can have far reaching, and often unintended, consequences. For instance, an overly broad interpretation of the FCA may discourage physicians from participating in Medicare. Approximately 52% of

physicians have indicated that Medicare's rules and requirements decrease their willingness to see Medicare patients. *Rethinking Medicare, supra*, at 18, 2. Complex federal regulations equate to thousands of hours of tedious and ultimately unproductive paperwork for physicians. *Id.* Consequently, many providers may choose to opt out of government programs entirely. *See* John T. Boese, *Can Substandard Medical Care Become Fraud? Understanding an Unfortunate Expansion of Liability Under the Civil False Claims Act*, The Brief, Vol. 29, 30-31 (2000).

Such withdrawal could have a tremendous impact on health care in this country. Medicare's annual costs are currently 2.7 percent of the Gross Domestic Product. *Status of the Social Security and Medicare Programs and Medicare Programs: A Summary of the 2004 Ann. Reports*, *at* http://www.ssa.gov/OACT/TRSUM/trsummary.html. Over 40 million Americans are now enrolled in Medicare at an annual cost to the federal government of $297 billion. *Statistics and Data*, *at* http://www.cms.hhs.gov/medicare; Congressional Budget Office, *Historical Budget Data*, *at* http://www.cbo.gov/showdoc.cfm?index=6060&sequence=11. A decrease in the number of Medicare providers would reduce the availability of health care for a significant percentage of the American population.

An individual found to have violated the FCA may also be ordered to pay damages of up to three times the amount of the claim, as well as mandatory

penalties of between $5,000 and $10,000 per claim, regardless of the size of the underlying claim. 31 U.S.C. § 3729(a)(7). There are collateral consequences as well, including exclusion from participation in federally funded health care programs (42 U.S.C. § 1320a-7 (2005)), loss of medical licensure (Fla. Stat. § 458.331 (2004)), and loss of hospital staff privileges.

Because of these consequences, no target of a FCA claim, however certain of the propriety of his or her conduct, would take such a threat lightly. Even the most avowedly innocent would be encouraged to settle claims that advance untested and aggressive legal theories. Frivolous actions will thrive in such an environment.

For the foregoing reasons, *Amicus Curiae* respectfully requests that the judgment of the district court be affirmed.

Respectfully submitted,

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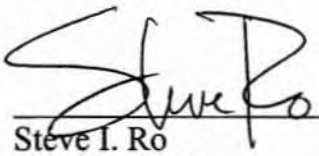
1. This brief complies with Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B), because it contains 3,286 words, excluding sections exempted by Rule 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2002 and Times New Roman 14 point font.



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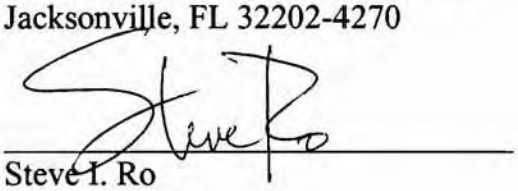

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