IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
DELTA DIVISION

UNITED STATES OF AMERICA,
ex rel, THOMAS F. JAMISON PLAINTIFFS

V. CAUSE NO.: 2:08CV214-SA-DAS

MCKESSON CORPORATION, et al. DEFENDANTS

MEMORANDUM OPINION

The parties[1] have filed the following motions:[2]

(1) The Beverly Defendant's Motion for Summary Judgment [111] on the basis of res judicata and collateral estoppel;

(2) The United States' Motion for Partial Summary Judgment [113] as to Counts III, IV, V, and VI;

(3) The Beverly Defendant's Cross-Motion for Partial Summary Judgment [132] on Counts III, IV, V, and VI;[3] and

(4) The McKesson Defendant's Motion for Partial Summary Judgment [141] as to Counts I and III, including portions of IV, V, and VI.

The Court finds as follows:

---

[1]Pursuant to the Court's earlier opinions, unless individual recognition is necessary, GGNSC Holdings, LLC, Golden Gate Ancillary, LLC, Beverly Enterprises, Inc., Ceres Strategies, Inc., and Ceres Strategies Medical Services, LLC (CSMS), will be referred to as the "Beverly Defendants," and McKesson Corporation and McKesson Medical-Surgical MediNet, Inc., will be referenced as the "McKesson Defendants."

[2]The United States has filed an Appeal of the Magistrate Judge's Order [199] denying its motion to compel production of documents. The appeal will be addressed in a later memorandum opinion.

[3]The United States has also filed a Motion for Leave to File a Supplemental Memo [180] in response to the Beverly Defendant's Cross-Motion. To the extent that the Court acknowledges Janet Houston to be the author of the previously-anonymous comment, that motion is granted.

Factual and Procedural Background

In 1998, Beverly Enterprises formed Ceres Strategies, Inc., to serve as the procurement arm for the company's nationwide conglomeration of more than three hundred skilled nursing facilities. When Beverly's contract with its enteral nutrition supplier was set to expire, Ceres set up Ceres Strategies Medical Services, LLC, (CSMS) to supply enteral nutrition, urological, and ostomy products to Beverly's nursing facilities. Ceres intended for CSMS to apply for and receive its own Medicare Part B durable medical equipment, prosthetics, orthotics and supplies (DMEPOS or DME) supplier number. CSMS solicited requests for proposals to engage a billing agent and received four bids. McKesson Medical-Surgical MediNet, Inc., (MediNet) was one of the bidders. MediNet is a Medicare Part B supplier itself and also specializes in billing and collection services.

CSMS submitted its application for enrollment as a DME supplier in February 2003 to the Centers for Medicare and Medicaid Services (CMS). CMS is the federal agency within the United States Department of Health and Human Services charged with administration of the Medicare program. As part of the application, CSMS certified that it "read, underst[ood], m[et] and w[ould] continue to meet all supplier standards as outlined in 42 C.F.R. § 424.57." The regulation section cited in that certification concerned what was known at the time as the "21 Supplier Standards" that a DMEPOS supplier must meet "in order to be eligible to receive payment for a Medicare-covered item."[4]

CMS contracted out its DME supplier enrollment and verification responsibilities to the Palmetto GBA National Supplier Clearinghouse (NSC). That entity was charged with ensuring only

[4]The Supplier Standards at issue are further outlined in the text of this opinion.

companies compliant with the Supplier Standards were certified to participate in the Medicare program and revoking enrolled suppliers who no longer satisfied those Supplier Standards.

At the time of enrollment, an NSC representative inspected CSMS's premises, reviewed documents, and declared it eligible to receive a DMEPOS supplier number. Claims for payment to Medicare were submitted under CSMS' supplier number in June of 2003.

In October of 2006, CSMS was again inspected by NSC for compliance upon re-enrollment of its supplier number. The inspector took pictures, viewed documents, and attached exhibits to his report. CSMS was again found in compliance with Medicare standards, and its supplier number was re-activated.[5]

A. First Administrative Proceeding

Following a March 6, 2007 on-site visit, NSC notified CSMS by letter dated March 23, 2007, that it was in violation of one or more of the 21 DMEPOS Supplier Standards.[6] In particular, NSC determined that CSMS violated the following standards for these reasons:

Standard One: A supplier "[o]perates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements."

> *A recent site visit and review of your Medicare file reveals that your company is dispensing enteral nutrition supplies to beneficiaries, in states other than Arkansas, which may require you to obtain Sales Tax Permits and DME licenses from the corresponding state licensing agencies permitting you to do so. Please provide copies of these licenses for the states that you are providing these services to or*

[5]CSMS's supplier number lapsed in 2006 due to an error in the CMS online renewal process. No party has asserted that claims submitted under CSMS's supplier number during that period were rejected.

[6]The supplemental material provided by the parties evidences that the 2007 investigation into CSMS's compliance with the Supplier Standards was instituted by a Department of Justice complaint to the NSC.

documentation from the licensing agencies stating that no Sales Tax Permit or DME license is required.

Standard Two: A supplier "[h]as not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.)"

It was revealed during the site visit that Salvatore Salamone is a Vice President of your company; however, this information has not been reported to the NSC. All officers, directors, and managing employees who directly or indirectly conduct the day-to-day operations of the DMEPOS supplier for this facility must be reported.

Standard Four: A supplier "[f]ills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. . . ."

There was no inventory stored on your premises and the contract agreements provided indicate that all equipment is shipped to the long term care facilities by your distributor for use and storage and is maintained by the facility.

The Social Security Act, Section 1128B(b) . . . prohibits anyone from knowingly and willfully receiving or paying anything of value to influence the referral of federal health care program business, including Medicare and Medicaid. If a supplier has entered into a rental arrangement with a physician-landlord, or other healthcare provider, whereby payments are made by the supplier to the lessor for the storage of DMEPOS items in a "consignment closet," it shall be the supplier's responsibility to ensure that such arrangement is lawful and in compliance with all the Medicare supplier standards.

A Medicare DMEPOS supplier that sets up such a "consignment closet" for their supplies in another healthcare provider's facility must possess a written lease agreement that conforms to the Federal regulatory provisions that set fourth [sic] safe harbor criteria for space rental arrangements (see 42 C.F.R. 1001.952), in order to establish immunity from prosecution. To confirm your compliance with the

regulation and statute cited above, we ask that you fax us a copy of the rental agreement(s) between your business and the physician-landlord, or other healthcare provider(s).

Standard Ten: A supplier "[h]as a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. . . ."

The certificate of insurance that was provided by your company expired on March 14, 2007. Please provide us with a current copy of your certificate proving compliance with this standard.

Standard Twelve: A supplier "[m]ust be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively)."

There were no delivery or instruction documents provided to support your compliance with this standard. Please provide us with documentation showing where you or another qualified party provides the beneficiaries with the necessary information and instructions on how to use the equipment safely and effectively.

Standard Twenty: A supplier "[m]ust maintain [certain] information on all written and oral beneficiary complaints, including telephone complaints, it receives . . . ."

The complaint log provided by your company does not contain all of the required fields . . . . Please provide us with a valid complaint log proving compliance with this standard.

The Notice Letter gave CSMS twenty-one days to demonstrate full compliance with the DMEPOS Supplier Standards. However, if CSMS did not comply with the deadline, "the [Supplier Audit and Compliance Unit of the National Supplier Clearinghouse or SACU] may initiate actions to revoke" CSMS's Medicare DMEPOS supplier number.

CSMS responded on April 13, 2007. As to Standard One, CSMS noted that it provides

enteral nutrition products to Golden Horizons and Beverly facilities in the following states: Alabama, Arkansas, California, the District of Columbia, Georgia, Illinois, Indiana, Kansas, Kentucky, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, North Carolina, Ohio, Pennsylvania, South Dakota, Tennessee, Virginia, West Virginia, and Wisconsin. CSMS contends that it attached business permits or registrations from each of the states in which it supplied enteral nutrition products.[7] CSMS also included sales and/or use tax permits and registration certificates for Alabama, Arkansas, California, the District of Columbia, Illinois, Indiana, Kansas, Kentucky, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, New Jersey, North Carolina, Ohio, Pennsylvania, South Dakota, Tennessee, Virginia, West Virginia, and Wisconsin. CSMS also had Georgia and Missouri sales/use tax permits, but was unable to find copies within the twenty-one days. Prior to receiving the Violation Notice, CSMS was not aware of the necessity of licensure in other states into which CSMS shipped enteral products. CSMS noted that its understanding that licensure was not required was "apparently consistent with NSC's because NSC had determined that CSMS met all 21 DMEPOS supplier standards as recently as October 2006." Thus, it attached the necessary licensure applications for distribution of enteral nutrition equipment in Arkansas, California, the District of Columbia, Illinois, Kansas, Maryland, New Jersey, North Carolina, Ohio, Pennsylvania, Tennessee, Virginia, and Wisconsin. After reviewing the specific state statutes for the remaining states, CSMS determined that no licensure was necessary for a medical equipment supplier that ships enteral nutrition equipment and does not sell

[7]The parties did not include the majority of the attachments traded during the administrative proceedings. The substance of what was sent is not seriously in dispute. The Court acknowledges that documents were attached to CSMS's submissions to NSC solely for the purpose of explaining the proceedings.

the equipment for resale, but bills patients or their insurance providers for such equipment. However, CSMS was unable to provide confirmation from the states' regulatory agencies, with the exception of the West Virginia Board of Pharmacy. Thus, CSMS attached confirmation letters written by CSMS and sent to those agencies explaining CSMS's understanding and requesting that the agency correct its interpretation if it determined licensure to be necessary.

CSMS further explained that it filed an updated notice of the change in managing control on April 2, 2007, with respect to Supplier Standard Two. CSMS explained that in relation to standard four, there was no rental arrangement with Golden Horizons or Beverly facilities because such arrangements are not necessary or appropriate. Because those facilities traditionally provided the enteral supplies storage space at their facilities to ensure that patients had adequate access to enteral nutrition supplies, CSMS did not pay rent for such space. Thus, CSMS contended that the consignment closet arrangement violation was baseless.

CSMS attached a then-current copy of their comprehensive liability insurance policy to answer for supplier standard ten. In responding to supplier standard twelve, CSMS attached a copy of its Policies & Procedures Manual outlining the process it takes to maintain proof of delivery for all products. Further, because medical professionals at the skilled nursing facilities administer most of the equipment supplied by CSMS, CSMS noted that instructions on the use of such equipment is rarely necessary.

With regard to Standard Twenty, CSMS asserted that because most of its complaints came from health care providers instead of patients, the information requested by NSC to be on the form was not applicable to its complainants. Regardless, CSMS revised its complaint log form to include the information requested by NSC.

By certified mail dated September 7, 2007, NSC notified CSMS that its Medicare supplier number for DMEPOS would be revoked fifteen days from the postmark of the letter. NSC cited violations of Standard One, Two, Seventeen, Eighteen, and Twenty-One as reasons for the revocation.

NSC stated as to Standard One, "You have failed to provide us with updated copies of your Sales Tax Permits displaying your correct physical address for the states that you are currently servicing. Additionally, you have failed to provide us with copies of the required DME licenses for the following states: AR, CA, DC, IL, KS, MD, MS, NJ, NC, OH, PA, TN, VA, and WI." The letter also noted that, with respect to Standard Two, "You have failed to notify the NSC of changes in your supplier file, including, but not limited to, ownership and address."

Standards Seventeen, Eighteen, and Twenty-One, previously unnamed in the Notice Letter, provide as follows:

Standard Seventeen: A supplier "[m]ust comply with the disclosure provision in Sec. 420.206 of this subchapter." NSC noted that CSMS failed to disclose all ownership information to the NSC.

Standard Eighteen: A supplier "[m]ust not convey or reassign a supplier number." According to NSC, "a change in ownership has taken place" within CSMS, "which suggests that you may have allowed another company to use your assigned supplier number."

Standard Twenty-One: A supplier "[p]rovides to CMS, upon request, any information required by the Medicare statute and implementing regulations." NSC commented that CSMS "failed to provide [NSC] with previously requested documentation to prove [CSMS'] compliance with the aforementioned standards."

Thereafter, CSMS submitted a corrective action plan (CAP) to NSC and noted that the CAP was "submitted solely in response to" the allegations of noncompliance and should not be constructed "as an admission of any noncompliance or as a waiver of any right to appeal from this revocation." CSMS explained that it never relocated its office - the city unilaterally changed the name of the street on which CSMS's office resided from Beverly Way to Fianna Way. Even though CSMS disputed whether it was necessary, it obtained new sales tax permits showing the new street name.

As to the DME licenses, CSMS attached its medical supplier license for Arkansas, where CSMS was located. However, because the enteral nutrition products were only supplied to patients in nursing homes, CSMS did not believe the home medical equipment licensure laws of the other states applied to CSMS. As a result of the revocation letter, CSMS received licenses in Arkansas, California, Illinois, Kansas, Maryland, Mississippi, New Jersey, Pennsylvania, Virginia, and Wisconsin. CSMS also applied for licensure or exemption in the District of Columbia, North Carolina, Ohio, and Tennessee. CSMS further confirmed that licensure was not required in the remaining states where CSMS operated.

As to Standards Two and Seventeen, CSMS noted that the updated CMS documents concerning the change in officers was reported by CSMS to NSC prior to the Notice Letter. CSMS attached another copy of the form and included higher levels of ownership. Moreover, CSMS contended that the change in street name did not rise to the level of a material "false statement or misrepresentation." CSMS disputed that it allowed another entity to use its supplier number in contravention of Standard Eighteen, and disputed that it had not produced any and all documentation to NSC in violation of Standard Twenty-One.

CSMS also filed a Notice of Appeal of the revocation of its DMEPOS supplier number and requested a hearing with an independent fair hearing officer pursuant to 42 C.F.R. Section 405.874. In that appeal, CSMS outlined all evidence submitted to NSC, including evidence that it had twice been found compliant with the Supplier Standards.

On January 23, 2008, a CMS representative notified CSMS that "upon review of your corrective action, CMS has approved reinstatement of your supplier number." CSMS's supplier number was reinstated with "an effective date of 09/21/2007, as this is the date that compliance with all 21 Medicare Supplier Standards was verified."

B. Second Administrative Proceeding

CSMS received another Notice Letter that it was not in compliance with the supplier standards on March 24, 2009. Specifically, NSC contended that CSMS was in violation of Standards One and Two. NSC requested documentation of DME type licenses for each of the states CSMS provided services in or documentation from the licensing agencies affirming that a DME license is not required. Moreover, NSC notified CSMS that it failed to notify NSC of the change in street name from Beverly Way to Fianna Way.

CSMS responded timely, noting that it did not provide DME services in some of the states NSC contended CSMS did business. Further, CSMS remarked that state licensure was not required in the remaining states, but that it was having trouble getting the regulatory agencies to issue a letter of exemption. CSMS additionally noted that because it was found to be in compliance with the 21 Standards in January of 2008, even though it had not received exemption letters, CSMS was in full compliance with those standards. Moreover, CSMS explained, as it did to NSC during the prior proceedings, that CSMS's physical location never changed, but the city in which CSMS is located

unilaterally changed the name of the street. CSMS further noted that the original "Beverly Way" address was still valid for mailing purposes. Additionally, CSMS noted that on its latest enrollment application, it listed Fianna Way as its current business location, and NSC confirmed that address in writing.

On June 16, 2009, NSC notified CSMS that its DMEPOS supplier number would be revoked thirty days from postmark of the letter. As a reason for revocation, NSC cited Supplier Standard One. In particular, NSC noted:

> A review of your Medicare file revealed that your company provides durable medical equipment (DME) to beneficiaries in states other than Arkansas, which may require you to obtain DME licenses from the corresponding state agencies. You failed to provide either documentation from the licensing agencies affirming that a DME license is not required or a DME type license for each of the following states: Alabama, California, Florida, Illinois, Indiana, Maryland, Missouri, Nebraska, North Carolina, New Jersey, South Carolina, Texas, and Wisconsin.

On July 14, 2009, CSMS submitted another CAP and a request for reconsideration of the revocation. CSMS then outlined how it maintained current licenses, or had license applications pending in each of the states listed in the revocation letter. Specifically, a renewal application was pending in California after it was determined and certified by the Arkansas Board of Pharmacy that a pharmacy license in the residence state was not necessary in order for the enteral supplies to be dispensed. CSMS attached a valid license from Illinois set to expire in March of 2012. CSMS noted that its Maryland license, while under renewal at the time of the response, was valid at the time of the initial notice letter. CSMS contended that it did not have to be licensed under North Carolina law as that state excluded medical equipment used in the normal course of treating patients by or on behalf of nursing facilities in its definition of "medical equipment" under the licensure statute. However, CSMS submitted an application to renew its license in North Carolina. CSMS further

noted that even though it held a New Jersey license as a wholesale distributor of prescription drugs, it did not believe it qualified as a "wholesale distributor of prescription drugs" for its distribution of DME supplies. Distributors of non-prescription drugs need only register with New Jersey, and CSMS maintained a current registration. Moreover, CSMS mentioned that "NSC's DMEPOS State License Directory indicates that a licensure is not necessary for DME suppliers [within New Jersey]." CSMS made further efforts to contact the New Jersey Department of Health and Senior Services seeking confirmation of their understanding. However, CSMS was unable to get any clarification from the agency. Moreover, CSMS submitted an application to renew its license in New Jersey that it would supplement to NSC when it received it.

As of June 1, 2008, Wisconsin no longer required a license to distribute devices or other non-prescription drugs; therefore, CSMS did not believe licensure was necessary to supply enteral nutrition to nursing facilities in the state. Furthermore, NSC's own DMEPOS State License Directory noted that in Wisconsin, a DME supplier did not need to obtain a DME, pharmacy, or other license. However, CSMS submitted an application to renew its license in Wisconsin.

After reviewing the applicable state licensure laws, CSMS determined that Alabama, Indiana, Missouri, and Nebraska did not require additional licensure. CSMS attached confirmations from Alabama, Missouri, and Nebraska agencies that CSMS did not need to secure licenses or permits in those states. However, it still had not received confirmation from the Indiana Board of Pharmacy to that effect. CSMS also explained that it did not supply any facilities in Florida, South Carolina, or Texas. Therefore, it did not maintain any licenses in those states.

NSC responded to CSMS's corrective action plan on August 5, 2009. The letter noted that "[t]he information submitted has been reviewed and at this time we are still unable to reinstate your

billing number." NSC explained further that CSMS was still not in compliance with Supplier Standard One. Specifically, NSC noted

> After review of the corrective action plan, it has been confirmed that Ceres Strategies Medical Services does not have the appropriate certificate or licensure to provide durable medical equipment in various states for Medicare beneficiaries. Ceres Strategies does not have durable medical equipment related licensure for the following states: Alabama, California, Indiana, Maryland, Nebraska, and South Carolina.

CSMS requested reconsideration on August 14, 2009, and explained why, in CSMS's view, it remained in full compliance with the law as to Supplier Standard One. Particularly, CSMS noted that it had a current permit in California, a renewal application pending in Maryland, had determined based on a regulatory search and communications with state agencies that a license was not required in Alabama, Indiana, and Nebraska, and did not supply DMEPOS within South Carolina. CSMS also attached written confirmation from South Carolina that no permit was required. CSMS supplemented its request for reconsideration with proof of a permit from Indiana on August 26, 2009.

On October 15, 2009, CSMS received the Medicare Hearing Officer's reconsideration decision. That hearing officer found CSMS to be non-compliant with Supplier Standard One. In particular, the officer noted that all documentation regarding state licensure had not been submitted to the NSC as had been requested. Moreover, the documentation provided by CSMS as to Alabama, Nebraska, Maryland, and California was found to be insufficient. The hearing officer found that CSMS failed to provide either documentation from the licensing agencies affirming that a DME license was not required or that CSMS held a current DME type license. The officer noted that CSMS's response that "[s]ome of those states have been reluctant to confirm in writing that no such requirement exists but have asked CSMS to rely upon its own interpretation of the law, which CSMS

has done," was not sufficient in establishing compliance with Supplier Standard One.

CSMS appealed that decision on December 9, 2009, to an administrative law judge, pursuant to 42 C.F.R. Section 498.40. CSMS pointed out that copies of its licenses and permits for California and Maryland, which were valid at the time CMS revoked CSMS's supplier number, had been provided. As to Alabama and Nebraska, CSMS provided CMS with written confirmation from state officials that it did not need a license or permit to ship DMEPOS in those states.

The administrative law judge entered an Order Dismissing Case on February 16, 2010. That Order indicated that CSMS and CMS reached a settlement. The Order held, "CMS agreed that [CSMS] was in compliance with Medicare supplier standards and reinstated its supplier number effective the date of the revocation."

C. This Action

In the meantime, the United States filed this action alleging that the Beverly and McKesson Defendants violated the False Claims Act and Anti-Kickback Statute by submitting claims to Medicare for certain durable medical equipment supplies that stemmed from illegal kickback arrangements concerning business referrals and discounts. The Government also contends the Defendants set up CSMS as a "sham" DME provider charging that all claims presented under the CSMS supplier number were false as CSMS did not comply with the Supplier Standards.

The Beverly Defendants have filed a Motion for Partial Summary Judgment [111]asserting that all counts based on the contention that the Defendants filed, conspired with, or violated the Anti-Kickback Statute or were unjustly enriched by filing claims for Part B reimbursement when CSMS was not in compliance with Supplier Standards are barred by the doctrines of res judicata or collateral estoppel. The United States filed a Motion for Partial Summary Judgment [113] seeking

adjudication of Counts III through VI on the basis that CSMS was knowingly created as a "sham" DME supplier that violated the conditions of payment under Medicare. Thus, the Government insists, there are no genuine issues of material fact, and the Court must grant summary judgment to the Plaintiff on these charges. The Beverly Defendants filed a Cross-Motion for Summary Judgment [111] on those same counts alleging that the Government could not show a violation of the False Claims Act as no claim submitted was "false," "knowingly made," or "material." Finally, the McKesson Defendants seek dismissal of all counts [141] based upon the Supplier Standards for many of the same reasons as the Beverly Defendants.

Summary Judgment Standard

Summary judgment is appropriate if the moving party can show that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). [8] A party asserting that a fact cannot be or is genuinely disputed must support the assertion by:

> (A) citing to particular parts of materials in the record, including depositions, documents, . . . affidavits or declarations, . . . admissions, interrogatory answers, or other materials; or
>
> (b) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.

FED. R. CIV. P. 56(c)(1). "[A] complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial" and "mandates the entry

[8]Effective December 1, 2010, Federal Rule of Civil Procedure 56 has been amended, and the summary judgment standard is now reflected in Rule 56(a). The amended Rule 56 contains no substantive change to the familiar summary judgment standard. See United States v. Caremark, Inc., 2011 U.S. App. Lexis 3610 *15 (5th Cir. Feb. 24, 2011).

of summary judgment" for the moving party." Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). Summary judgment is also mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id., 106 S. Ct. 2548.

Discussion and Analysis

The Government contends that the Defendants submitted or caused to be submitted legally false claims based upon CSMS's violations of Supplier Standards and certifications that CSMS was complying with those standards.

The False Claims Act prohibits:

> (1) knowingly present[ing], or caus[ing] to be presented, to an office or employee of the United States Government . . . a false or fraudulent claim for payment or approval;
>
> (2) knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]
>
> (3) conspir[ing] to defraud the Government by getting a false or fraudulent claim allowed or paid.

31 U.S.C. § 3729(a). In order to establish a violation of the False Claims Act, a plaintiff must show by a preponderance of the evidence that: (1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the Government to pay out money or to forfeit moneys due (i.e. that involved a claim). United States ex rel. Longhi v. Lithium Power Tech. Inc., 575 F.3d 458, 467 (5th Cir. 2009) (citing United States ex rel. Wilson v. Kellog Brown & Root, Inc., 525 F.3d 370, 376 (4th Cir. 2008) (citations omitted)).

The submission of a false claim is the "sine qua non of a False Claims Act violation." Hopper

v. Solvay Pharms., Inc., 588 F.3d 1318, 1328 (11th Cir. 2010) (quoting United States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002)). The statute is "aimed at false claims" and defines a "claim" as "any request or demand, whether under a contract or otherwise, for money or property" made to someone, including the Government itself, who will at least in part use government money or property to pay it. United States v. Southland Mgmt. Corp., 326 F.3d 669, 674 (5th Cir. 2003) (quoting 31 U.S.C. § 3729(c)). Thus, "whether a claim is valid depends on the contract, regulation, or statute that supposedly warrants it." Id. "It is only those claims for money or property to which a defendant is not entitled that are 'false' for purposes of the False Claims Act." Id. at 674-75 (citing Costner v. URS Consultants, Inc., 153 F.3d 667, 677 (8th Cir. 1998) ("Only those actions by the claimant . . . [calculated to] cause the United States to pay out money it is not obligated to pay . . . are properly considered 'claims' within the meaning of the FCA."); United States ex rel. Wilkins v. N. Am. Constr. Corp., 173 F. Supp. 2d 601, 626 (S.D. Tex. 2001)). Moreover, to satisfy this first element of an FCA claim, the statement or conduct alleged must represent an objective falsehood. Wilson, 525 F. 3d at 376 (citing United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999)).

The Court finds that the Government has not proved that Defendants submitted a false claim as a matter of law for four reasons: (1) CSMS was at all times entitled to payment by Medicare; (2) the Government has not proved an objective falsehood necessary for a finding of false claim; (3) the Government has failed to prove non-compliance with any particular Supplier Standard; and (4) Defendants acted in good faith reliance on NSC and CMS's determinations of compliance when submitting claims under CSMS's supplier number.

In order to receive billing privileges from Medicare, a supplier of medical equipment must

submit, and renew every three years, a Medicare Enrollment Application. CSMS submitted its Enrollment Application on February 23, 2003, and renewed its Application in 2006. CMS awarded CSMS a supplier number in 2003, and honored claims submitted by CSMS as a DMEPOS supplier from that date. Pursuant to issuing the supplier number, NSC undertook an investigation to determine if CSMS complied with the Supplier Standards. CSMS was found to be in compliance in 2003, and upon re-enrollment in 2006. Moreover, CSMS was investigated and confirmed to be acting in accordance with the Supplier Standards in 2007 and 2009. Prior to the 2007 and 2009 confirmations, the NSC had access to and reviewed the contract between MediNet and CSMS, the same contract which the Government contends evidences that CSMS was a "sham" supplier. Even though NSC issued letters of revocation of CSMS's supplier number in 2007 and 2009, all claims submitted from 2003 through 2009 were honored because NSC determined CSMS's date of compliance to be retroactive to the date of revocation. An NSC Senior Investigator testified that suppliers are given an opportunity to bring themselves back into compliance prior to revocation of billing privileges. Thus, CSMS was, at all times relevant, a valid DMEPOS supplier and entitled to payment under Medicare. "[U]nless [CSMS] submitted claims for money to which they were not entitled[,] no False Claims Act liability arises." Southland, 326 F. 3d at 675. As CSMS was entitled to the reimbursements claimed, both under the regulations and pursuant to CMS and NSC's determinations, no false claims were made.

Further, the Government's contention here rests not on an objective falsehood, as required by the FCA, but rather on its subjective interpretation of Defendants' regulatory duties. See Wilson, 525 F.3d at 377. The Northern District of Oklahoma encountered a similar issue in the case United States ex rel. Sharp v. Eastern Oklahoma Orthopedic Center, 2009 U.S. Dist. Lexis 15988 (N.D.

Okla. Feb. 27, 2009). There, a former employee of the defendant contended she witnessed at least seven practices of alleged fraud. Included in the list of allegations was that defendant delivered DME to patients without maintaining a written record of delivery, a violation of a Supplier Standard. The court noted that "if the practices are compliant [with Medicare regulations], there can be no 'false' claims and no 'false' certifications of regulatory compliance." Id. at *27. The defendant countered that a good faith reading of the standard did not require a signature; thus, a false claim could not exist simply because defendant did not utilize the "most appropriate" (according to plaintiff) proof of delivery. Id. at *28. The court determined that the plaintiff failed to state a claim for false certification under the False Claims Act. Id. at *67. Specifically, the court held that the Medicare regulations did not explicitly require a signature, therefore, there was a failure to allege any underlying non-compliance. Accordingly, plaintiff failed to sufficiently allege falsity or knowledge under the False Claims Act. Id. at *68.

The Government failed to prove that CSMS submitted false claims due to its differing interpretations of the Supplier Standards. If the regulations were thoroughly unclear, as a matter of law, the FCA's knowledge and falsity requirements have not been met. See Southland, 326 F.3d at 684 (Jones, J., concurring) ("Where there are legitimate grounds for disagreement over the scope of the contractual or regulatory provision, and the claimant's actions are in good faith, the claimant can not be said to have knowingly presented a false claim").[9] Indeed, "imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under

[9]The Fifth Circuit recently elected not to address the issue of whether ambiguity in the governing law concerns the falsity element of the FCA, or whether the existence of ambiguity concerns whether the defendant acted knowingly. See United States v. Caremark, Inc., 2011 U.S. App. Lexis 3610, at * 27-28 (5th Cir. Feb. 24, 2011). Because this Court does not reach the scienter element, ambiguity is only analyzed under the falsity element.

the FCA." Lamers, 168 F.3d at 1018.

The administrative history of CSMS as a supplier proves that grounds for disagreement over the scope of the regulatory provision are present here. In 2003 and 2006, NSC determined CSMS to be in compliance with the 21 Supplier Standards. The Government has not identified any change in circumstance or practice between October of 2006, when CSMS was recertified, and March of 2007, when the Department of Justice instituted a complaint to NSC against CSMS prompting the first administrative proceeding identified above. This suggests that NSC interpreted the 21 Supplier Standards, in particular Standard One, differently than the Department of Justice. On this basis alone, the Government has failed to allege an objective falsehood capable of supporting a false claim violation. Further, all claims submitted by CSMS between 2003 and 2007 were submitted in good faith reliance on NSC's determination that CSMS was in compliance with the 21 Supplier Standards. As noted above, NSC is the entity charged with enrollment and compliance checks of the 21 Supplier Standards. Thus, a finding by NSC that CSMS complied with those 21 Supplier Standards provides a basis for reasonable reliance on that determination by the supplier. See Southland, 326 F.3d at 684 (Jones, J., concurring).

Aside from the Plaintiff's inability as a matter of law to prove an essential element of its case - that Defendants made a false claim - the Government has additionally failed to carry its burden of proof that Defendants violated the Supplier Standards. See United States ex rel. Farmer v. City of Houston, 523 F.3d 333, 343 (5th Cir. 2008) (for purposes of summary judgment, the plaintiff "must show specific evidence that would allow a reasonable jury to find" that the Supplier Standards have

been violated).[10]

The Government alleges in its Complaint that Defendants "continually violated" Supplier Standards One, Eight, and Twelve.[11] However, a liberal reading of that pleading expands the Government's contentions to violations of Standards Two, Four, Five, Six, Seven, Thirteen, Fourteen, Eighteen, Nineteen, and Twenty.

Standard One is outlined above and concerns furnishing Medicare-covered items "in compliance with all applicable Federal and State licensure and regulatory requirements." 42 C.F.R. 424.57(c)(1). The Government contends that because CSMS did not obtain the requisite state licensure for the four years prior to its first CAP, CSMS violated Standard One. CSMS noted in all its responses to NSC notices and revocations that its research did not indicate licensure was necessary in states in which it shipped enteral nutrition products to skilled nursing facility residents. Neither NSC or CMS disputed CSMS's legal interpretation,[12] and in fact, ultimately concluded that CSMS was in compliance with all state licensing regulations. The Government has failed to put forth any specific proof that the Defendants were not in compliance with all state licensure and

---

[10]To the extent the Government seeks to introduce the OIG Special Advisory Bulletin and Palmetto GBA FAQ's from its website as evidence of Supplier Standard non-compliance, the Court deems such evidence as improper. The OIG Bulletin does not reference the Supplier Standards, therefore, is irrelevant to this determination. Moreover, neither document has the force of authoritative law. Both documents are entity and agency interpretations of regulations that are not binding on this Court. See Christensen v. Harris County, 529 U.S. 576, 587, 120 S. Ct. 1655, 146 L. Ed. 2d 621 (2000) (interpretations contained in opinion letters, policy statements, agency manuals, and enforcement guidelines, "all of which lack the force of law" do not warrant judicial deference).

[11]These are the only enumerated Supplier Standards the Government explicitly alleges CSMS has violated with respect to this litigation.

[12]CSMS was never told their statutory interpretation was erroneous, just that without confirmation from a state agency, it was insufficient proof of compliance.

regulatory requirements. Plaintiff simply relies on the fact that CSMS, in an attempt to remain certified to submit claims to Medicare, applied for and received licensure or permits in states that may not have been arguably necessary. Conclusory allegations, speculation, unsubstantiated assertions, and legalistic arguments are not an adequate substitute for specific facts showing a genuine issue for trial. TIG Ins. Co. v. Sedgwick James of Wash., 276 F.3d 754, 759 (5th Cir. 2002); SEC v. Recile, 10 F.3d 1093, 1097 (5th Cir. 1997); Little v. Liquid Air Corp., 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc). Thus, Plaintiff has failed to carry its burden as to Supplier Standard One.

The second standard states that a supplier "[h]as not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges." While the Government fails to expound on this allegation, when it was presented to CSMS in the first administrative proceeding, it concerned CSMS's alleged failure to amend the identity of a particular governing officer of CSMS. CSMS corrected its managing control form in 2007. The Government has put forth no other evidence of violations of Standard Two.

Standard Four notes that a supplier "[f]ills orders . . . from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order." CSMS contracted with MediNet to fill orders from its inventory. There is no prohibition against contracting with another party to fill orders under this statute. Indeed, an NSC Senior Investigator testified that it is perfectly permissible under the supplier standards to have a contract for the shipment of DME supplies. NSC checked this compliance four times and verified that CSMS complied with supplier standards each time.

Standards Five, Six, Thirteen, Fourteen, Nineteen, and Twenty concern information allegedly not supplied by CSMS to its beneficiaries. With the exception of Standard Twenty, NSC never cited

CSMS for non-compliance with any of these standards. Standard Twenty, dealing with the information in the complaint log, was sufficiently remedied according to NSC's notice letter of September 7, 2007. The Government has put forth no evidence in support of its claim that CSMS violated this standard.

The seventh standard obligates suppliers to "[m]aintain[] a physical facility on an appropriate site." The standard further requires that the "physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communications records." The Government contends that this Supplier Standard has been violated as CSMS occupied 438 square feet of space at the Beverly headquarters and was later upgraded to 1158 square feet of space. The regulations promulgated do not require a specific square footage of space available to DME suppliers. All the standard requires is space for "storing business records . . . ." Plaintiffs have failed to prove that CSMS lacked storage space for business records.

Standard Eight requires DMEPOS suppliers to "[p]ermit[] CMS, or its agents to conduct on-site inspections to ascertain supplier compliance . . . ." Moreover, that Standard provides that the "supplier location must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation." 42 C.F.R. § 424.57(c)(8). In its Complaint, the Government contends CSMS refused to allow NSC inspectors to conduct an on-site investigation at CSMS on July 18, 2006. However, no summary judgment evidence has been introduced to support this contention.

Supplier Standard Twelve explicitly provides that a supplier

> [m]ust be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively).

42 C.F.R. § 424.57(c)(12). The Government contends in its Complaint that "CSMS never itself undertook day-to-day responsibility for delivering or furnishing DME enteral services to Medicare beneficiaries, and therefore continually violated Supplier Standard No. 20." In 2007, NSC cited a violation of Supplier Standard Twelve as a reason for non-compliance with the Supplier Standards. CSMS responded by attaching a copy of its Policies & Procedures Manual outlining the process it takes to maintain proof of delivery for all products. Further, CSMS explained, because medical professionals at the skilled nursing facilities administer most of the equipment supplied by CSMS, instructions on the use of such equipment is rarely necessary. CSMS was ultimately found to be in compliance with this Supplier Standard in 2007 and 2009. The Government has failed to put forth specific evidence showing a violation of this Supplier Standard.

Moreover, NSC, the agent of CMS for enrollment and compliance with Medicare standards, found CSMS to be compliant with those standards prior to submitting any claims to Medicare. That entity confirmed that CSMS was in compliance in 2003, 2006, 2007, and 2009. Thus, to the extent that the Government now contends CSMS was never in compliance, Defendants cannot be held to have submitted false claims where the governmental agency charged with compliance certified that CSMS was in compliance with the regulations. See Southland, 326 F.3d at 684 (Jones, J., concurring) ("Where there are legitimate grounds for disagreement over the scope of the contractual or regulatory provision, and the claimant's actions are in good faith, the claimant can not be said to have knowingly presented a false claim").

Indeed, "[i]f the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim." Southland, 326 F. 3d at 682 (quoting United States ex rel. Durcholz v. FKW, Inc.,

189 F.3d 542, 545 (7th Cir. 1999)); Sharp, 2009 U.S. Dist. Lexis 15988, at *26 ("in the absence of non-compliance, [defendants] could not possibly have submitted 'false' claims, let alone intentionally false claims"). Defendants have supplemented the record to include evidence that the Department of Justice, the Plaintiff to this action, complained to the NSC regarding CSMS's possible violations of the False Claims Act and Anti-Kickback Statute. Thus, in 2007, NSC was aware of these allegations against Defendants. NSC went on to confirm CSMS's compliance with the Supplier Standards and allowed that entity to continue billing Medicare Part B under its supplier number.

Further, the Fifth Circuit has held that the "False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." United States ex rel. Willard v. Humana Health Plan of Tex., Inc., 336 F.3d 375, 381 (5th Cir. 2003) (citing Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4th Cir. 1999)). "For a statement to be knowingly false, it must be more than merely . . . [a] misrepresentation of a regulatory requirement." Sharp, 2009 U.S. Dist. Lexis 15988, at * 17. Moreover, "claimants [do not] 'knowingly' present[] false claims where there were instances of 'mere' contractual or regulatory non-compliance," because the "FCA is not an appropriate vehicle for policing technical compliance with administrative regulations. The FCA is a fraud prevention statute; violations of [agency] regulations are not fraud unless the violator knowingly lies to the government about them." Southland, 326 F.3d at 682 (Jones, J., concurring); see United States ex rel Steury v. Cardinal Health, Inc., 625 F.3d 262, 268 (5th Cir. 2010) ("The FCA is not a general 'enforcement device' for federal statutes, regulations, and contracts"); Mikes v. Straus, 274 F.3d

687, 699 (2d Cir. 2001) (observing that the FCA "was not designed for use as a blunt instrument to enforce compliance").

The Government has not proved that Defendants submitted a false claim as a matter of law as (1) CSMS was at all times entitled to payment by Medicare; (2) there was no objective falsehood on which to base a "false" claim; (3) CSMS was at all times compliant with the Supplier Standards; and (4) Defendants acted in good faith reliance on NSC and CMS's determinations of compliance. Accordingly, Defendants did not knowingly submit false claims pursuant to the DMEPOS Supplier Standards, and those claims must be dismissed. Beverly's Motion for Partial Summary Judgment [132] is GRANTED,[13] and the Government's Motion for Partial Summary Judgment [113] is DENIED.[14] The McKesson Defendants' Motion for Partial Summary Judgment [141] is also GRANTED. All allegations concerning non-compliance with Supplier Standards are stricken.

The Court's ruling is not indicative or determinative of whether false claims were submitted for other violations, including the Anti-Kickback Statute, from which the allegations regarding discounts and referrals stem.

SO ORDERED, this the 28th day of March, 2011.

/s/ Sharion Aycock
U.S. DISTRICT COURT

---

[13]The Court will not analyze whether those prior administrative proceedings against CSMS bar under res judicata or collateral estoppel this lawsuit as to the 21 Standards as the Court has dismissed those claims. Accordingly, Beverly's Motion for Partial Summary Judgment [111] is deemed MOOT.

[14]As the Government's Motion for Partial Summary Judgment [113] is denied, the Court deems it unnecessary to specifically address all contentions in the McKesson Defendants' Objections to Evidence Submitted by the United States in its Motion for Partial Summary Judgment [133].