RECOMMENDED FOR FULL-TEXT PUBLICATION
Pursuant to Sixth Circuit Rule 206

File Name: 12a0355p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA, ex rel., JULIE WILLIAMS, *Plaintiffs-Appellees,* JOHN MARTINEZ, M.D., *Plaintiff,* *v.* RENAL CARE GROUP, INC.; RENAL CARE GROUP SUPPLY COMPANY; FRENSENIUS MEDICAL CARE HOLDINGS, INC., *Defendants-Appellants.*	No. 11-5779

Appeal from the United States District Court
for the Middle District of Tennessee at Nashville.
No. 3:09-cv-738—William J. Haynes, Jr., District Judge.

Argued: July 25, 2012

Decided and Filed: October 5, 2012

Before: COLE and COOK, Circuit Judges; ROSEN, Chief District Judge.[*]

COUNSEL

ARGUED: James F. Bennett, DOWD BENNETT, LLP, St. Louis, Missouri, for Appellants. Michael P. Abate, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** James F. Bennett, Megan S. Heinsz, DOWD BENNETT, LLP, St. Louis, Missouri, Michael L. Dagley, Matthew M. Curley, BASS BERRY & SIMS, Nashville, Tennessee, for Appellants. Michael P. Abate, Michael S. Raab, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees.

COLE, J., delivered the opinion of the court in which, COOK, J., and ROSEN, C. D.J., joined. ROSEN, C. D.J. (pp. 22–25), delivered a separate concurring opinion.

---

[*]The Honorable Gerald E. Rosen, Chief Judge of the United States District Court for the Eastern District of Michigan, sitting by designation.

OPINION

COLE, Circuit Judge. Renal Care Group, Inc., a dialysis provider, created a wholly-owned subsidiary to take advantage of loopholes in the Medicare regulatory scheme that would permit it to increase profits. The United States, by and through its relators, brought suit against Renal Care Group, its subsidiary, and its successor, alleging that such actions constituted a number of False Claims Act violations. The district court granted summary judgment in favor of the United States as to the main claim, Count One—the only claim upon which damages were sought—and then proceeded to enter summary judgment as to the ancillary claims as well, though without explanation. For the reasons set forth below, we REVERSE the district court's judgments as to Counts One and Two, and GRANT summary judgment on those counts in favor of the defendants. Further, we REVERSE the district court's judgments as to all remaining counts and REMAND for proceedings consistent with this opinion, but DENY the defendants' motion for reassignment of this case to another district judge.

I. BACKGROUND

A. Factual Background

Renal Care Group, Inc. (RCG) was, for all times relevant to the instant case, the parent company of Renal Care Group Supply Company (RCGSC). Fresenius Medical Care Holdings, Inc., (Fresenius) is the successor-in-interest to both RCG and RCGSC. RCG provided dialysis to patients with end-stage renal disease (ESRD) at more than 260 RCG dialysis facilities, in addition to providing dialysis supplies and services to home dialysis patients. RCGSC, meanwhile, supplied only dialysis equipment to home dialysis patients. Both entities submitted claims for payment for these services to Medicare.

1. End-stage renal disease and Medicare

ESRD occurs when the kidneys are no longer able to function at a level needed for daily life because they are unable to remove waste and excess water from the body. Persons suffering from ESRD must undergo some form of kidney disease treatment, which may include either hemodialysis or peritoneal dialysis. Patients undergoing hemodialysis use a machine that removes blood from the body, runs it through a filter, and then returns the blood to the body. In peritoneal dialysis, a dialysis solution travels through a catheter into a patient's abdomen and draws wastes, chemicals, and extra water from blood vessels in the peritoneal membrane. The solution is then removed, and the process repeated. There are two types of peritoneal dialysis: continuous ambulatory peritoneal dialysis (CAPD), which requires no machine, and continuous cycler-assisted peritoneal dialysis (CCPD), in which a machine called a "cycler" fills and empties the abdomen while the patient sleeps.

In 1972, Congress expanded Medicare to provide insurance coverage for patients suffering from ESRD, regardless of their age. Pub. L. No. 92-603, § 2991, 86 Stat. 1329, 1463-64 (1972). In 1978, citing a need to lower costs, Congress amended the program to permit Medicare to reimburse dialysis facilities for the cost of home dialysis equipment. Pub. L. No. 95-292, § 2, 92 Stat. 307, 308 (1978). Initially, all services, including home dialysis, were reimbursed at a uniform composite weighted payment. Pub. L. No. 97-35, § 2145(a), 95 Stat. 357, 799-800 (1981). This reimbursement rate is known as "Method I" reimbursement.

The uniform Method I reimbursement rate did not apply to independent companies that provided only equipment and supplies (but not services) directly to home dialysis patients. Those companies were reimbursed under a "Method II" protocol, whereby payment is made on a "fee-for-service basis, which is the reasonable charge method used for [Medicare] Part B services." 57 Fed. Reg. 54,179 (Nov. 17, 1992). Method II reimbursements eventually became more expensive than Method I reimbursements. *See* H.R. Conf. Rep. No. 101-386, *reprinted in* 1989 U.S.C.C.A.N. 3018, 3429.

Congress eventually capped Method II payments at the Method I rate, except for payments for supplies for CCPD treatments, which were capped at 130% of the Method I rate. 42 U.S.C. § 1395rr(b)(7).

Congress further restricted Method II reimbursements with 42 U.S.C. § 1395rr(b)(4)(B), which permits such reimbursements only "to a supplier of home dialysis supplies and equipment furnished to a patient whose self-care home dialysis *is not under the direct supervision of an approved provider of services or renal dialysis facility* . . . ." (emphasis added). This was clarified in 1994, when Congress required that Method II payments may only go to an entity that is not "a provider of services [or] a renal dialysis facility . . . ." 42 U.S.C. § 1395rr(b)(1); *see also* 42 C.F.R. § 400.202 (defining a supplier as "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare"). Such an entity must obtain a supplier number before it can bill Medicare for supplies and equipment, 42 U.S.C. § 1395m(j)(1)(A), and may only be reimbursed if it is "not a Medicare approved dialysis facility," 42 C.F.R. § 414.330(a)(2)(i). In 2010, the Secretary for Health and Human Services eliminated Method II reimbursements altogether. 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).

2. Conversion of RCG patients to RCGSC patients

RCGSC had its basis in a 1997 e-mail written by Russell Dimmitt, RCG's director of material management, which compared Method I and Method II reimbursements. The e-mail made clear that Method II reimbursements were substantially higher, and would result in less overhead. A subsequent memorandum to RCG associates directed them to "convert CCPD Medicare patients to method 2." The memorandum also instructed associates to place new CCPD patients on Method II, even those who might initially be CAPD patients (which had an equivalent reimbursement rate for Method I CAPD patients), because the companies would "plan to convert them later."

RCGSC was formed in 1998 as a wholly-owned subsidiary of RCG, and RCG employees, officers, and directors all held key roles in RCGSC's corporate structure.

Gary Brukardt, RCG's chief executive officer, was also RCGSC's president. The companies shared office space, payroll, insurance benefits, contracts, and human resource services. Money deposited into RCGSC's account was swept into RCG's corporate account nightly, RCG's accounts payable department paid RCGSC's supply vendors, and RCGSC's director could not spend RCGSC's funds. All RCGSC employees were managed or directed by RCG employees. From 1999 to 2005, RCG and RCGSC received close to eighty-four million dollars in Medicare Method II reimbursements, comprising approximately seventy-seven percent of all Medicare reimbursements the two entities received.

On October 26, 1998, David Jones, RCG's chief operating officer for RCG's south central region, expressed his hesitation to convert Method I patients into Method II patients in an e-mail to Dimmitt. Jones wrote that such a plan "is not in the best interests of our patients. . . . I do not think it is legal to force our patients into a Method II arrangement simply to increase profits of our Company. I do not wish to go to jail . . . ." Jones left the company in 1999.

3. RCG's attempts for clarification

Around the time that Jones told Dimmitt that he believed RCG's plan was illegal, RCG itself began inquiring into the plan's legality. On October 28, 1998, Dawn Alexander, outside counsel for RCG, prepared a memo on "Method I v. Method II Issues." Alexander noted that a joint entity between a dialysis facility, like RCG, and another party could not be eligible for Method II reimbursements. She reserved judgment, however, on whether a wholly-owned subsidiary, like RCGSC, could do so, but noted that the Office of Inspector General (OIG) had issued a fraud alert concerning the use of shell corporations to maximize Medicare reimbursements. The OIG cautioned that hallmarks of such shell corporations could be that the parent corporation owned the capital equipment, and that the parent corporation was responsible for all day-to-day operations of the shell.

Alexander also sought clarification from Gene Richter, a federal official with the Health Care Financing Administration (HCFA), on the legality of establishing an entity

like RCGSC (though never mentioning either RCG or RCGSC). In a letter to Richter, Alexander referred to a previous conversation with Richter in which Alexander asked whether "a dialysis facility's wholly-owned subsidiary supply company could act as a Method II supplier," and noted that Richter's interpretation was that "as long as the wholly owned supply company has its own provider number and is established as a separate entity, it may act as a supplier for Method II patients [legally]." Richter's justification for this interpretation, Alexander memorialized, was "that there is now a payment cap on Method II payments that did not exist in the past." Alexander closed the letter by asking for confirmation that this understanding was correct. She received no response.

RCGSC underwent a Medicare site investigation in 2000 to ensure compliance with regulatory standards, and no referral of improper operations was made. Additionally, other supply companies, such as St. Louis Supply Company, Midwest Renal Support, and Dialysis Associates LLC, made clear in their Medicare disclosures that RCG either owned them outright or managed their day-to-day operations. RCGSC repeatedly disclosed to Medicare that it was owned by "RCGI" or RCG, and that it shared personnel, contracts, and insurance policies with RCG. RCG eventually closed RCGSC upon its merger with Fresenius in 2005.

B. Procedural Background

Also in 2005, two former RCG employees, Julie Williams and Dr. John Martinez ("the relators"), filed a *qui tam* action under the False Claims Act, 31 U.S.C. §§ 3729-33, against RCG and RCGSC in the United States District Court for the Eastern District of Missouri. The relators contended that RCGSC "is not a legitimate and independent durable medical equipment supply company," but a "billing conduit" used to unlawfully inflate Medicare reimbursements. Two years later, the United States intervened in the case, and the relators' claim was voluntarily dismissed.

The United States alleged that the defendants violated the False Claims Act by submitting claims while knowing that RCGSC was a sham corporation created for the sole purpose of increasing Medicare reimbursements (Count One); while knowing that

RCGSC was not in compliance with Medicare rules and regulations (Count Two); while knowing that RCGSC was misleading patients over their right to choose between Method I and Method II reimbursements (Count Three); and for facility support charges for services rendered to home dialysis patients who had selected Method II reimbursements (Count Four). The United States also sought recovery under common law theories of payment by mistake (Count Five) and unjust enrichment (Count Six). The district court denied the defendants' affirmative defenses of estoppel, waiver, and laches, noting that the government does not "waive a defendant's liability for false claims simply due to the government's knowledge of the circumstances." The defendants thereafter moved to transfer the case to the Middle District of Tennessee in the interests of justice, which was granted.

1. The Alexander letter

During discovery, the defendants sought evidence related to whether Medicare/Centers for Medicare and Medicaid Services (CMS) was aware of the RCG/RCGSC relationship. As part of this effort, they requested evidence related to CMS's consideration of Alexander's October 1998 letter to Richter. In September 2008, the United States denied that it was in possession of the letter. Richter also testified that the conversation described in the letter never occurred, and that he was positive that he had never received the letter.

In April 2009, a few weeks before the deadline for completion of all discovery, the United States informed defense counsel that responsive documents may have been inadvertently archived. Leila Carp, an attorney in the Office of General Counsel of the United States Department of Health and Human Services (HHS), had been asked by an HHS employee for assistance in drafting a response to the Alexander letter. Carp did so, and then archived the requested materials. The United States sent a letter explaining this to defense counsel and included a copy of the Alexander letter with a handwritten annotation in the corner reading, "assign to: Gene," as well as a privilege log indicating that a "[d]raft letter to Dawn Alexander discussing Method II" was being withheld for

"DP, AC." "DP" and "AC" stand for "deliberative process" and "attorney-client" privilege, respectively.

The defendants moved the district court to compel the United States to turn over the documents, as well as to provide unredacted versions of related documents that had already been provided. The defendants also moved the district court to impose sanctions on the United States for maintaining "for more than two years that Richter (a) did not recall having the conversation with Alexander and (b) did not receive the confirming letter sent by [Alexander]." The United States opposed the motion, contending that it "made good faith efforts to satisfy [its] discovery obligations[,] did not make false discovery responses, offer false deposition testimony, or coerce a partial waiver of the attorney client privilege." The district court denied both the motion to compel and the motion for sanctions without explanation.

2. The Initial Grant of Summary Judgment

Immediately prior to the case being transferred, the United States moved for partial summary judgment, but only as to the issues of falsity and materiality, two of the four elements of Count One (violating the False Claims Act by submitting claims to Medicare while knowing that RCGSC was a sham corporation), as well as liability under Count Six (the unjust enrichment claim). The United States noted that granting the motion would "streamline and greatly simplify the issues for trial, focusing the fact-finder on the key issues[,] defendants' knowledge under the FCA and the scope of any remedy to be awarded under Counts I and VI." The defendants also filed a motion for summary judgment, but as to all counts.

The district court granted the government's motion and denied the defendants' motion ("the March 2010 order"). It noted that the Defendants acted with "reckless disregard" of relevant Medicare statutes and regulations, and that in doing so they were unjustly enriched. It then adopted the United States's damages calculation and noted that it is "unnecessary to consider the United States'[s] other claims."

The defendants promptly appealed this and eleven other orders to this Court. The United States sought an indicative ruling from the district court clarifying, *inter alia*, whether the partial grant of summary judgment was in fact a total grant of summary judgment. In its ruling ("the June 2010 order"), the district court made clear that, "based on undisputed facts," it decided the issue of knowledge (an element of a False Claims Act allegation), even though the United States only sought summary judgment as to the issues of materiality and falsity in Count One. And, although the defendants had not discussed the issue of knowledge in their response to the United States's motion for summary judgment, the district court noted that by virtue of their own motion for summary judgment, the defendants "were on actual notice to come forth with all of their proof." The district court also made clear that it "would have also granted summary judgment on the United States's claims in Counts 2 through 5."

This Court denied the defendants' appeal because "the March [2010] order does not resolve all claims pending in this action, [so] the order is not appealable as a final order . . . ." *United States ex rel. Williams et al. v. Renal Care Group et al.*, No. 10-5327/5746 (6th Cir. Sept. 23, 2010). On remand, the United States requested an award under Count One of $105,898,930 and a grant of summary judgment as to Counts Two through Five. The district court granted that motion, but also reconsidered its previous damages calculations ("the May 2011" order). It clarified that "the United States seeks a judgment on the merits of all of its claims, but only an award of damages and penalties on its FCA claims in count one of its amended complaint." The award included $12,957,864 on Count One, which, because it was a False Claims Act liability, was trebled for a total damage award of $38,873,592. Additionally, the district court granted statutory penalties of $43,769,000 based on its determination that the defendants "admitted 3979 patients to whom equipment was provided under the Method II program and the $11,000 statutory penalty standard" under the False Claims Act. Thus, the total award equaled $82,642,592.

The United States notified the district court that it did not intend to seek a higher amount of damages. The district court then issued another indicative ruling, noting that

the March 2010 order "was a final judgment awarding damages on count I," and the May 2011 order "awarded the United States judgment against the Defendants on the remaining counts II-VI and awarded damages." The defendants timely appealed fourteen of the district court's orders to this Court.

II. ANALYSIS

A. Discovery Disputes

The defendants appeal two of the district court's discovery rulings. First, they contend that the district court erred in failing to issue sanctions against the United States over the Alexander letter/Richter response. Second, they contend that the documents protected by the deliberative process privilege should have been produced. We review the district court's rulings on these discovery disputes for an abuse of discretion. *Bentkowski v. Scene Magazine*, 637 F.3d 689, 696 (6th Cir. 2011). "[A]n abuse of discretion occurs when (1) the district court's decision is based on an erroneous conclusion of law, (2) the district court's findings are clearly erroneous, or (3) the district court's decision is clearly unreasonable, arbitrary or fanciful." *Tisdale v. Fed. Express Corp.*, 415 F.3d 516, 525 (6th Cir. 2005) (alterations and quotations omitted).

1. The Alexander letter

The defendants' motion for sanctions had been premised on a number of issues surrounding the Alexander letter and CMS officials' response to it. These included the filing of interrogatories and document request responses that contained false information, as well as the testimony of Richter, who stated under oath that he was positive that the exchange with Alexander had never taken place. In their motion, the defendants requested the dismissal of the entire action as sanction, but did not indicate whether the sanctions should be awarded pursuant to any particular Federal Rule of Civil Procedure or under the district court's inherent authority. The district court denied the defendants' motion for sanctions without discussion.

Factors to consider in determining whether the district court abused its discretion in failing to award sanctions include "prejudice resulting from the discovery abuse,

whether the noncooperating party was warned that violations would result in sanctions, and whether the court considered less drastic sanctions." *Id.* Two of the three factors outlined in *Tisdale* are at issue here and weigh in the defendants' favor. First, Richter's false testimony and the United States's late turnover of the Alexander letter prejudiced the defendants' ability to meaningfully depose Richter, which would have assisted in their efforts to prove that they were not in reckless disregard of the truth of their requests for payment. Second, although the defendants requested particularly strident sanctions—the dismissal of the complaint with prejudice—they also requested the "intermediate, interim relief" of "compelling Richter to appear for re-deposition at the government's expense" and "precluding [the United States] from enlarging upon the waiver of Defendants' privileges." Although the United States contends that no prejudice resulted because "the alleged conversation with Richter was not even the primary basis for the lawyers' advice to [the defendants]," such a position is far too reliant on questionable inferences drawn from out-of-context statements by Alexander.

We have previously remanded close questions regarding a motion for sanctions if the district court's denial of sanctions lacks explanation, *Moross Ltd. P'ship v. Fleckenstein Capital, Inc.*, 466 F.3d 508, 519-20 (6th Cir. 2006), and do so here. This issue, of course, may become moot should the defendants not seek to depose Richter again; assuming otherwise, their request to do so should be granted.

2. Documents protected by deliberative process

The defendants requested documents related to CMS's interpretation of the relevant Medicare provisions and its knowledge of industry practice. The United States refused, submitting instead a privilege log showing that the documents were protected by the deliberative process privilege. The district court denied the defendants' motion to compel the production of 323 documents, stating that "the materials are both predecisional and deliberative" and that "[i]n the absence of a showing that the privilege is claimed in error or in bad faith, no *in camera* review is warranted."

The deliberative process privilege, a carve-out of the Freedom of Information Act (FOIA), 5 U.S.C. § 552, aims to protect documents that are both "predecisional" and

"deliberative." *Norwood v. FAA*, 993 F.2d 570, 576 (6th Cir. 1993). "A document is predecisional when it is received by the decisionmaker on the subject of the decision prior to the time the decision is made, and deliberative when it reflects the give-and-take of the consultative process." *Id.* (quotation marks and alterations omitted). The privilege extends when "the disclosure of materials would expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions." *Id.* at 577 (quotation marks omitted). Purely factual and investigative matters that are severable without compromising the confidentiality of other documents do not enjoy the privilege. *Id.*

We have previously held that the district court must be aware of "how each document fits into the deliberative process" and whether it is an "essential element of that process . . . ." *Parke, Davis & Co. v. Califano*, 623 F.2d 1, 6 (6th Cir. 1980). Given that FOIA encourages complete disclosure, the privilege may only be invoked with specificity and "detailed explanations," and the burden lies with the agency to prove that disclosure would create a chilling effect. Id. In camera review may be undertaken by the district court after consideration of judicial economy, agency bad faith, strong public interest, and the parties' wishes. *Rugiero v. U.S. Dep't of Justice*, 257 F.3d 534, 543-44 (6th Cir. 2001). "This circuit, however, encourages use of *in camera* review sparingly, when no other procedure allows review of the agency's response to a FOIA request." *Id.* at 544. One such alternative procedure is a detailed affidavit, which is entitled to a presumption of good faith. *Id.* The affidavit is sufficient if it describes "the content of the material withheld and adequately states its grounds for nondisclosure, and if those grounds are reasonable and consistent with the applicable law . . . ." *Id.*

The United States provided an eight-paragraph listing of the documents contained in the privilege log, as well as declarations and testimony from government officials employed by the Office of Inspector General. The affiants do not discuss each of the 323 documents individually, but place them in categories, and then discuss why each category is covered by the deliberative process privilege. Total materials submitted

in defense of the privilege's assertion include more than sixty pages of deposition testimony, and thirty pages of affiant declarations . The materials covered solely by the deliberative process privilege (and not also covered by attorney work product or other privileges) include HHS e-mails on agency comments and clearance of OIG draft reports, e-mails on a draft of an agency's report, e-mails comprising suggestions on a draft OIG report, and correspondence on a draft ESRD publication. The affiants' declarations, which carry a presumption of good faith, explain the nature of the documents, how disclosure would affect the agency process, and are not blanket assertions. The district court did not abuse its discretion in denying the defendants' motion to compel.

B. Count One

The complaint against the defendants centers around RCGSC's requests for Method II reimbursements. A number of other actions were also alleged to be false claims violations, though there is little in the way of factual development that provides us with a basis to affirm or reverse the district court's decisions on those claims. The United States made clear to the district court that it would not seek damages under those ancillary counts if the defendants were liable under Count One, and the district court's damages calculations were based entirely on the conduct alleged under Count One of the complaint.

For a defendant to be liable under the False Claims Act, it must knowingly present, or cause to be presented, "a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Liability does not require proof of specific intent to defraud, 31 U.S.C. § 3729(b)(1)(B), but does require that the falsity be material to the claim, *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp. Inc.*, 400 F.3d 428, 444 (6th Cir. 2005). The defendants put forth two distinct bases for their position that their actions do not constitute False Claims Act violations. First, they contend that the United States's interpretation of the federal laws and regulations at issue is erroneous, and that the submitted reimbursements were not in fact false. Second, they contend that even if the claims technically were false, the statutory guidance is ambiguous, such that

they did not act with the requisite knowledge to be held liable under the False Claims Act. We address both in turn.

1. Falsity

The district court's March 2010 order provides minimal insight into whether a separately incorporated entity with its own Medicare supplier number was an entity eligible for Method II reimbursements. After conducting a lengthy inquiry into the origins of Medicare's regulations for Method II reimbursements, the district court concluded that "RCG's creation, operation and control of RCGSC was to receive the higher Method II payments." The district court did not, however, articulate any reason as to why this was inherently improper. Indeed, it stated that Congress passed relevant Medicare regulations that would reimburse "legitimate supply companies," but the statute at issue in that discussion, 42 U.S.C. § 1395rr(b)(1)(B), highlights only that home dialysis supply companies are eligible for Medicare reimbursement.

The United States's argument boils down to this: dialysis facilities may not seek Method II reimbursements, and RCGSC was an alter ego of RCG, a dialysis facility; ergo, RCGSC improperly sought Method II reimbursements. The flaw in the argument, however, is that it misunderstands the contours of our alter-ego jurisprudence. As became clear during oral argument, the United States focuses, somewhat obsessively, on evidence demonstrating that RCG sought Method II reimbursements for the sole purpose of increasing its profit margins.

Why a business ought to be punished solely for seeking to maximize profits escapes us. The corporate form need not be disregarded when its adoption was meant to "secure its advantages and where no violence to the legislative purpose is done by treating the corporate entity as a separate legal person." *Schenley Distillers Corp. v. United States*, 326 U.S. 432, 437 (1946). The United States does not, however, identify any clear legislative purpose emanating from either the text of 42 U.S.C. § 1395rr or from the legislative materials predating its passage. Its failure to do so is fatal for its assertion of the alter-ego doctrine, for we are similarly unable to divine any such purpose from the scheme transgressed by the defendants' acts.

Courts have not addressed why Congress adopted a bifurcated reimbursement model for home dialysis ESRD suppliers. In the statutory text, Congress made clear that it wanted to encourage ESRD patients to have dialysis at home in order to reduce costs for the patient and Medicare. 42 U.S.C. § 1395rr(b)(3)(B) (requesting the HHS Secretary to promulgate ESRD reimbursement methods which will "effectively encourage[] the efficient delivery of dialysis services and provide incentives for the increased use of home dialysis"); *see also* 75 Fed. Reg. 49, 030-01, 49, 062 (Aug. 12, 2010) ("[T]here remain very good reasons to develop and expand home [peritoneal dialysis] programs. For example, PD treatment costs considerably less than comparable in-facility treatments."). But Method I and Method II both apply to home dialysis suppliers—the only difference is that Method I suppliers also offer support services. Based on the structure of the statute, Congress seems to have differentiated between Method I and Method II for two reasons: first, to ensure that home dialysis patients could engage in cost comparisons for their supplies and purchase dialysis supplies and equipment from a broader range of providers; and second, to make clear that Method II suppliers would have to have some type of written agreement with their patients, ensuring that support services would be offered if necessary. *See* 57 Fed. Reg. 54, 179, 54, 179 (Nov. 17, 1992) ("Method II is an alternative to Method I which allows the beneficiary to make his or her own arrangements for supplies and equipment."). Neither of these purposes are violated by allowing RCGSC to receive Method II reimbursements.

The relevant statute, 42 U.S.C. § 1395rr(b)(4)(B) precludes Method II payments to dialysis suppliers that are also "renal dialysis facilit[ies]," and 42 C.F.R. § 400.202 defines a "supplier" as "an entity other than a provider, that furnishes health care services under Medicare." Other federal regulations provide insight into what an "entity" is, which, in many ways, is the key question—whether RCGSC is an "entity" for purposes of 42 C.F.R. § 400.202. *See* 42 C.F.R. § 1001.1001 (allowing the Office of Inspector General to exclude entities from participation if certain individuals have a direct or indirect ownership of five or more percent in the entity); 42 C.F.R. § 73.7 (articulating when an entity—there, a private institution of higher education—is

controlled by another); 42 C.F.R. § 420.206 (discussing what information about an entity's ownership structure needs to be disclosed). Additionally, federal regulations routinely address the common ownership/control inquiry. *See* 42 C.F.R. § 417.484 (defining a "related entity" as "any entity that is related to the [party] by common ownership or control . . . ."); 42 C.F.R § 433.52 (noting that an "entity related to a health care provider" is, *inter alia*, "an organization, association, corporation, or partnership formed by or on behalf of a health care provider"); 42 C.F.R. § 423.501 ("Related entity means any entity that is related . . . by common ownership or control . . . ."). Although not dispositive, these regulations suggest that an organization can be controlled by another and yet still be considered an "entity" for purposes of Method II reimbursement.

All of this points to the conclusion that the structure of RCG and RCGSC is not obviously inconsistent with Congress's goals for the payment scheme. As the district court noted, "[i]f 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." We agree, and therefore must next answer the question of whether the defendants' actions constituted reckless disregard of the relevant federal statutes and regulations.

2. Knowledge

The defendants contend that they did not knowingly submit false claims; that is, that they did not know, at the time that the claims were submitted, that RCGSC was not a valid entity for purposes of receiving Method II reimbursements. The United States's original motion for summary judgment was limited to two of the four elements of a False Claims Act violation—falsity and materiality. The defendants moved for total summary judgment, but the theory underlying that motion was specific to the element of falsity. The district court, however, answered the question of knowledge as well, noting that the Defendants acted with "reckless disregard" of relevant Medicare statutes and regulations. This determination is reviewed de novo. *See United States ex rel. Schell v. Battle Creek Health Sys.*, 419 F.3d 535, 537-38 (6th Cir. 2005).

For a defendant to be liable under the False Claims Act, it must have acted knowingly; such knowledge can be actual, 31 U.S.C. § 3729(b)(1)(A)(i), or constructive, either because it acted in deliberate ignorance of the truth, 31 U.S.C. § 3729(b)(1)(A)(ii), or in reckless disregard of it, 31 U.S.C. § 3729(b)(1)(A)(iii). The "reckless disregard" prong was enacted in a 1986 amendment to the False Claims Act, and what appears to be the only congressional report accompanying that bill states that the obligation is "to make such inquiry as would be reasonable and prudent to conduct under the circumstances. . . . Only those who act in 'gross negligence' of this duty will be found liable under the False Claims Act." S. Rep. 99-345, at 20, 1986 U.S.C.C.A.N. 5266, 5285. The provision is meant to target that defendant who has "buried his head in the sand" and failed to make some inquiry into the claim's validity. *Id* at 21, 1986 U.S.C.C.A.N. at 5286. The inquiry, however, need only be "'reasonable and prudent under the circumstances,' which clearly recognizes a *limited duty to inquire as opposed to a burdensome obligation*." *Id.* (emphasis added).

In *United States ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296 (6th Cir. 1998), the defendant was accused of violating the False Claims Act by failing to comply with a testing requirement for Army jeep brake shoes that it supplied. This Court affirmed the district court's grant of summary judgment in favor of the United States, noting that the defendant had a reckless disregard for the falsity of its claims for payment:

> Midwest's president testified in his deposition that he knew the plug-welded brake shoes were subject to the testing requirement. Despite knowledge of this requirement, Midwest did not test the brake shoes as required by the contracts. Midwest then submitted claims for payment to the government attesting that the brake-shoe kits conformed to contract requirements. This is sufficient to constitute "reckless disregard" of the truth of its representations as to contract compliance.

Id. at 304. No similar allegations are made here by the United States—there is no claim that RCG or RCGSC officials knew that submitting Method II claims by a wholly-owned subsidiary ran afoul of the Medicare regulations. Rather, the United States contends that

the regulations were clear that wholly-owned subsidiaries were ineligible, and that reliance on statements by government officials could not surmount such clear direction.

Other circuits have had the opportunity to define the exact contours of the "reckless disregard" standard. *See United States ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) ("Reckless disregard under the FCA is an extreme version of ordinary negligence.") (quotation marks omitted); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 945 n.12 (10th Cir. 2008) (equating "reckless disregard" with "an aggravated form of gross negligence"); *see also United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Grp., Inc.*, 370 F. Supp. 2d 18, 41 (D.D.C. 2005) ("Reckless disregard, as used in the False Claims Act, lies on a continuum between gross negligence and intentional harm.") (quotation marks and emphasis omitted). Given that 1) the defendants sought legal counsel on this issue; 2) defendants' legal counsel sought clarification on the rules from CMS officials; 3) the Alexander letter referenced a positive conversation with Richter, and her notes and billing records reflect as such; 4) the defendants were aware of large dialysis providers that had wholly-owned subsidiaries filing for Method II reimbursements; 5) industry publications openly encouraged the use of Method II reimbursements to increase profit; 6) RCGSC was a separately incorporated entity with its own Medicare supplier number; and 7) CMS and OIG knew of RCGSC's ownership structure, the defendants were not in reckless disregard of the truth or falsity of their claims. Rather, they consistently sought clarification on the issue, followed industry practice in trying to sort through ambiguous regulations, and were forthright with government officials over RCGSC's structure. To deem such behavior "reckless disregard" of controlling statutes and regulations imposes a burden on government contractors far higher than what Congress intended when it passed 31 U.S.C. § 3729(b)(1)(A)(iii).

The defendants did not act with reckless disregard of the alleged falsity of their submissions to Medicare. And given that there is no evidence in the record that they acted with actual knowledge (in violation of 31 U.S.C. § 3729(b)(1)(A)(i)), or in deliberate ignorance of the truth (in violation of 31 U.S.C. § 3729(b)(1)(A)(ii)), they are

therefore not liable under Count One of the complaint for False Claims Act liability. As such, we need not address their claim of error regarding the district court's damages calculations.

C. Counts Two Through Six

The district court granted summary judgment, without explanation, as to the remainder of the United States's substantive claims against the defendants. There is little in the record for us to review as to those counts, and what little we can find must be gleaned from the vague language in the initial complaint. As such, we are unable to review substantively the district court's judgments as to the majority of those claims.

The one exception to this, however, is Count Two, which alleges that the defendants violated the False Claims Act by "submitting false and fraudulent claims . . . knowing full well that RCGSC was merely a billing conduit [that] was not in compliance with the durable medical equipment supplier standards set forth at 42 U.S.C. § 1395m and 42 C.F.R. § 424.57." For a dialysis supplier like RCGSC to receive reimbursement, it "must meet and must certify in its application for billing privileges that it meets and will continue to meet" certain standards, including honoring warranties, filling orders from its own inventory or via contract, and maintaining an appropriate place of business. 42 C.F.R. § 424.57(c). The provision also has an independent sanction. 42 C.F.R. § 424.57(d) ("CMS will revoke a supplier's billing privileges if it is found not to meet the [applicable standards]."). The defendants contend that violations of such conditions do not render a claim materially false, and thus may not subject them to False Claims Act liability.

The defendants are correct, irrespective of whether they in fact violated the regulations. The False Claims Act is not a vehicle to police technical compliance with complex federal regulations. *See, e.g., United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011) ("[An allegation] that appellees violated the regulations do[es] not state a plausible claim for relief under the FCA inasmuch as the Government's payments of appellees' Medicare claims were not conditioned on their compliance with the marketing regulations."); *United States ex rel. Gross v. AIDS*

Research Alliance-Chicago, 415 F.3d 601, 604 (7th Cir. 2005) ("An FCA claim premised upon an alleged false certification of compliance . . . also requires that the certification of compliance be a condition of or prerequisite to government payment.") (alteration omitted); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) ("[T]he punitive treble damages and penalties afforded by civil FCA actions are not interchangeable with remedies for ordinary breaches of contract."); *United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 679 (N.D. Miss. 2011) ("Defendants cannot be held to have submitted false claims where the governmental agency charged with compliance certified that [the defendant] was in compliance with the regulations."); *Hansen v. Freedom Mobility, Inc.*, No. 5:08-CV-131, 2009 WL 3784958, at *2 (W.D.N.C. Nov. 10, 2009) ("Failure to comply with regulations regarding billing or insurance might result in removal of Medicare billing privileges by the government, but would not establish any tort or negligence liability here.") (citation omitted); *United States ex rel. Landers v. Baptist Mem'l Health Care Grp.*, 525 F. Supp. 2d 972, 978-79 (W.D. Tenn. 2007) (precluding False Claims Act liability for violations of conditions of participation, which are "the requirements providers must meet to participate in the Medicare program," because the HCFA/CMS forms do not expressly or impliedly condition payment upon compliance with participation conditions) (citation and alteration omitted).

The regulations set forth in the United States's complaint are conditions of participation, the violation of which do not lead to False Claims Act liability. Consequently, the district court erred in granting summary judgment in favor of the United States on this claim, and the defendants' motion for summary judgment as to Count Two is granted. There is insufficient evidence in the record, however, for us to conduct a similar analysis as to the remaining counts, and we therefore reverse and remand those district court judgments for further proceedings that are consistent with this opinion, if necessary.

D. Reassignment

Finally, the defendants ask that the case be reassigned to another district judge if a remand is necessary. To determine whether reassignment is necessary, the following factors are considered:

> (1) whether the original judge would reasonably be expected to have substantial difficulty in putting out of his or her mind previously expressed views or findings; (2) whether reassignment is advisable to preserve the appearance of justice; and (3) whether reassignment would entail waste and duplication out of proportion to any gain in preserving the appearance of fairness.

Solomon v. United States, 467 F.3d 928, 935 (6th Cir. 2006). Reassignment "is an extraordinary power and should be rarely invoked." *Id.* (quotation marks omitted).

There is no question that this is a case with a "complex factual record." *Hamad v. Woodcrest Condo. Ass'n*, 328 F.3d 224, 239 (6th Cir. 2003) (declining reassignment based, in part, on the "extensive joint appendix and hundreds of pages of briefs"). And, unlike our decisions in other cases supporting reassignment, there are no comments made by the district court here that would undermine the appearance of justice. *See, e.g.*, *United States v. Gapinski*, 422 F. App'x 513, 521-22 (6th Cir. 2011) (listing a series of statements by the district court that warranted reassignment). False Claims Act cases are exceedingly fact-determinative and technical, and mistakes of law should not warrant the use of a tool that should be wielded with "the greatest reluctance," *Solomon*, 467 F.3d at 935. The defendants' request for reassignment is therefore denied.

III. CONCLUSION

The district court's judgments as to Counts One and Two are REVERSED, and the defendants' motion for summary judgment as to those counts is GRANTED. The district court's judgments as to all remaining counts are REVERSED and REMANDED for further proceedings consistent with this opinion, but the defendants' motion for reassignment is DENIED.

CONCURRENCE

ROSEN, Chief District Judge, concurring. I concur with the majority's decision to reverse the district court's grant of summary judgment in favor of the plaintiff United States of America on Counts One and Two of the complaint, and to instead award summary judgment in the defendants' favor on these claims. As the majority observes, the Government's claim in Count One rests upon the proposition that defendant Renal Care Group Supply Company ("RCGSC") did not qualify as a separate "entity" from its parent corporation, defendant Renal Care Group, Inc. ("RCG"), and the numerous subsidiaries of RCG that operated renal dialysis facilities, so that RCGSC therefore was ineligible for so-called "Method II" reimbursement under the pertinent Medicare statutory provisions and regulations. I write separately to emphasize that the governing statutory and regulatory scheme offers virtually no signposts for resolving this key question of RCGSC's eligibility for Method II payments, and to explain why, in my view, this uncertainty alone leads fairly directly to the conclusion that the evidence marshaled by the Government fails as a matter of law to establish the "knowledge" element of its Count One claim under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33.

As is evident from the majority opinion, it is no simple task in this case to determine whether the claims submitted by RCGSC for Method II reimbursement truly qualified as "false" within the meaning of the FCA. In asserting that these claims were indeed false, the Government relies principally upon statutory language that authorizes Method II payments to a "supplier of home dialysis supplies and equipment" only if this supplier "is not a provider of services [or] a renal dialysis facility." 42 U.S.C. § 1395rr(b)(1)(C). As explained by the majority, the Government maintains that RCGSC failed this test for Method II reimbursement because it was a mere alter ego of its parent company, RCG, which in turn had a number of other subsidiaries that operated renal dialysis facilities. The defendants, in contrast, argue that RCGSC was a separate

legal entity from the RCG subsidiaries that provided renal dialysis services, and that this supply company therefore was eligible for Method II payments by virtue of its separate corporate existence.

The crux of the parties' dispute, then, is the degree of "separateness" demanded under the pertinent Medicare statutory provisions and regulations in order for a supplier to be deemed "not a provider of services [or] a renal dialysis facility." As the defendants observe, there is no basis in the Medicare statute or its implementing regulations for concluding that a Method II supplier must be wholly independent from any service provider or renal dialysis facility, without any corporate affiliation whatsoever. On the other hand, there surely must come a point at which a supplier could be deemed "separate" from a service provider or dialysis facility in only the most formalistic or technical sense, with one of these two entities being a mere shell of the other.

Accordingly, to determine whether RCGSC's claims for Method II reimbursement were false, we must first ascertain where Medicare draws this line, and then decide whether the defendants crossed it. Yet, upon reviewing the various Medicare provisions and regulations cited by the parties, I see no clear answers to these questions, nor even a fixed, determinate set of criteria that a supplier must meet in order to be considered a separate "entity" from an affiliated service provider or renal dialysis facility. The majority evidently shares my reluctance to declare that RCGSC's Method II claims either were or were not false, as it concludes only that "the structure of RCG and RCGSC is not obviously inconsistent with Congress's goals" in creating the Method I/Method II reimbursement scheme. (Majority Op. at 19.)

Against this backdrop, I agree with the majority that the Government cannot show that RCGSC's claims for Method II reimbursement reflected a reckless disregard of the relevant Medicare statutes and regulations. As the majority observes, it certainly made business sense for RCG and its subsidiaries to attempt to secure a greater share of the more lucrative Method II payments, provided that this profit-maximizing goal could be lawfully achieved. As it commenced this effort, RCG took a number of steps to ensure that its newly formed subsidiary, RCGSC, was eligible for Method II

reimbursement as a supplier of home dialysis supplies and equipment, including (i) engaging a law firm to analyze this issue, and (ii) reaching out to federal agency officials to obtain their views on the lawfulness of the parent/subsidiary relationship between RCG and RCGSC. RCG then largely followed the advice it received through these communications with counsel and with federal officials, creating RCGSC as a separate entity with its own Medicare provider number. In addition, RCG took steps to ensure the separate corporate existence of RCGSC and the RCG subsidiaries that operated renal dialysis facilities; although parent RCG provided payroll, legal, human resources, and accounting support for RCGSC's operations, furnished office space to this subsidiary, and allowed RCGSC to obtain supplies through RCG's contracts with various manufacturers, the defendants state without contradiction that there was no similar sharing of office space, employees, or resources among RCGSC and any of the RCG subsidiaries that provided renal dialysis services. Finally, the defendants divulged this chosen corporate organizational scheme to the Government on a number of occasions over the years, including in Medicare re-enrollment applications and in audits and inspections, without ever being advised that this arrangement was problematic.

To be sure, there were a few "storm warnings" along the way that raised questions about the legality of RCGSC's claims for Method II reimbursement. Yet, in each such instance, RCG made further inquiries to satisfy itself that its supplier subsidiary was acting in accordance with the relevant Medicare statutes and regulations. For instance, when the chief operating officer of RCG's South Central Region, David Jones, expressed concern in an October 1998 e-mail that RCG's proposed plan to obtain Method II payments might be an illegal scheme "simply to increase profits of our Company," the company did not ignore this warning or sweep it under the rug. Instead, Jones's message was forwarded to a number of senior company officials, who in turn continued their exploration, through outside counsel and contacts with federal officials, into the lawfulness of Method II reimbursement through a supplier subsidiary. Similarly, when RCG later learned that a competitor, Gambro Healthcare, was under federal investigation, resulting in a Gambro subsidiary pleading guilty to health care

fraud related to its Method II billing, company officials reviewed RCGSC's operations to ensure that RCG's supplier subsidiary was not operating in a similar fashion.[1]

In short, when RCG sought to increase its profits through greater utilization of Method II reimbursement, it elected to accomplish this objective by forming a wholly-owned subsidiary, RCGSC. In order for this supplier to lawfully collect Method II payments, RCG had to ensure that this newly-formed subsidiary was sufficiently separate and distinct from other RCG subsidiaries that provided dialysis services, such that RCGSC would not also be deemed "a provider of services [or] a renal dialysis facility." 42 U.S.C. § 1395rr(b)(1)(C). Although the district court construed the pertinent Medicare statutes and regulations as clearly prohibiting the parent/subsidiary arrangement adopted by RCG, my colleagues and I agree that the statutory scheme provides little or no guidance as to whether and how suppliers and service providers may co-exist within the same corporate family tree. Faced with this unclear and ambiguous statutory scheme, RCG sought the advice of counsel and federal officials as to whether its plan for Method II reimbursement was lawful, and it made no secret of the corporate arrangement it had chosen to pursue Method II payments. Under this record, I cannot see how the defendants could be found to have acted in reckless disregard of the Medicare statutes and regulations governing Method II reimbursement. Because the majority reaches this same conclusion, I join in its decision.

[1]As the defendants observe, the federal criminal charge against Gambro's subsidiary, REN Supply Corporation, was based on REN's failure to disclose that Gambro was its parent company. Although RCGSC's initial 1999 application for a Medicare supplier number suffered from a similar defect — *i.e.*, a failure to identify RCG as the parent of this supplier — RCGSC's subsequent renewal applications correctly disclosed this parent/subsidiary relationship, as did other communications with Government officials during the relevant period.