IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA *ex rel*. JULIE WILLIAMS, *et al*.,	)	
Plaintiffs	)	NO. 3:09-00738 JUDGE HAYNES
v.	)	
RENAL CARE GROUP, *et al.*,	)	
Defendants.	)	

M E M O R A N D U M

Plaintiff, Julie Williams as relator, filed this action[1] under the False Claims Act, ("FCA"). 31 U.S.C. §§ 3729 through 3733 against the Defendants: Fresenius Medical Care Holdings, Inc. ("FMCHI"), Renal Care Group ("RCG"), the former parent corporation of the RCG Supply Company ("RCGSC"). FMCHI is the successor-in-interest to RCG and RCGSC. Defendant RCG provided dialysis supplies to patients with end-state renal disease ("ESRD") at RCG facilities. Defendant RCGSC supplied dialysis equipment to patients who receive dialysis treatment at their homes. Defendants RCG and RCGSC submit claims for payment for these services and supplies to the Medicare program. The United States later intervened and the Relator non-suited her claims without prejudice. The United States's FCA claims are that RCGSC's claims for payment from the Medicare program between 1999 and 2005 for home support dialysis supplies were in violation of Medicare statutes and regulations because RCG, a dialysis facility, actually created controlled and operated RCGSC, a dialysis supplier rendering RCGSC ineligible for higher payments from Medicare for dialysis supplies for in-home dialysis

[1]This action was filed originally in 2005 in the Eastern District of Missouri and was later transferred to this District in 2009. (Docket Entry No. 188).

treatment.

Before the Court is the United States's motion for partial summary judgment (Docket Entry No. 165), on counts one and six of its first amended complaint, contending, in sum, that the Medicare program in the United States Department of Health and Human Services ("HHS") has two payment methods, Method I and Method II. Method I pays dialysis "facilities" for dialysis supplies and equipment at a lesser rate than legitimate dialysis "suppliers" who provide dialysis equipment for home dialysis treatment. Medicare pays an additional 30% to firms that sell dialysis supplies and equipment for dialysis treatment at the patient's home. Congress prohibits the higher payments to such firms that also supply dialysis equipment at facilities. Given the mandatory language of the federal statute and regulations, the United States asserts in count one that RCG operated a chain of dialysis facilities and later created as well as operated RCGSC as a shell company solely to capture the additional 30% reimbursement rate for dialysis supplies and equipment used at the patient's home. The United States contends that RCGSC is not a legitimate supplier that is qualified to submit claims for payment under Medicare's "Method II" payment scheme. In count six, the United States asserts a claim of unjust enrichment contending that because RCGSC failed to meet the statutory and regulatory conditions for the higher Method II payment from the United States, RCG and RCGSC received more Medicare funds than they were eligible to receive.

Also before the Court is RCG's and RCGSC's motion for summary judgment (Docket Entry No. 204) on all claims asserting, in essence, that Medicare officials knew of RCG's corporate structure and a Medicare official informed RCG's attorney that RCGSC's role as a supply company for RCG's patients was legal. In addition, Defendants cite Medicare's

payments of RCG's and RCGSC's claims for more that six years as evidence of RCGSC's compliance with the applicable Medicare rules. Defendants also refer to the widespread industry practice for such related companies as well as legal advice that RCG relied upon in establishing RCGSC. Defendants contend that they lacked any fraudulent intent and did not make any false representations that were material to their Medicare payments. For these same reasons, Defendants argue that the United States's common-law claims of mistake and unjust enrichment are barred. Moreover, in Defendants' view, if the United States is correct, then the United States's remedy is a breach of contract claim that is an adequate remedy at law thereby precluding any claims for equitable relief.

A. Findings of Fact[2]

1. The RCG and RCGSC Relationship

RCG provides dialysis services to patients primarily at more than 260 freestanding dialysis facilities. In its 2004 filing with the Securities and Exchange Commission ("SEC"), RCG described its business as providing a dialysis services to patients with chronic kidney failure also known as "End State Renal Disease" through its hundreds of out-patient centers in multiple states.

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[2]Upon a motion for summary judgment, the factual contentions are viewed in the light most favorable to the party opposing the motion for summary judgment. Duchon v. Cajon Co., 791 F.2d 43, 46 (6th Cir. 1986). As discussed infra, upon the filing of a motion for summary judgment, the opposing party must come forth with sufficient evidence to withstand a motion for directed verdict, Anderson v. Liberty Lobby, 477 U.S. 242, 247-52 (1986), particularly where there has been an opportunity for discovery. Celotex Corp. v. Catrett, 477 U.S. 317, 326 (1986). Under the applicable law and the parties' factual submissions, the Court concludes that there are not any material factual disputes. From the Court's perspective, the parties' purported factual disputes are actually challenges to the probative value and effects of undisputed facts Thus, this section constitutes findings of fact under Fed. R. Civ. P. 56(d).

In this market, there are two types of home peritoneal dialysis treatment, Continuous Ambulatory Peritoneal Dialysis ("CAPD") and Continuous Cycling Peritoneal Dialysis ("CCPD"). CAPD involves between two and five daily dialysate fluid exchanges that are done manually by the patient through a catheter that is surgically placed in his or her abdomen. In contrast, CCPD treatment utilizes a machine called a cycler. Each night, the patient attaches the cycler machine to a catheter which has been surgically placed in the patient's abdomen. The machine fills the patient's abdomen with a dialysate solution. The dialysate solution interacts with the patient's peritoneum and transfers toxins from the blood to the dialysate. The solution is then drained from the abdomen by the cycler while the patient sleeps.

RCG focused on Medicare patients using a cycler under CCPD because of its incremental higher reimbursement under Method II. After earlier acquisitions, RCG formed RCGSC in 1998 to provide dialysis equipment and supplies to the dialysis patients who elected to have their dialysis treatments at their homes. RCG owns 100% of RCGSC's stock and RCG employees, officers, or directors are also RCGSC's officers, directors, and managing employees. Gary Brukardt, RCG's chief executive officer, was RCGSC's President, but did not receive a separate salary in the latter capacity. Dr. Ray Hakim, RCG's chief medical officer, was RCGSC's vice president in 2004, but was not involved with RCGSC's daily operations nor did he expend any time on RCGSC's business in 2004 and 2005.

Dan Alexander, a RCG lawyer, advised RCG in October 1998 that RCGSC must maintain a physical facility on an appropriate site and that using RCG space was unwise. Yet, RCGSC shared office space with RCG at several addresses without a lease. RCGSC and RCG employees used the same conference room. RCGSC used RCG for payroll as well as insurance,

benefits and human resources services. RCG's finance department employees handled RCGSC's accounts receivable. RCGSC's chief financial officer came from RCG. RCGSC also used RCG's e-mail system for business communications. Any money deposited in RCGSC's account was "swept" into RCG's corporate collection account at the end of the day and commingled with RCG's funds. RCGSC's director did not have a RCGSC checkbook to write checks and RCG's account payable section paid RCGSC's supply vendors. RCGSC's director could not spend RCGSC's revenue or access its funds.

2. The Origin of RCGSC

On September 2, 1997, Russell Dimmitt, RCG's director of material management wrote an e-mail summarizing Medicare payments under Method I and Method II for dialysis patients using various treatment modalities. Dimmitt noted that under Method II, Medicare would pay two thousand ninety dollars forty-five cents ($2,090.45) per month for a patient using the "CCPD" treatment modality at the patient's home, but under Method I, Medicare would pay only one thousand seven hundred twenty-nine dollars eighty cents ($1,729.80) to RCG, a difference of an extra three hundred sixty-one dollars ($361) per patient per month.

In a December 1997 memorandum, Dimmitt wrote RCG regional personnel stating, in part, "...RCG has acquired several Method 2 supply companies. . . . This will increase your facility revenue and decrease the associate time over supply orders." (Docket Entry No. 168-20).[3] Dimmitt also requested RCG employees to complete new patient packets "for each patient that is to be switched from Method 1 to Method 2" and return the forms to "RCG Nashville," the

[3]For clarity and consistency, the citations are to the appropriate docket entry and the pagination of that entry by the Court's electronic filing system.

Defendants' headquarters. Id. Dimmitt further stated "...this move is strictly for RCG and will not effect [sic] the patient's care. You will still be the primary care giver, all RCG Supply will do is provide supplies and a friendly voice." Id.

In a February 5, 1998 memorandum, Dimmitt wrote to RCG's regional chief operating officers that "[i]n an effort to assist the regions of Renal Care Group," RCGSC would commence billing for Method II supply patients, with RCGSC "converting patients to Supply Companies, customer service department, one region at a time." (Docket Entry No. 168-23).

On October 26, 1998, Dimmitt requested David Jones, RCG's chief operating officer for RCG's south central region with 60 RCG dialysis facilities in Missouri, Texas, Arkansas and Oklahoma, to convert RCG's patients in RCG dialysis facilities to Method II for RCGSC. (Docket Entry No. 168-15). In his response, Jones objected and stated, in part:

> The South Central Region opts not to participate in this Plan. It is not in the best interests of our patients. Furthermore, I do not think it is legal to force our patients into a Method II arrangement simply to increase the profits of our Company. I do not wish to go to jail and I do not wish to destroy the PD program within our Region. I believe this program, as I understand it, should not be implemented for these reasons. If, in fact, we are ordered to participate, I respectfully request that such demand be put in writing with an acknowledgment that I have forewarned all concerned that I feel this program is illegal, ill-advised and that it is being implemented against my experienced consul [sic] and best judgment."

Id. (emphasis added).

In his deposition, Jones explained Dimmitt's request was "...ultimately . . . setting up a separate independent supply company that's actually a subsidiary of a large chain, while it technically may basically make the definition of being a supply company that's independent, the question as to whether it could really operate as an independent entity or whether it could be in a position to be influenced by the dialysis company itself were two entirely different matters. And

basically from my perspective at the time and what I felt was that the supply company owned by a large chain truly could not be independent because there would be influence to try to direct patients into that supply company." (Docket Entry No. 168-8 at 2). According to Jones:

> "...being independent, which means [RCGSC] having its own provider number and in effect own structure if, in fact, that's the case, while it meets the technical definition of independence, in terms of the practical implementation of the day-to-day operation of the supply company and the dialysis business, I couldn't see that ultimately a supply company that the people involved in the company are trying to encourage all of us that are operating with the dialysis patients to direct patients into would by definition be independent. So the technical definition, while it could be technically correct that they are independent, from a practical standpoint if there's a benefit financially to the dialysis company to direct patients into the supply company from that perspective the definition breaks down the particular point...."

Id. at 4, 5 (emphasis added).

In sum, Jones's understanding was that RCGSC would direct to RCG's doctors to prescribe for home dialysis solutions and "direct the types of products that were going to be basically purchased by the entire company." Id. at 11. As to Dimmitt's patient conversions, Jones explained:

> "The directive pretty much was that we would transfer all of our patients into Method II beginning the first of the year, with that is an underlying assumption that, in fact, our employees, our nurses could pretty much direct the patients into whatever methodology, you know, we would like to have done, mainly because the dialysis patients were really dependent on our people and would normally do whatever it is that we would recommend. . . . And once we made the decision implicit to that in effect we're directing them into whatever methodology we prefer as opposed to which one is actually in their best interest."

Id. at 16-17.

In May 1999, Jones left RCGSC before a full conversion or implementation of the RCGSC arrangement noting that RCG had "dodged that bullet for the time being. Whether or not, you know, somebody was going to reload and shoot it again, I'm not sure I was convinced

that that wasn't going to happen." Id. at 23. After Jones's complaint, RCG considered closing RCGSC in 1998, but Gary Brukardt RCG's chief operating officer ultimately decided to continue RCGSC's operations.

From 2003 through 2005, Cheryl Vaughn, a RCGSC manager[4] gave presentations about RCGSC and its Method II reimbursement to home program staff, home program nurses, and social workers who were RCG employees at RCG dialysis facilities. Vaughn stated, RCGSC "was operated for our patients who choose Method II" with "our patients" referring to RCG. (Docket Entry No. 168-3 at 16). In response to the question, "where is the separation from a patient perspective between the Supply Company and RCG?", Vaughn responded: "I think some patients didn't even realize it was the same company. RCG Supply Company probably didn't register." Id. at 34. When asked "did you think RCG's dialysis facilities were very important to the success of the Supply Company in terms of enrolling patients?," Vaughn replied "without the facilities, without the home programs, and without those patients there would be no supply company." Id. at 19-20.

As to whether RCG and RCGSC were the same company, Michelle Dawson, RCGSC's customer service representative responded "...I don't know when you - I never know when you're saying - when you're talking about Renal Care Group or when you're talking about RCG Supply Company....Because we would just say RCG. And we were in the same building so I'm just never sure what you're asking me." (Docket Entry No. 168-9 at 5).

As its mode of operation, RCG facility employees presented patients at the clinics with Method Selection 385 Form that authorized patients to elect Method II with RCGSC. By

[4]Vaughn noted that her pay stub probably reflected RCG. (Docket Entry No. 168-2 at 3).

directive of the Centers for Medicare and Medical Services ("CMS"), the presentation of this Form was by clinic personnel. RCGSC did not undertake any television or radio advertising that was aimed at physicians, nurses, or patients. RCGSC did not meet directly with patients on method election issues, but RCG's facility staff did so at the RCG facility.

Historically, Method II patients generally only accounted for between 25% to 35% of all RCG home patients. RCGSC budgeted only for a 20% increase in Method II patients each year. To be sure, RCG facilities had many Medicare-primary Method I patients in both CCPD and CAPD modalities. As an example, in 2004, the company noted in its budget presentation that RCG had literally hundreds of patients who were eligible to chose Method II, but did not select Method II. Yet, RCGSC dialysis did not provide supplies to patients from other dialysis facility chains. RCGSC's business model only sought patients in RCG's dialysis facilities. The overwhelming majority of RCGSC's Method II patients now come from RCG's dialysis facilities. Only one or two RCG patients received supplies under Method II from a supply company other than RCGSC.

RCG and RCGSC use the same contracts with dialysis supply manufacturers, Fresenius Medical Care ("FMC") and Baxter Healthcare ("Baxter"), and obtained the same brand and type of home dialysis supplies provided to RCG's patients under both Method I or Method II. Only RCG employees were authorized to sign contracts with Baxter or FMC for home dialysis supplies. RCGSC did not have any warehouses of home dialysis supplies. Baxter assisted RCGSC with managing its supply inventory and delivering supplies to patients. Without Baxter's assistance, RCGSC would have to hire more staff to deliver supplies.

If Medicare inquired about a specific patient's dialysis supplies, RCG and RCGSC

needed Baxter or FMC's assistance to respond or track supplies of RCGSC patients. RCGSC also used its vendors' invoices to prepare reports on shipments to patients. In 1998, Dawn Alexander, another RCG counsel, advised that a supplier must keep signed and dated physician orders for supplies and equipment on file. (Docket Entry No. 168-3 at 3-4).

Dr. Joseph Pulliam, RCG's associate chief medical officer, authored a memorandum in 2000 about RCGSC's patient supplies, writing in part: "the staff noted that in many facilities the nurse first places the order with either Baxter or Fresenius, and the vendor assigns modality selection rather than having RCG Supply be the first point of contact by the facility nurse." From a process prospective, Dr. Pulliam agreed that the vendor should not be assigning a patient's modality selection. (Docket Entry No. 168-11 at 44). In a July 2002 memorandum about RCGSC, Dr. Pulliam wrote: "the method II company has not provided a framework for inventory control" of home dialysis supplies, (Docket Entry No. 168-27), meaning patients were either getting too much or not enough dialysis supplies. (Docket Entry No. 168-11 at 18-19, Exhibit 152).

On October 24, 2003, a Medicare contractor informed RCGSC of its overpayment of $364,141.80 that should be returned to Medicare by November 22, 2003. (Docket Entry No. 168-37). The RCGSC director referred the inquiry to a RCG employee and on March 4, 2004, after a review of RCGSC's billing for a specific beneficiary, a Medicare contractor requested RCGSC to provide a written order, delivery/pick-up slip, and other records that supported the services billed and RCGSC responded. After reviewing RCGSC's response, the Medicare contractor found another written order without a signed delivery slip for the services billed and imposed another overpayment order. (Docket Entry No. 168-38).

In 2005 after a chart audit of RCGSC's patient files, Vaughn RCGSC's director wrote that "a recent chart audit in RCG Supply Company has shown that many of our patients trained over the years may not have received required information. . . ." (Docket Entry No. 168-3 at 64-68 and Docket Entry Nos. 168-36 and 246). As to patient files missing required information. Vaughn responded "one hundred percent of those files that I went through were missing certain pieces. . . Sometimes the time frames when the records were not in the Supply Company files could be as long as a year." (Docket Entry No. 168-3 at 67).

Ninety-five percent of RCGSC's reimbursement was allocated to RCG's facilities to cover costs at a facility level when RCG used Method II in RCG facilities. Id. at 31-51. RCGSC's returned its revenue to the region of the RCG facility in which the patients resided. Id. at 32. Gary Brukardt, RCG Chief Executive Officer, testified that Method II Medicare reimbursement from RCGSC'S patients would go back "to whatever region the patient resided in . . . the revenue would be recognized there." (Docket Entry No. 168-2 at 21). In evaluating the performance of RCG's regions or facilities, RCG managers counted RCGSC's revenue in the regions, facilities, budgets and performance. RCGSC's Method II revenue enabled region facilities to make their financial targets. With RCGSC's revenue allocated to RCG's facilities, RCGSC always operated at a loss.

As stated earlier, RCGSC relied on RCG's facility staff to enroll patients for Method II. At least 90% of RCGSC's patients were also treated in RCG's dialysis facilities. RCGSC only accepted patients with Medicare as their primary insurance coverage, and from 2003 through 2005, Medicare was the primary insurer for over 90% of RCGSC's patients. (Docket Entry No. 168-3 at 17). When Medicare provided more reimbursement under Method II, a patient's co-

insurance obligation was higher. RCGSC patients complained of charges and co-insurance obligations for after conversion to Method II. RCGSC did not actively collect co-payments from beneficiaries after the conversion to Method II. Dr. Pulliam described as common practice and an industry standard not to collect co-payments from Medicare beneficiaries for Method II services. (Docket Entry No. 168-11 at p. 19).

For the years 1999-2005, RCG and/or RCGSC received approximately eighty-three million eight hundred six thousand six hundred nineteen dollars ($83,806,619) in Method II payments of its total Medicare reimbursements of approximately one hundred seven million eight hundred sixty thousand sixty-seven dollars ($107,860,067). According to the United States, the net reimbursement for RCG and RCGSC if all their Method II claims were presented under Method I during 1999-2005 would have been nineteen million three hundred sixty-six thousand seven hundred five dollars ($19,366,705). (Docket Entry No. 168-43 at 7). The Defendants' calculation is twelve million nine hundred fifty-seven thousand eight hundred sixty-four dollars ($12,957,864). Id. at 13.

4. Defendants' Interactions with Medical Officials

For its business practices, Defendants cite their interactions with federal officials who manage the Medicare program. Defendants cite the letter of December 2, 1998 by Dawn Alexander, a RCG counsel, inquiring of Gene Richter at the Health Care Administration Facility ("HCFA") on the legality of establishing a subsidiary supply company such as RCGSC and reflecting her "understanding" of his favorable response. (Docket Entry No. 203-76). Defendants cite the Medicare contractors' site investigations in 2000 to ensure the Defendants' compliance with the supplier standards. After these investigations of RCGSC, the Medicare

contractor did not make a referral of improper operations. Defendants cited applications of its affiliated company, the St. Louis Supply Company, that revealed RCG as one of the owners. This application also disclosed St. Louis Supply Company's employment of RCG Tennessee personnel to manage it supply company operations. CMS never raised on issue of a RCG employee managing its suppliers business. Another disclosure of this arrangement is in the 1998 application of Midwest Renal Support and Dialysis Associates LLC that RCG acquired in 2003 and 2004, respectively. Dialysis Associates, another RCG affiliate, disclosed RCG's day-to-day management of its dialysis chain.

In its earlier 1999 Medicare re-enrollment application, RCGSC stated its "owner" billed Medicare and listed the owner's name as "RCGI." (Docket Entry No. 203-93). In a November 18, 1999 request for a study, RCGSC disclosed that, "the RCG patients who are currently participating and those who will participate in our study are Medicare ESRD Method II patients whose dialysis equipment and supplies are billed to your DMERC by RCG's Supply Company, Medicare supplier #0799680001." (Docket Entry No. 203-96 at 2). RCGSC's November 18, 2002 supplier re-enrollment application listed RCG as the owner of RCGSC since February 1996 and the "managing controller" of RCGSC's day-to-day operations. (Docket Entry No. 203-93 at 13). In this application, Carolyn Latham is listed as RCGSC's managing employee, and a "managing employee" of RCG. This application discloses RCGSC use of RCG's contracts with Baxter and Fresenius and RCGSC and RCG's shared insurance policies.

Palmetto GBA, a Medicare contractor processes RCGSC's claims for the Medicare program and examines the billing number to the supplier. Nancy Parker, Palmetto's corporate representative, admitted that "if RCG, Inc., controlled the day-to-day operations of RCG Supply

Company, RCG Supply Company told the National Supplier Clearinghouse that in 2002." (Docket Entry No. 203-32 at 19). RCGSC disclosed in 2002 that RCG owned and controlled RCGSC and had done so since 1996. Id. at 21.

Palmetto paid RCGSC as long as RCGSC maintained its supplier number. In addition, RCGSC disclosed in June, 2003 to the Office of Inspector General for the Department of Health and Human Services that "[t]he Vice President, Clinical Operations, for Renal Care Group, Inc., is head of the RCG Supply Company" and that "The Group Chief Financial Officer for Renal Care. (Docket Entry No. 203-106 at 2).

B. Conclusions of Law

For a FCA claim, "[n]o proof of specific intent to defraud is required." 31 U.S.C. § 3729(b)(3). The false statement to the federal government must be to receive payment of federal funds. United States ex rel. SNAPP v. Ford Motor Co., 532 F.3d 496 505 (6th Cir. 2008). The false statement also "must have been made with the purpose of 'getting a false or fraudulent claim 'paid or approved by the Government.'" Id. Finally, the false statement must have been material to the government's payment decision, *i.e.*., must have a "natural tendency" to influence the decision-maker. United States ex rel. A+ Homecare, Inc. v. Medshares Mgt. Group, Inc., 400 F.3d 428, 445 (6th Cir. 2005). The issues of falsity and intent in a FCA action are "closely related." United States ex rel. Augustine v. Century Health Servs. Inc., 136 F. Supp. 2d 876, 889 (M.D. Tenn. 2000). For purposes of FCA, a person acts knowingly if he: (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 of falsity of the information. 31 U.S.C. § 3729(b)(1)(3).

In 42 U.S.C. § 1395rr(b)(7), Congress established two methods to pay for home dialysis supplies and equipment used by beneficiaries when dialyzing: Method I for dialysis facilities and Method II for legitimate supply companies. 42 U.S.C. § 1395rr(b)(1)(B) authorizes Medicare to pay for "home dialysis supplies and equipment." Congress directed that Medicare could pay dialysis facilities directly for "home dialysis supplies and equipment "furnished to patients whose self care home dialysis was under the direct supervision of the dialysis facility, but only under Method I. 42 U.S.C. § 1395rr(b)(4)(A). Drawing sharp distinction between suppliers and dialysis facilities, Congress allowed Method II payments to suppliers only when their patients' home care was "not under the direct supervision of an approved provider . . . or renal dialysis facility." 42 U.S.C. § 1395rr(b)(4)(B); see also 42 U.S.C. § 1395rr(b)(1)(C) (authorizing payments to "suppliers" for drug erythropoietin only when the supplier was not a "renal dialysis facility" or "provider"). As pertinent here, Medicare pays 30% more to suppliers of CCPD dialysis supplies used at Medicare patients' homes under Method II than Medicare pays to dialysis facilities under Method I. 42 U.S.C. § 1395rr(b)(7). The Second Circuit provided an historical context of the Medicare Method I-II payment scheme:

> In 1972 Congress extended . . .coverage to individuals who have permanent kidney failure (regardless of age), and who therefore require transplantation or dialysis. 42 U.S.C. § 1395rr. In doing so, it established two alternative methods of payment, commonly known as "Method I" and "Method II". Method I provides for reimbursement by HHS to a certified facility for dialysis treatment administered by the facility. . . . Method II-now obsolete-provided for reimbursement by HHS to or on behalf of individuals for the costs of home dialysis supplies and equipment supplied by an entity other than a certified facility.

Nat'l Kidney Patients Ass'n v. Sullivan, 958 F.2d 1127, 1128 (D.C. Cir. 1992) (upholding Medicare's efforts to recover excessive Method II payments from provider).

The legislative history of these statutes confirm Congress's later clear intention to encourage home dialysis in an effort to reduce costs to the Medicare program and beneficiaries. In enacting the statute, Congress stated its intention to "provide incentives for more extensive use of lower cost medically appropriate self care dialysis settings" by providing coverage for suppliers and facility support services. S. Rep. 95-714, 1978 U.S.C.C.A.N 848, 849-50. With "Method II" payments, Congress sought "to allow the patient to make his or her own arrangements for supplies and equipment," with the expectation that "the patient" (and indirectly the program) would "save on coinsurance expenses." House Committee Report on Medicare and Medicaid Heath Budget Reconciliation Amendments, 101st Congress, 1st Session, August 1989, p. 40; see also "Medicare Program: Payment Change for Home Dialysis," 55 Fed. Reg. 53007-53011 (Dec. 26, 1990) (HHS's general comments regarding Method II payment when implementing payment scheme).

Congress delegated to HHS to determine the details for payment of home dialysis supplies. 42 U.S.C. § 1395rr(b)(7) directs HHS's Secretary to promulgate by regulations "a method or methods" to determine the amount of payments to be made for home dialysis supplies and equipment furnished to ESRD patients. After notice and comment, HHS enacted a 42 C.F.R. § 414.330 that permits payments for home dialysis supplies only when "the patients elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility." HHS also defined "dialysis facility" as an entity that "provides" outpatient maintenance dialysis services and/or home dialysis training and support services through its own staff and employees. 42 C.F.R. § 494.10. A "provider" is a hospital, skilled nursing facility, home health agency, clinic, rehabilitation facility or agency, or community mental health center.

In contrast, HHS defined "supplier" to mean "a physician or other practitioner, or an entity other than a provider that furnishes health care services under Medicare." 42 C.F.R. § 400.202 (emphasis added). In addition, HHS's regulations require that "supplier" to have a written contract with a "dialysis facility" within the patient's geographical area to provide support services and backup dialysis. 42 C.F.R. § 414.330(a)(2). In a word, under Method II, the supplier may not provide support services and the dialysis facility may not provide home dialysis supplies and equipment. 42 C.F.R. § 410.52.

In light of the relevant Medicare statutes, legislative history and regulations, the Court deems the Defendants' proof of RCG's disclosures to HCFA counsel and its various reports insufficient to bar FCA liability. The Defendants cannot effectively set aside these statutes and regulations and thereby Congress's intention by its cited contacts with Medicare officials. If the Medicare statutes or regulations were unclear and ambiguous, the Defendants' proof on their contacts and disclosures would be probative on the United States's FCA claim.

Under the earlier version of the FCA, Plaintiffs' proof must show that "the defendant intended the false record or statement be material to the Government's decision to pay or approve the false claim." Allison Engine Co., Inc. v. United States ex rel Sanders, 553 U.S. 662, 128 S. Ct. 2123, 2126 (2008). This "intent" requirement refers to the defendant's awareness that its statements would potentially be relied upon by the government, not to the defendant's awareness of the truth or falsity of its statement. Id. at n. 2 ("§ 3729(b) refers to specific intent with regard to the truth or falsity of the 'information,' while our holding refers to a defendant's purpose in making or using a false record or statement"). Congress, however, subsequently amended the FCA to overrule Allison Engine by removing from § 3729(a)(1)(B) the words "to

get" and substitute the words "material to." As amended, § 3729(a)(1)(B) imposes liability under the FCA if a defendant "knowingly makes . . . a false record or statement that is "material to" a false or fraudulent claim," P.L. 111-21, § 4(a) (emphasis added).[5] This amendment was to "take effect as if enacted on June 7, 2008," the date of the Allison Engine decision, and applies to all claims under the False Claims Act. . . that are pending on or after that date. Id. at § 4(f)(1).

In Medshares, the Sixth Circuit also adopted the implied certification theory, "which holds a defendant liable for violating the 'continuing duty to comply with the regulations on which payments is conditioned'" 400 F.3d at 454 n. 20; accord Augustine, 289 F.3d at 415 (a defendant "violates its continuing duty to comply with regulations on which payment is conditioned."). Reckless disregard is sufficient for FCA liability because a specific intent to defraud is not required under the FCA. See United States v. Krizek, 111 F.3d 934, 941-42 (D.C. Cir. 1997) (finding reckless disregard in submission of Medicare claims sufficient for FCA violation).

For the reasons stated earlier, namely, the clarity of the applicable Medicare statutes, their legislative history, and relevant Medicare regulations, the Court concludes that the Defendants exhibited reckless disregard of those legal mandates. The Defendants cannot effectively set aside those commands by their cited interactions with Medicare officials. The Defendants in some respects failed to heed the advice of their counsel to maintain RCGSC as a separate office.

[5]Material is now defined by the FCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 32 U.S.C. § 3129(b)(4).

Defendants contend that RCGSC's status presents a condition of participation in the Medicare program that is not actionable under the FCA. To be sure, the distinction between conditions of participation and conditions of payment is critical in FCA actions in some courts, including district courts in this circuit, that hold repeated violations of conditions of participation cannot give rise to a FCA claim. See e.g., Landers, 525 F. Supp. 2d at 978. See also Conner, 543 F.3d at 1220 (refusing to find FCA liability for alleged violation of conditions of participation because they are enforced by the Government through administrative mechanisms); United States ex rel. Mikes v. Straus, 274 F.3d 687, 692 (2d Cir. 2001); United States ex rel Gross v. AIDS Research Alliance-Chicago, 4 15 F.3d 601, 604 (7th Cir. 2005) (affirming dismissal and finding that "[a]n FCA claim premised upon an alleged false certification of compliance with statutory or regulatory requirements also requires that the certification of compliance be a condition of or prerequisite to government payment"); United States ex rel. Williard v. Humana Health Plan, 336 F.3d 375, 381-85 (5th Cir. 2003) (affirming dismissal of Medicare FCA claims because the alleged regulatory violations were not conditions of payment and the FCA "does not create liability for a healthcare provider's disregard of government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asked the government to pay amounts it did not owe."). These courts hold that violations of quality standards are addressed through CMS's administrative process, not FCA actions. See, e.g., Landers, 525 F. Supp. 2d at 978; Conner, 543 F.3d at 1220 (refusing to find FCA liability for alleged violation of conditions of participation because they are enforced by the Government through administrative mechanisms).

Yet, the Medicare statues and regulations at issue as well as the facts giving rise to the

creation of RCGSC clearly demonstrate to the Court that RCG's creation, operation and control of RCGSC was to receive the higher Method II payments. Thus, in the Court's view, this action involves a condition of payment, not a condition of participation.

Aside from its FCA claims, the Court concludes that the United States is also entitled to recover on its unjust enrichment claim. "The elements of a federal common law claim of unjust enrichment are: (1) the Government had a reasonable expectation of payment; (2) [the defendant] should reasonably have expected to pay; or (3) society's reasonable expectations of person and property would be defeated by nonpayment.'" United States v. Rogan, 459 F. Supp. 2d 692, 728 (N.D. Ill. 2006) aff'd, 517 F.3d 449 (7th Cir. 2008) (citations omitted).

Here, for the reasons discussed above, the Court concludes that Defendants RCG and RCGSC were "unjustly enriched [by] the retention of [a] benefit," Restatement of Restitution, § 1 (1937), namely Method II payments under Medicare statutes that should not have been paid to RCGSC. RCGSC was not a legitimate supplier of home dialysis supplies. The United States can recover the substantial benefits that accrued to RCG by virtue of its creation, operation and control of RCGSC such that RCG was the actual operating entity that received the Method II higher payments that RCG was ineligible to receive. See United States ex rel. Roberts v. Aging Care Home Health Inc., 474 F. Supp. 2d 810, 821 (E. D. La. 2007) ("Government is entitled to recover the amounts improperly paid to [the defendant]"). To allow RCG to retain the United States' payments undermines a clear Congressional mandate and would be inequitable. There is not any breach of contract remedy "because Medicare Provider Agreements create statutory, not contractual rights." Roberts, 470 F. Supp. 2d at 820.

The remedy for this unjust enrichment is to require the Defendants to return the net

reimbursement for all of RCGSC's Method II claims paid by Medicare during 1999-2005 minus the amount of Method I payments for the same time period. The United States calculates this amount at nineteen million three hundred sixty-six thousand seven hundred five dollars ($19,366,705) that represents a 22.5 % overpayment. (Docket Entry No. 1683-43 at 13). Although the Defendants calculate a lower amount, the Court adopts the 22.5% overpayment as a percentage that more likely corresponds to the 30% higher payment under Method II that gives rise to this action. To make the Government whole, the Court awards prejudgment interest from the date of the last improper payment to RCGSC until the judgment is paid as well as post-judgment interest. The rate of interest shall be determined under 28 U.S. C. §1961(a). With these conclusions, the Court deems it unnecessary to consider the United States' other claims.

For the reasons stated above, the United States's motion for partial summary judgment (Docket Entry No. 165) should be granted on counts one and six of its complaint. The Defendants' motion for summary judgment (Docket Entry No. 204) should be denied.

An appropriate Order is filed herewith.

ENTERED this the _____ day of March, 2010.

WILLIAM J. HAYNES, JR.
United States District Judge