IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNTIED STATES OF AMERICA,
ex rel. FRANK TRA,

Plaintiff,

v. Case No. 14-2249-JWB

DR. MARK R. FESEN and
HUTCHINSON CLINIC, P.A.,

Defendants.

MEMORANDUM AND ORDER

This case comes before the court on Defendants' motions to dismiss the government's intervenor complaint. (Docs. 41, 43.) The motions are fully briefed and ripe for decision. (Docs. 42, 44, 51, 54, 55.) Defendants' motions are GRANTED IN PART AND DENIED IN PART for the reasons stated herein.

I. Facts and Procedural History

This is an action under the False Claims Act, 31 U.S.C. § 3730(b)(4) (the "FCA"). The action was originally filed by relator Frank Tra on May 28, 2014. (Doc. 1.) After numerous extensions of time to intervene were granted, the government filed its intervenor complaint on October 26, 2018. The government brings this action on behalf of the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services ("HHS"). The facts set forth herein are taken from the intervenor complaint, which are assumed to be true at this stage of the proceedings.

Defendant Dr. Mark Fesen ("Fesen") is a licensed medical oncologist. Fesen formerly practiced at Defendant Hutchinson Clinic, P.A. (the "Clinic"). While practicing at the Clinic, Fesen was a Medicare provider. Relator Tra is a clinical oncology pharmacist who worked at the

Clinic from 2007 to 2014. Because of his role as an oncology pharmacist, Tra was aware of the chemotherapy and other anti-cancer drugs used by the oncologists at the Clinic. (Doc. 25 at 1-2, 11.)

Medicare pays for health-care services for the elderly and disabled, including services and drugs by physicians.[1] CMS contracts with a Medicare Administrative Contractor ("MAC") to process and pay claims in specific areas. For the state of Kansas, Wisconsin Physician Services Insurance Corporation ("WPS") is the MAC that processes claims for providers. To be a Medicare provider, a physician must submit a Medicare Enrollment Application. In order to receive payment from Medicare, Fesen submits a CMS Form 1500 Health Insurance Claim Form ("Form 1500") to WPS, who would then pay or deny the claim on behalf of CMS. In doing so, WPS follows the applicable Medicare rules, regulations, and procedures. (Doc. 25 at 5-6.)

By statute, Medicare only pays for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). With respect to drugs, those are covered only if they "are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice." (Doc. 25 at 6) (citing Medicare Benefit Policy Manual, Ch. 15 at 50.) A provider and facility must ensure that the services provided to the beneficiary are medically necessary. (*Id.* at 7) (citing 42 U.S.C. § 1320c-5(a)). Form 1500 requires providers to certify that "the services on this form were medically necessary." (*Id.*)

[1] The intervenor complaint also alleges that payments were paid for certain beneficiaries under Tricare, which is a program that provides health-care benefits to military members. These benefits are paid secondary to Medicare. (Doc. 25 at 6.)

As of May 16, 2009, local coverage determination L28576 ("LCD") issued by WPS provided coverage guidance and limitations for chemotherapy drugs. According to the LCD, a drug must be used as set forth in certain compendia ratings, including the National Comprehensive Cancer Network (NCCN) Drugs and Biologies Compendium and the Thomson Micromedex DrugDex (collectively, the "compendia"). The Clinic followed the guidelines and incorporated the requirements into its own policy and stated that "Medicare guidelines require NCCN category 1 or 2A, or DrugDex Class 1, 2a, or 2b for payment," and that "[c]overage for medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia ratings." (Doc. 25 at 8-9.)

From 2008 to 2011, Fesen provided oncology services to his patients, which included prescribing and administering treatments. The Clinic's billing department would then bill the insurance company. In late 2008 or early 2009, Tra noticed problems with Fesen's practice, including the use of the drug Avastin for prostate cancer, as to which it was allegedly not indicated. In September 2009, there was a meeting regarding the clinical billing concerns regarding the regimens being prescribed by Fesen. The Clinic's board decided that the Medicare guidelines will be followed in the oncology department. In October 2009, the Board issued a mandate requiring that Fesen "become compliant with Medicare rules." (Doc. 25 at 14.) Allegedly, Fesen continued to fail to comply with Medicare requirements and continued to submit false claims, i.e. claims that were medically unnecessary. The Clinic allegedly failed to take any action to determine whether it had submitted improper claims to Medicare. (Doc. 25 at 11-14.)

In 2010, the Clinic hired an outside consultant, Dr. Gingrich, to perform chart reviews of oncology patients. After reviewing five charts from both Fesen and Dr. Estephan, another oncologist at the Clinic, Gingrich found no concerns with Estephan's charts but found that all treatments were inappropriate and not in compliance with compendia guidelines with respect to Fesen's patients. (Doc. 25 at 15-16.) With respect to one patient, Fesen was prescribing the powerful drug Rituxan even though the patient had no positive pathology after 2005. Gingrich stated that the prescribing of the drug to this patient was "unnecessary" and "unbelievable." (*Id.* at 16.) After this review, the patient was not provided any additional Rituxan. (*Id.*) Gingrich even sought confirmation from the Clinic that the five charts he was provided were random samples.

Gingrich did a second review with a larger sample in September 2010. This sample included 59 Fesen patients and 16 Estephan patients. Again, Gingrich determined there were no significant issues with Estephan's patients. Gingrich determined that 30 of Fesen's patients received treatments that were not evidence-based or in accordance with the compendia. In seven cases, Gingrich found that the drug Rituxan was "given either inappropriately as to a patient with large cell lymphoma in the maintenance phase [where current data do not support extended therapy] or given >2 years to patients with follicular lymphoma [where current data support every 6 months x 2 years maintenance]." (Doc. 25 at 17) (brackets in original.) Rituxan is expensive and Medicare pays between $2,000 to $4,000 per infusion. Gingrich also found the medical records to be poorly documented in about six cases and he could not discern a clear indication of clinical intent or direction from those records. On September 27, 2010, the Clinic's board met to discuss the audit. On October 12, the Clinic's administrative counsel met with Fesen and discussed the findings. (Doc. 25 at 19.)

At the meeting, Fesen resisted moving toward so-called "evidence-based medicine." (*Id.*) Gingrich responded by telling Mike Harms, the chief financial officer of the Clinic ("CFO"), that Fesen was ignoring national guidelines for the treatment of cancer patients. Fesen eventually agreed to comply with some of the Board's mandates. The Clinic then tasked Tra with overseeing Fesen's treatments. "Tra consistently caught and corrected attempts by Fesen to inappropriately fractionate doses to allow more frequent infusions, to use regimens not approved by the compendia, and to give Rituxan maintenance beyond the two years permitted." (Doc. 25 at 20.) On April 12, 2010, Tra forwarded information regarding private insurance denials to the CFO. Those denials determined that the treatment was not medically necessary, including Rituxan claims that were given beyond two years. Tra recommended that the Clinic go in and review patients who had Rituxan for more than two years and to stop the medication. Tra also recommended removing patients who have been prescribed off-label Avastin. In one case, Tra reported a patient who had been on Rituxan for eight years. In another case, a patient was prescribed Rituxan even though there were repeated negative bone-marrow scans. The prolonged use of Rituxan for that patient allegedly caused numerous health problems. (Doc. 25 at 20-21.)

On November 30, 2010, the CFO, CEO, and the board discussed Fesen's misuse of the drug Navelbine. They had concerns that the drug was being administered against board policy and without Tra's approval. Fesen was fined $10,000 by the board in December 2010 to compensate the Clinic for legal expenses and exposure of the Clinic. The board, however, did not report the misuse of Navelbine to Medicare or repay any reimbursement. (Doc. 25 at 21-22.)

A third audit was conducted in April 2011 and included a sample of 49 Fesen patients. Gingrich found that out of 15 patients with hematological problems, 10 were given inappropriate therapies. These included inappropriate medications or inappropriate dosages. A summary of

talking points was compiled to discuss with Fesen. The summary stated that Fesen's "practice was not consistent with acceptable oncologic standards" and he was putting the Clinic "at risk for billing and medical necessity issues." (Doc. 25 at 24.)

Ultimately, the board encouraged Fesen's resignation from the Clinic. Fesen resigned effective December 31, 2011. After Fesen's resignation, the Clinic did not take any action to investigate previous claims to Medicare or to report any overpayments to Medicare. (Doc. 25 at 24-25.)

The intervenor complaint also lists nine specific examples of patients who were treated by Fesen. With respect to Patient A, the patient was seen for a diagnosis of stage 1 lymphoma, the medically appropriate treatment for that diagnosis is resection/radiation, not Rituxan. On February 25, 2010, a lab report stated that there was no evidence of lymphoma. On June 3, 2010, a consulting oncologist stated that Patient A was without evidence of the disease. Nevertheless, from March 2010 to October 2010, Fesen and the Clinic submitted claims for Rituxan and chemotherapy infusions that were allegedly medically unnecessary. Patient B was being treated by Fesen for non-Hodgkin's lymphoma. Fesen and the Clinic submitted claims for Rituxan that were allegedly medically unnecessary because the patient was given the medication for more than two years. For Patient G, the medical records showed a diagnosis of lymphoma but there was no progression of the disease and biopsies showed no lymphoma at all. Fesen and the Clinic submitted claims for 13 infusions of Rituxan that were allegedly medically unnecessary. Patient H was diagnosed with non-Hodgkin's lymphoma and received Rituxan for several years, even after there was a negative PET scan and a determination that the disease could not be found. (Doc. 25 at 25-39.)

The government alleges that these specific incidents are "representative examples of the medically unnecessary services Fesen and Hutchinson Clinic repeatedly billed to Medicare and Tricare." (Doc. 25 at 39.)

During May 2008 to December 2011, Fesen and the Clinic billed at least 289,407 claims to Medicare for Fesen's treatments and were paid over $30 million. Of that, $17 million was for cancer drugs. Specifically, Medicare was billed approximately $3.8 million for Rituxan. The government alleges that the audit results indicate that a significant portion of those payments were for claims that were false because they were for treatments that were medically unnecessary. The government alleges that the Clinic had knowledge of the false claims based on the audits but that it failed to repay the government. (Doc. 25 at 39-41.)

The intervenor complaint asserts five claims against Defendants. Counts 1 through 3 are claims under the FCA for false claims, reverse false claims, and false records. Count 4 is a claim for unjust enrichment and count 5 is for payment by mistake. Defendants now move for dismissal of the intervenor complaint on the basis that it fails to state a claim and fails to allege fraud with particularity.[2]

II. Motion to Dismiss Standard

In order to withstand a motion to dismiss for failure to state a claim, a complaint must contain enough allegations of fact to state a claim to relief that is plausible on its face. *Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1974 (2007)). All well-pleaded facts and the reasonable inferences derived from those facts are viewed in the light most favorable to the government. *Archuleta v. Wagner*, 523

[2] The Clinic has submitted four exhibits in support of its motion, three of which are subpoenas and the last exhibit is a copy of Form 1500. While the court may consider the government's subpoenas issued to the clinic under Fed. R. Evid. 201, the court declines to consider the exhibits at this stage of the proceeding.

F.3d 1278, 1283 (10th Cir. 2008). Conclusory allegations, however, have no bearing upon the court's consideration. *Shero v. City of Grove, Okla.*, 510 F.3d 1196, 1200 (10th Cir. 2007). Rule 12(b)(6) "does not require that Plaintiff establish a prima facie case in her complaint, but rather requires only that the Plaintiff allege enough factual allegations in the complaint to set forth a plausible claim." *Pueblo of Jemez v. United States*, 790 F.3d 1143, 1171–72 (10th Cir. 2015) (internal citations omitted). In the end, the issue is not whether the government will ultimately prevail, but whether the government is entitled to offer evidence to support its claims. *Beedle v. Wilson*, 422 F.3d 1059, 1063 (10th Cir. 2005).

III. Analysis

A. FCA

The government brings this action under the FCA. The government asserts three claims under the FCA: (1) false claims under 31 U.S.C. § 3729(a)(1)(A); (2) false records under 31 U.S.C. § 3729(a)(1)(B); and (3) reverse false claims against the Clinic under 31 U.S.C. § 3729(a)(1)(G). The FCA "covers all fraudulent attempts to cause the government to pay out sums of money." *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 734 (10th Cir. 2018) (quoting *U.S. ex rel. Conner v. Salina Regional Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)).

To prove a claim under the FCA for a false claim under subsection (A), the government must show that Defendants: (1) made a claim; (2) to the government; (3) that is materially false or fraudulent; (4) knowing of its falsity; and (5) seeking payment from the federal government. *United States ex rel. Duffy v. Lawrence Mem'l Hosp.*, No. 14-2256-SAC-TJJ, 2018 WL 4748345, at *5 (D. Kan. Oct. 2, 2018) (citing *U.S. v. The Boeing Company*, 825 F.3d 1138, 1148 (10th Cir. 2016)).

A false claim may be either legally false or factually false. *Boeing*, 825 F.3d at 1148. Based on the allegations in the intervenor complaint, the government is asserting that these claims were legally false because the payment is conditioned on compliance with Medicare statutes, regulations, and guidance. *Polukoff*, 895 F.3d at 741. A factually false claim involves a claim for services that were not provided or an incorrect description of services provided. *Id.* Legally false claims can be express or implied. *Boeing*, 825 F.3d at 1148. "Express false certification occurs when a government contractor falsely certifies compliance with a particular statute, regulation, or contract term and compliance is a prerequisite to payment. Implied false certification occurs when a government contractor doesn't expressly certify compliance, but knowingly and falsely implies that it is entitled to payment when it submits a claim." *Id.* (internal citations omitted). The government makes claims of express false certification because the government alleges that Defendants submitted claims with the express statement that they were medically necessary, a statement that the government alleges was false in violation of the statute and Medicare guidelines. *See Polukoff*, 895 F.3d at 741.

In order to establish a claim under the FCA, the government must prove that the claim submitted was "both knowingly and materially false." *Boeing*, 825 F.3d at 1148. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court has instructed that "materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2002 (2016) (citing 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003) (Williston)).

> The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," *Allison Engine*, 553 U.S., at 672, 128 S. Ct. 2123 or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government

> designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543, 63 S. Ct. 379, 87 L. Ed. 443 (1943) (contractors' misrepresentation that they satisfied a non-collusive bidding requirement for federal program contracts violated the False Claims Act because "[t]he government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive"); *see also Junius Constr*., 257 N.Y., at 400, 178 N.E., at 674 (an undisclosed fact was material because "[n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood" of the undisclosed fact).
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> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003-04.

In determining materiality, courts should take a holistic approach. *Duffy*, 2018 WL 4748345, at *7. "Materiality is more likely to be found where the information at issue goes to the 'very essence of the bargain.'" *Id.* (quoting *U.S. v. Coloplast Corp.*, 2018 WL 4029549 *6 (D. Mass. Aug 17, 2018) (quoting *United States ex rel. Escobar v. Universal Health Servs., Inc*., 842 F.3d 103, 109 (1st Cir. 2016) (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 n.5 (2016)).

i. False Claim

Defendants argue that the government's claim under the FCA for the submission of false claims fails to state a claim because it does not plausibly allege a material falsity. The Clinic

additionally moves for dismissal on the basis that the intervenor complaint fails to sufficiently plead knowledge by the Clinic.

Materiality. The government's allegations center around Fesen's treatments for his patients. The government alleges that these treatments were not medically necessary and reasonable. Essentially, as set forth above, the government has alleged that Fesen treated patients with Rituxan and other medications that were not medically appropriate treatments based on the compendia and standard practices. The government has specifically alleged that some patients were treated with this powerful drug even though they had no evidence of the disease. The government has also alleged that some patients were treated with this powerful drug beyond two years, which is the maximum time period that Rituxan is considered medically necessary. The government set forth specific examples of patients, their diagnosis, and the treatments given. The government also has alleged that the three internal audits resulted in numerous findings that the treatment was not medically necessary for Fesen's patients. Notwithstanding the specific allegations that span more than 30 pages in the intervenor complaint, Defendants contend that the government has not satisfied the materiality requirement.

Defendants first argue that the government has failed to show materiality because the government has not alleged a basis for the court to find that Rituxan was not appropriate for some patients who were diagnosed with lymphoma. (Doc. 42 at 15.) Defendants cite to *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 779-80 (7th Cir. 2016), for the proposition that the court should refuse to credit the allegations regarding the patients with lymphoma because Rituxan is medically appropriate for patients with certain types of lymphoma. As pointed out by the government, the complaint in *Presser* provided "no medical, technical, or scientific context which would enable a reader of the complaint to understand why Acacia's alleged

actions amount to unnecessary care forbidden by the statute. For instance, the complaint does not reference policies or practices at other medical clinics, regulations, or other publications which call Acacia's policies into question." *Id.* at 779. The allegations in this case contain specific statements regarding medical necessity. For example, Patient A was allegedly seen for stage 1 lymphoma. The allegations state that the "medically appropriate treatment is resection/radiation, not Rituxan." (Doc. 25 at 25.) This is clearly sufficient to identify that Rituxan is not a medically appropriate treatment for this disease and yet Fesen allegedly submitted claims to Medicare indicating that it was.

In this case, the government has specifically identified why the treatments amounted to unnecessary care. In *Polukoff*, the Tenth Circuit was faced with allegations regarding medically unnecessary procedures. The district court had granted a motion to dismiss on the basis that a medical judgment could not be false under the FCA. The circuit reversed. The court of appeals held that a "doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." *Polukoff*, 895 F.3d at 743. After reviewing the allegations, the circuit court held that there were sufficient allegations to state a claim. The specific allegations that supported this conclusion included that the provider performed a high number of procedures, the procedures violated industry and hospital guidelines, other physicians objected to the practice, audits showed that guidelines were violated, and the provider represented that they were performed on other indications. *Id.* This case has similar allegations. There is a high number of Rituxan prescriptions. The treatments of Fesen's patients violated the compendia and the Clinic's guidelines. There were other providers in the Clinic that objected to Fesen's practice. The internal audits showed numerous violations of the compendia and industry standards, including medical

records that did not support the diagnosis of the patient's alleged disease. The allegations in the complaint clearly state that Medicare and Tricare do not pay claims that are not medically necessary. Accordingly, the court concludes that the complaint sufficiently alleges that the claims were false because the medications and services provided were not reasonable and necessary, and furthermore that defendants' certification to the contrary was material to the decision to pay the claim because Medicare does not pay claims unless they are medically necessary.

Fesen also cites to *United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, No. 4:05CV570MLM, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006), for the proposition that the allegations in this case do not show that the patient's disease is material to the government's decision to pay for the identified treatments. (Docs. 44 at 10; 55 at 3-5.) In *Hess*, the plaintiff alleged that the drug manufacturer was fraudulently marketing off-label use of a certain drug by marketing the cancer drug for later stages of cancer. The plaintiff asserted that this caused doctors to submit false claims. The plaintiff claimed the manufacturer violated the FCA by promoting the drug "to use beyond the second line setting." *Hess*, 2006 WL 1064127 at *4. The plaintiff, however, did not allege that "a single doctor prescribed [the drug] improperly" and conceded that the Medicare contractor exercised its authority to cover the drug beyond the second line setting. *Id.* The allegations in the complaint were that the manufacturer was working with the government for approval of use of the drug. Notably, the drug was ultimately approved by the FDA. Moreover, the plaintiff failed to specifically make allegations regarding the claims made to the government for payment. The court did conclude that the plaintiff's allegation that Medicare did not require the stage of cancer on the form for payment resulted in a finding that the stage of cancer was not material to the decision on payment for the drug. The factual allegations in the *Hess* case, however, stated that the provider was not required to document the stage of cancer on the request for

payment. *Id.*, 2006 WL 1064127 at *7. There is no such allegation in this case. Moreover, there are other distinguishing facts in this case. Notably, as discussed previously and pointed out by the government, this case includes allegations that Fesen's patients, in some cases, have no medical records to support a diagnosis.[3] As such, a claim for reimbursement for a chemotherapy drug and an indication that the patient had cancer, when in fact the patient did not, would be material. Moreover, construing the facts in a light most favorable to the government, the allegations in this case are that the treatments were not medically necessary and that the claims would not have been paid had the government known of the facts.

Defendants also argue that the false claims concerning the extended use of Rituxan and prescribing Rituxan for maintenance, which are allegedly not supported by the compendia, do not state a claim because the government "does not plausibly allege that the lack of compendia support" was material. (Doc. 42 at 15.) Defendants essentially argue that WPS's payment of these claims is evidence that lack of compendia support is not material because WPS is familiar with the guidelines, WPS relies upon the information presented, and there is no allegation that the Form 1500 lacked information. Basically, Defendants are arguing that WPS must have known that the treatments were not medically necessary based on the compendia but paid them anyway. The Clinic cites to *Escobar*, 136 S. Ct. at 2003-04, for the proposition that "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements [at issue] are not material." (Doc. 42 at 16.) The problem with this argument is that the intervenor complaint does not allege that WPS knew that the treatment was medically unnecessary. Rather,

[3] Fesen argues that the allegations that Patient A was seen for stage 1 lymphoma support the conclusion that the patient had lymphoma. (Doc. 55 at 5.) The allegations, however, state that there were reports that there was no evidence of the disease. (Doc. 25 at 26.) Moreover, there are allegations that Defendants falsified records and incorrectly diagnosed patients. At this stage, the court must view the allegations in a light most favorable to the government.

the allegations are that if the government would have known, the government would not have paid. While continued payment after learning of facts that the treatment was not in compliance with the standards could support a finding that the requirement was not material, there are no allegations here that WPS had such knowledge. The Clinic also cites to *United States ex rel. Harman v. Trinity Indus. Inc*., 872 F.3d 645, 663 (5th Cir. 2017), for the proposition that continued payments "indicates that compliance with a particular regulatory requirement is not material." (*Id.* at 18.) While that is a consideration, that case is not helpful in this matter as it was dealing with a motion for judgment after trial and not the standard on a motion to dismiss. Defendants are free to raise these arguments, along with the related evidence regarding the claims submitted, on summary judgment.

Knowledge by the Clinic. Alternatively, the Clinic asserts that the § 3729(a)(1)(A) false claim must be dismissed because the intervenor complaint fails to show that the Clinic had knowledge of the false claims submitted. Knowledge may be proven by: (1) actual knowledge; (2) deliberate ignorance; or (3) reckless disregard. 31 U.S.C. § 3729(b)(1). The Clinic essentially argues that the government's allegations are not sufficient because the Clinic took swift action to address the concerns regarding Fesen. The Clinic, however, cites no authority for the proposition that taking action to address a provider's improper and medically unnecessary treatment means that the Clinic had no knowledge of Fesen's conduct.

Knowledge may be alleged generally. Fed. R. Civ. P. 9(b). The allegations in the intervenor complaint are that the Clinic had knowledge of the submission of the false claims and the payments made by the government. The allegations also specifically identify instances where the Clinic's board was informed of improper treatments and a lack of documentation in the medical

records. Therefore, the Clinic's motion to dismiss this claim on the basis that the allegations are insufficient to show knowledge is denied.

Rule 9(b). Defendants also assert that the government failed to state this claim with specificity as required under Fed. R. Civ. P. 9(b). Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." With respect to claims under the FCA, a plaintiff must plead the "who, what, when, where and how of the alleged [claim]." *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc*., 614 F.3d 1163, 1171 (10th Cir. 2010) (quoting *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006)). This requires the government to "identify the time, place, content, and consequences of the fraudulent conduct." *Id.* (citing *Koch v Koch Indus., Inc*., 203 F.3d 1206, 1236 (10th Cir. 2000)). The allegations of the claim "need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *Id.* at 1172.

The government's intervenor complaint complies with Rule 9(b). The government has provided specific examples of claims that were submitted, including patient identification, the treatment provided, and the date provided. Additionally, the government has alleged why the treatment provided was not medically necessary for that patient. The government's intervenor complaint provides Defendants with fair notice of the claims, which is the purpose of Rule 9(b). *Lemmon*, 614 F.3d at 1172.

Therefore, Defendants' motions to dismiss the false claim count are denied.

ii. False Records

Defendants assert that the government fails to state a claim for submission of false records because the intervenor complaint fails to identify any false statement or record, the statements were not material, and they were not knowingly made.

Liability under the FCA for a false record claim requires the government to show that Defendants made a false record or statement that was material to the false claim. § 3729(a)(1)(B). This does not require the false record or statement to be presented to the government. *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 671 (2008). This statute is otherwise "practically identical to the requirements for a count brought under section 3729(a)(1)(A)." *United States ex rel. Scott v. Pac. Architects & Engineers (PAE), Inc*., 270 F. Supp. 3d 146, 154 (D.D.C. 2017). "[M]any violations of § 3729(a)(1)(B) may also be considered violations of § 3729(a)(1)(A), which imposes liability on persons who 'knowingly present[ ], or cause[ ] to be presented, a false or fraudulent claim for payment or approval.'" *United States ex rel. Brooks v. Stevens-Henager Coll., Inc*., 359 F. Supp. 3d 1088, 1109 (D. Utah 2019)

The allegations in the intervenor complaint state that Defendants made or used false records or statements that were material to the claims. (Doc. 25 at 42.) The allegations further state that this was done by "incorrectly diagnosing patients or certifying that treatments were medically necessary when they actually were not." (*Id.*)

The government asserts that it has sufficiently alleged that "Fesen's records are false and were used to justify claims for the administration of Rituxan when it was not medically indicated as the Clinic billed for services provided by Fesen. (Doc. 25 at ¶ 71)." (Doc. 51 at 20.) The government also argues that there are allegations of specific claims made to Medicare when the treatment was not medically necessary. (Doc. 51 at 21.) Reviewing the intervenor complaint, the allegations state that a provider, such as Defendants, must submit a Form 1500 with each claim for

payment. That form requires express certification that the treatment is medically necessary. The intervenor complaint has identified specific instances of treatment that were submitted as claims but were not medically necessary. Therefore, viewing the facts in a light most favorable to the government, the government has alleged that false statements were made on claims for payment. *See Polukoff*, 895 F.3d 730 at 743 ("a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase."); *Groat*, 255 F. Supp. 3d at 30-31 (express statement on Form 1500 that treatment was medically necessary is sufficient to state a claim for a false statement under subsection 3729(a)(1)(B)).

Defendants argue that the express statement regarding medical necessity is not false unless the complaint includes the submitted claim's treatment justification. (Doc. 54 at 2.) Defendants further argue that there is insufficient detail regarding the medical context to determine that the statement regarding medical necessity is false. The court disagrees. As discussed *supra*, the allegations provide a sufficient basis to determine that the statement regarding medical necessity submitted on claims for payment were false based on the compendium and Clinic standards. Based on these allegations, the government has sufficiently alleged that Defendants submitted claims with false statements.

With respect to materiality and knowledge as to the claims regarding the express false statements, the court finds that the intervenor complaint has sufficiently alleged both as discussed herein. The court also finds the government has pled these claims with specificity as required by Rule 9(b) for the reasons stated previously.

Therefore, Defendants' motion to dismiss the false records claim is denied.

iii. Reverse False Claim

The intervenor complaint also alleges that the Clinic knowingly concealed or avoided an obligation to pay money to the government. It did so by failing to "return overpayments identified or that should have been identified as a result of repeated audits, warnings, and reviews of Fesen's oncology practice." (Doc. 25 at 42.) This type of claim is known as a reverse false claim. The Clinic moves for dismissal of this claim on the basis that 1) any claim regarding conduct prior to May 20, 2009, does not sufficiently allege a reverse false claim; 2) the allegations fail to sufficiently allege the existence of an obligation; and 3) the complaint fails to allege the fraud with specificity.

With respect to the first argument, the statute at issue was amended on May 20, 2009. Prior to that date, the reverse false claim statute required the making or use of a false record or statement that was material in order to avoid having to repay the government. *United States ex rel. Barrick v. Parker-Migliorini Int'l, LLC*, 878 F.3d 1224, 1230 (10th Cir. 2017), *cert. denied sub nom. U.S. ex rel. Barrick v. Parker-Migliorini Int'l, LLC*, 139 S. Ct. 78 (2018) ("Before 2009, the reverse-false-claims provision imposed liability on any person who 'knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.' 31 U.S.C. § 3729(a)(7) (1994).")

> The reverse-false-claims provision now imposes liability on any person who: [1] knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or [2] knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government. 31 U.S.C. § 3729(a)(1)(G).

Id. at 1230.

The Clinic moves for dismissal of this claim for any conduct prior to May 20, 2009, on the basis of a failure to allege a false statement that was material to the obligation to pay money to the government. The government does not specifically respond to this argument, but its heading

concerning this claim states that it has sufficiently stated a claim regarding conduct after May 20, 2009. Moreover, the court is unable to identify any allegations in the Complaint that identify false records or statements made by the Clinic that are material to an obligation to return an overpayment. Therefore, the Clinic's motion is granted to the extent this claim entails conduct prior to May 20, 2009. The court will now turn to the sufficiency of the allegations regarding conduct after that date.

In order to state a claim under the reverse false claim provision, the government must show that the Clinic knowingly concealed or knowingly and improperly avoided an obligation to pay money to the government. 31 U.S.C. § 3729(a)(1)(G). The Clinic argues that the government has not sufficiently alleged the existence of an obligation under the FCA or under the Affordable Care Act of 2010 ("ACA"). An obligation is defined under the FCA as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3). The Tenth Circuit has explained that the word "established" is "the key word in this definition" and that "a duty to pay must be formally 'established' before liability can arise under the False Claims Act. In other words, there is no liability for obligations to pay that are merely potential or contingent." *Barrick*, 878 F.3d at 1230-31 (internal citations omitted).

In *Barrick*, the circuit stressed that any potential or contingent obligation is not sufficient to establish a claim. *Id.* The government argues that the allegations are that the "audits identified past claims by Fesen that were false because they were not medically indicated, and alleges that the Clinic took no action to look further and took no action to return the payments." (Doc. 51 at 26.) The Clinic argues that the obligation is not established until after litigation. (Doc. 54 at 8.)

The Clinic cites no authority for that assertion. Rather, by statute, a Medicare provider is required to return an overpayment to the government. *See* 42 U.S.C. § 1320a–7k(d)(4)(B).

The parties make extensive arguments regarding the definition of obligation and whether or not the obligation was identified. The Clinic also argues that the ACA has been held unconstitutional and, therefore, the provisions from that statute cannot be used to determine whether the Clinic had an established duty to pay. The court need not resolve all of these issues as the court finds that the government failed to state this claim with specificity.

Under Rule 9(b), the government must plead facts as to the time, place, or substance of any retained overpayment that are sufficient to support a reverse false claim. *Lemmon*, 614 F.3d at 1171. Unlike the government's allegations regarding specific patients as to the false claims and false records counts, there are no facts regarding specific overpayments for the patients that were audited. In apparent recognition of the numerous cases holding that section 3729(a)(1)(G) cannot be construed so as to be redundant with false claims and records under subsections (a)(1)(A) and (a)(1)(B), *see United States ex rel. Myers v. Am.'s Disabled Homebound, Inc.*, No. 14 C 8525, 2018 WL 1427171, at *3 (N.D. Ill. Mar. 22, 2018) (citing cases) and *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014), the government has asserted that the reverse false claims are not based on the specific patient examples set forth in the intervenor complaint but are only based on the patients that were audited by Gingrich. (Doc. 51 at 26.) And therein lies the problem: the intervenor complaint is largely devoid of details regarding the matters identified in the audits. Compounding the issue is the fact that the government has essentially conceded that it has not pled a claim for payments received for claims through May 2009.[4] This

[4] Although the government has alleged that the clinic prevented Tra from reviewing cases prior to November 2009, there is no allegation that the three audits included a similar restriction. Notably, the first internal audit discusses the fifth patient receiving Rituxan from 2004 to 2010. (Doc. 25 at 15; 20.)

is notable because the audits were done from early 2010 to April 2011 and the intervenor complaint lacks allegations regarding the dates of treatment that were reviewed for these patients that were audited, specific claims that were made to the government for payment, and payments that the Clinic received as a result of the claims. Without such information, the allegations have not supported an obligation to pay.

There were three audits completed by Gingrich. For the first audit, there were five Medicare patients sampled. For these patients, the allegations only include some specifics as to patient five. That patient was given Rituxan, dates unknown, and it was determined that the diagnosis of the patient was not clear. There are no further allegations specific to the other four patients, only an allegation that Gingrich rejected the treatment approach. (Doc. 25 at 15.) The intervenor complaint also quotes from the third internal audit, explaining problems with ten patient charts. Although there are allegations of inappropriate treatment, there are no facts regarding the specific treatment, date of payment, or the patient's identity. (Doc. 25 at 23.) Thus, the court and defendants are left to wonder what activity distinct from that encompassed by the false claims and false records counts is contemplated under the reverse false claims count. That sort of pleading fails to satisfy the heightened pleading standards of Rule 9(b).

The government cites to two cases in support of its position that the Clinic cannot ignore audits that reveal overpayments and retain payments from medically unnecessary claims. (Doc. 51 at 25.) Those cases, however, included significantly more facts regarding the overpayments. In *Kane ex rel. United States v. Healthfirst, Inc*., 120 F. Supp. 3d 370 (S.D.N.Y. 2015), a billing code error due to a software glitch was uncovered. As a result, there were 900 potential erroneous claims submitted. In filing the complaint, the plaintiff attached an exhibit of the 900-claim spreadsheet. *Kane*, 120 F. Supp.3d at 378-79. In *United States ex rel. Keltner v. Lakeshore*

Medical Clinic, Ltd., No. 11-cv-00892, 2013 WL 1307013 (E.D. Wis. Mar. 28, 2013), the court granted the defendant's motion to dismiss in part. Specifically, the court dismissed claims where the relator provided no examples of claims actually submitted to the government. *Id.* at *4.

The intervenor complaint does not provide the Clinic or the court with sufficient information regarding the retention of any overpayments that could result in the obligation for that claim. Therefore, the government has failed to plead this claim with specificity as required under Rule 9(b).

B. Common Law Claims

Finally, Defendants argue that the government's common law claims of unjust enrichment and payment by mistake must be dismissed because they are quasi-contract claims and the government has failed to allege that the provider agreement with Defendants is invalid. Defendants cite to various out-of-district authority stating that a claim for unjust enrichment or payment by mistake must include an allegation that the contract is void. (Doc. 42 at 29.) In response, the government cites to several cases, again, out-of-district, asserting that the government may plead these claims in the alternative. (Doc. 51 at 28). The government also argues that Medicare Provider Agreements only create statutory and not contractual rights.

In making their argument, Defendants fail to cite any Tenth Circuit authority for the proposition that the government cannot plead in the alternative in an FCA action or that the pleading must allege that the contract is void. Additionally, the cases cited do not include actions against Medicare providers. (Doc. 42 at 29-30.) In light of the absence of applicable authority, the court declines to dismiss the claims. Moreover, the allegations in the complaint do not allege that the conduct at issue is expressly covered by the contract between the parties nor is this an action for a breach of the provider agreement. *See Rezac Livestock Comm'n Co., Inc. v. Pinnacle*

Bank, 255 F. Supp. 3d 1150, 1171 (D. Kan. 2017) ("[W]hen conduct could satisfy the elements of both a breach of contract or of an independent tort, unless the conduct is permitted by the express provisions of a contract, a plaintiff may pursue both remedies." (quoting *Burcham v. Unison Bancorp, Inc*., 276 Kan. 393, 414, 77 P.3d 130, 145 (2003)).

Reviewing the allegations in a light most favorable to the government, the court finds that they have sufficiently stated a claim under common law. *See United States v. DeFelice*, No. CIV-14-415-RAW, 2015 WL 7018018, at *4 (E.D. Okla. Nov. 10, 2015) (citing elements of unjust enrichment and payment by mistake under federal common law).

IV. Conclusion

The Clinic's motion to dismiss is GRANTED IN PART AND DENIED IN PART. (Doc. 41.) The Clinic's motion to dismiss count 3, the FCA reverse false claim, is GRANTED. The Clinic's motion to dismiss all other counts is DENIED. Fesen's motion to dismiss is DENIED. (Doc. 43.)

The government also requests an opportunity to amend. (Doc. 51 at 29.) The government has not attached a proposed amended complaint, nor has it suggested how it will cure any deficiencies. The court declines to grant the request without a motion and attached draft amended complaint. The government is free to seek leave to amend its intervenor complaint in accordance with the local rules.

IT IS SO ORDERED this 31st day of July, 2019.

s/ John W. Broomes
JOHN W. BROOMES
UNITED STATES DISTRICT JUDGE