# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA and STATE OF NEVADA ex rel. MICHAEL D. KHOURY, M.D.,

Plaintiffs.

v.

INTERMOUNTAIN HEALTHCARE, INC. d/b/a INTERMOUNTAIN HEALTHCARE; IHC HEALTH SERVICES, INC.; MOUNTAIN WEST ANESTHESIA, LLC; DAVID A. DEBENHAM, M.D.; ERIC A. EVANS, M.D.; JOSHUA J. LARSON, M.D.; JOHN E. MINER, M.D.; TYLER W. NELSON, M.D.; and DOE ANESTHESIOLOGISTS 1 through 150,

### MEMORANDUM DECISION AND ORDER

Case No. 2:20-cv-00372-TC-CMR

District Judge Tena Campbell Magistrate Judge Cecilia M. Romero

Defendants.

In this qui tam suit under the False Claims Act, Plaintiff—Relator Michael D. Khoury, M.D. alleges that Defendants Intermountain Healthcare, Inc., IHC Health Services, Inc., Mountain West Anesthesia, LLC, and five anesthesiologists submitted false claims for reimbursement to several federal healthcare programs, including Medicare. The gist of Dr. Khoury's complaint is that these anesthesiologists used their personal electronic devices (PEDs) during surgery and billed the government for the entire surgery—a practice Dr. Khoury asserts is fraudulent. The Defendants have filed two motions to dismiss under Federal Rule of Civil Procedure 12(b)(6). (ECF Nos. 62 & 64.) For the following reasons, the court GRANTS the motion to dismiss filed by Intermountain Healthcare and IHC Health Services (ECF No. 62) and GRANTS IN PART and DENIES IN PART the motion to dismiss filed by Mountain West Anesthesia, LLC and the five anesthesiologists (ECF No. 64).

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#### **BACKGROUND**<sup>1</sup>

Dr. Khoury is a vascular surgeon who worked at Dixie Regional Medical Center (DRMC)<sup>2</sup> in St. George, Utah, from 2007 to 2018. Defendant IHC Services, Inc. owns this hospital, along with twenty-three other hospitals, mostly in Utah. Defendant Intermountain Healthcare, Inc. is IHC Services, Inc.'s parent company. (These two defendants will simply be called "Intermountain.") Defendant Mountain West Anesthesia, LLC (MWA) is an anesthesiology group medical practice that employs over 150 anesthesiologists across Utah. MWA contracts with Intermountain to provide anesthesia services at Intermountain hospitals. MWA also employs the five anesthesiologists named as defendants: Drs. David A. Debenham, Eric A. Evans, Joshua J. Larson, John E. Miner, and Tyler W. Nelson. These anesthesiologists regularly perform anesthesia services at DRMC, where Dr. Khoury practiced. (These five defendants are collectively the "Anesthesiologist Defendants.")

#### I. <u>Background on Anesthesiology, Government Healthcare, and Billing</u>

Anesthesiologists are physicians who, among other things, administer anesthetic drugs to patients during surgery. There are different categories of anesthesia, including general anesthesia. General anesthesia places a patient in the deepest level of sedation; the patient becomes unconscious. It consists of three phases: induction (causing unconsciousness), maintenance (maintaining unconsciousness), and emergence (reversing unconsciousness). An anesthesiologist's job does not simply consist of administering anesthetic drugs, waiting for the procedure to end, and turning off the anesthesia. General anesthesia can be dangerous—and at

<sup>&</sup>lt;sup>1</sup> All factual allegations come from Dr. Khoury's amended complaint. The court accepts them as true for purposes of this order. <u>See Albers v. Bd. of Cnty. Comm'rs</u>, 771 F.3d 697, 700 (10th Cir. 2014).

<sup>&</sup>lt;sup>2</sup> DRMC recently changed its name to St. George Regional Hospital, but for simplicity the court will refer to the hospital by its former name.

times unpredictable—so it is critical for the anesthesiologist to constantly monitor the patient during surgery.

The Defendants participate in federal healthcare programs, including Medicare, Utah's and Nevada's Medicaid programs, and TRICARE. These federal programs provide health insurance coverage for people over sixty-five, people with end-stage renal disease, certain people with disabilities, people with low incomes, and active and retired members of the uniformed services (and their families). Because the federal government pays for all or part of Medicare, Medicaid, and TRICARE, claims submitted to these programs must comply with complex federal regulations and are subject to the False Claims Act. By submitting a claim to Medicare for payment, healthcare providers certify that they have complied with healthcare laws, Medicare regulations, and coverage rules. (Similar rules govern claims submitted to state Medicaid programs and TRICARE.) For example, the government will not pay for any services that are not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A).

For surgical patients with Medicare, Medicaid, or TRICARE insurance, the anesthesiologist will bill the federal government for the anesthesia services provided. To do so, the anesthesiologist submits a claim form with three primary pieces of information: (1) a uniform billing code ("CPT code") that corresponds to the anesthesia service rendered, (2) the duration of the anesthesia service in minutes ("anesthesia time"), and (3) the anesthesiologist's level of involvement, represented by a modifier code. These three variables are part of a formula that determines the amount of reimbursement.

Anesthesia CPT codes, which range from 00100 to 01999, reflect the anatomical region undergoing surgery. The government assigns a "base unit" of 0 to 30 units to each CPT code

based on the procedure's difficulty and risk. Base units reflect "all activities other than anesthesia time," including "usual preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, and monitoring services." 42 C.F.R. § 414.46(a)(1). Next, "anesthesia time" is "the time during which an anesthesia practitioner is present with the patient." § 414.46(a)(3). Anesthesia time must be continuous; i.e., if there is an "interruption" in anesthesia time, that time must be excluded from the total. The total time is converted into fifteen-minute time units for the formula. Finally, the modifier code reflects the level of physician involvement in the service. An "AA" modifier code applies when the anesthesiologist "personally performs the anesthesia procedure." § 414.46(c). Personally performed services—the highest level of anesthesiologist involvement—require the physician to "perform[] the entire anesthesia service alone." § 414.46(c)(1)(i).

Every claim for anesthesia reimbursement contains these three variables. Providers submit their claims to Medicare, Medicaid, or TRICARE using a form called "CMS Form 1500" (or the electronic version, an "837P File"). By submitting a CMS Form 1500, providers certify that the information is true, the claim complies with all laws and regulations, and the services performed were "medically necessary." Providers must also sign these forms. 42 C.F.R. § 424.33(b).

Hospital billing is different. To enroll in Medicare and Medicaid, hospitals must first sign a CMS Form 855A, which obligates them to comply with all laws and regulations. To continue to participate in these programs, hospitals must meet Conditions of Participation set by the Centers for Medicare & Medicaid Services (CMS). Some of the Conditions of Participation related to anesthesia services are that the services "must be provided in a well-organized manner under the direction of a qualified doctor" and that an "intraoperative anesthesia record" must be

provided for each patient. 42 C.F.R. § 482.52(b). This record details anesthesia-related events during surgery. Another Condition of Participation is that "[a] hospital must protect and promote each patient's rights," including the rights "to receive care in a safe setting" and "to make informed decisions regarding his or her care." § 482.13, (b)(2) & (c)(2).

Hospitals are reimbursed for their facility costs related to anesthesia care, such as the use of the operating room, anesthesia drugs, and other anesthesia-related supplies and equipment. Hospitals use CMS Form 1450 (or the electronic version, an "837I File") to submit these claims. Like for providers, these forms require citing the applicable CPT code, anesthesia time, and modifier code for the anesthesia services.<sup>3</sup> By submitting a CMS Form 1450, a hospital also certifies the accuracy of the information.

#### II. <u>Dr. Khoury's Allegations from DRMC</u>

Dr. Khoury, as the only vascular surgeon at DRMC for over a decade, worked closely with the Anesthesiologist Defendants. When Dr. Khoury started at DRMC, he immediately noticed that the Anesthesiologist Defendants would use PEDs, including smartphones, tablets, and laptop computers, during surgery. These devices were not being used for any work-related purposes. Rather, the Anesthesiologist Defendants engaged in personal tasks while the patient was sedated—when they should have been monitoring the patient. Concerned about patient safety because of these digital distractions, Dr. Khoury raised the issue at a surgical departmental meeting in 2007. His concerns fell on deaf ears, and Dr. Khoury continued to witness the Anesthesiologist Defendants use their PEDs in the operating suite.

<sup>&</sup>lt;sup>3</sup> Intermountain disputes that CMS Form 1450 contains these variables (Intermountain Mot. to Dismiss at 15, ECF No. 62), but the court assumes that these facts are true.

Dr. Khoury provides representative examples of the Anesthesiologist Defendants' behavior during surgery. Dr. Debenham disputed a power bill over the phone, Dr. Evans shopped online and read the news, Dr. Larson planned an extensive vacation to Lake Powell, Dr. Miner watched football games with headphones in, and Dr. Nelson selected music for and coordinated disc jockey gigs. At times, these behaviors were distracting to the rest of the surgical team. Dr. Khoury alleges that he asked Dr. Debenham to leave the room because of his heated phone call, that Dr. Miner's football-watching habit once caused Dr. Khoury to suspend the surgery, and that Drs. Evans, Miner, and Nelson were often so distracted that they had to be prompted to check patient vital signs. In total, Dr. Khoury estimates that these anesthesiologists spent up to 90% of the surgery focused on their PEDs—not the patient.

Dr. Khoury also gives three examples of surgeries from 2016 affected by the PED use of unnamed Anesthesiologist Defendants. First, Dr. Khoury performed an endovascular aneurysm repair on an elderly Medicare recipient. The anesthesiologist focused on his PED, which caused him to ignore patient vitals and miss signs that the patient's anesthesia was insufficient. It was only at Dr. Khoury's urging that the anesthesiologist did his job, but the anesthesiologist, MWA, and Intermountain billed Medicare for the whole anesthesia service. Second, Dr. Khoury performed carotid endarterectomies on two elderly Medicare recipients. Like in the first example, the unnamed Anesthesiologist Defendant used his PED for substantial portions of the surgery and failed to adequately monitor the patients, and the Defendants billed the government all the same. Third, Dr. Khoury performed a femoral-artery-to-tibial-artery "in-situ" vein bypass on an elderly Medicare recipient. Again, an unnamed Anesthesiologist Defendant performed personal tasks on his PED instead of monitoring the patient. Because the anesthesiologist was distracted, the patient lost blood and fluid, needed vasopressor medication to maintain blood

pressure, and endured greater kidney stress. Still, this anesthesiologist billed the government for the entire surgery. These examples, Dr. Khoury explains, are not outliers. This was the Anesthesiologist Defendants' common practice.

#### III. Procedural History

Dr. Khoury filed a five-count sealed complaint in June 2020. Nine months later, the United States declined to intervene as plaintiff, so Dr. Khoury continued as the Relator and the case was unsealed. Dr. Khoury then filed an amended complaint, operative here. After the case was reassigned to this court in August 2021, Intermountain filed a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), as did MWA and the Anesthesiologist Defendants. Both motions have been fully briefed, and the court heard oral argument on January 11, 2022.

#### **LEGAL STANDARDS**

To survive a Rule 12(b)(6) motion to dismiss, a plaintiff's complaint "must plead facts sufficient to state a claim to relief that is plausible on its face." Slater v. A.G. Edwards & Sons, Inc., 719 F.3d 1190, 1196 (10th Cir. 2013) (internal quotation marks omitted) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). A claim is facially plausible when the complaint contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Burnett v. Mortg. Elec. Registration Sys., Inc., 706 F.3d 1231, 1235 (10th Cir. 2013) (quoting Iqbal, 556 U.S. at 678). The court must accept all well-pleaded allegations in the complaint as true and construe them in the light most favorable to the plaintiff. Albers, 771 F.3d at 700. The court's function is "not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted." Sutton v. Utah Sch. for the Deaf & Blind,

173 F.3d 1226, 1236 (10th Cir. 1999) (quoting Miller v. Glanz, 948 F.2d 1562, 1565 (10th Cir. 1991)).

#### **ANALYSIS**

The False Claims Act imposes liability on those who defraud federal governmental programs. It targets anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"; "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 knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government"; or conspires to do any of those things. 31 U.S.C. § 3729(a)(1)(A), (B), (G) & (C). Anyone who violates the False Claims Act is liable for treble damages, plus civil monetary penalties. § 3729(a). Private parties (relators) who learn of false claims can sue on behalf of the United States, and they are given an incentive to do so by the potential for a portion of the recovery. § 3730(d). This is what Dr. Khoury did here.

Dr. Khoury's chief allegation is that by using their PEDs during surgery, the

Anesthesiologist Defendants failed to adequately monitor their patients, but they billed the
government as if they had monitored them. This tainted MWA's and Intermountain's invoices,
which violated the False Claims Act. His nearly hundred-page amended complaint lists four
False Claims Act causes of action against the Defendants: False Claims for Payment (under
subparagraph (A)), False Records and Statements Material to False Claims (under subparagraph

(B)), Retention of Overpayments (under subparagraph (G)), and Conspiracy (under subparagraph

(C)). In a fifth count, the amended complaint also alleges identical violations of the Nevada False Claims Act. The court will analyze each claim in turn.

## I. <u>False Claims for Payment & False Records and Statements Material to False Claims</u>

Dr. Khoury's first claim is for false claims for payment. 31 U.S.C. § 3729(a)(1)(A) penalizes anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." His second claim is for false records and statements material to false claims. 31 U.S.C. § 3729(a)(1)(B) penalizes anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

Subparagraphs (A) and (B) require falsity and scienter. Subparagraph (B) and certain claims under subparagraph (A) also require materiality. The Defendants argue that Dr. Khoury has failed to adequately plead any of these elements. Because subparagraphs (A) and (B) are interrelated, the court will discuss them together. The Defendants also argue that Dr. Khoury has failed to allege fraud "with particularity" as required under Federal Rule of Civil Procedure 9(b). The court will discuss Rule 9(b) last.

#### A. Falsity

Every false claim must be, well, false. Subparagraphs (A) and (B) require that a defendant must submit or cause to be submitted a "false or fraudulent claim" to the government. Falsity includes both factual and legal falsity. <u>United States ex rel. Polukoff v. St. Mark's Hosp.</u>, 895 F.3d 730, 741 (10th Cir. 2018). Dr. Khoury argues that the Defendants' claims were both factually and legally false, so the court will analyze both theories of falsity. Dr. Khoury also argues that Intermountain "cause[d]" false claims "to be presented" by "fail[ing] to assure the delivery of complete and adequate anesthesia services" by the Anesthesiologist Defendants,

which violated § 3729(a)(1)(A) and (B). (Opp'n at 32, ECF No. 71.) The court will address this argument last.

#### 1. <u>Factual Falsity</u>

A claim is factually false when a "payee has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided."

Polukoff, 895 F.3d at 741 (quoting United States ex rel. Thomas v. Black & Veatch Special

Projects Corp., 820 F.3d 1162, 1168 (10th Cir. 2016)). Dr. Khoury argues that the Defendants' claims were factually false for three reasons. First, the Defendants used CPT codes (and base units) that expressly cover "monitoring services," and that monitoring never happened because the anesthesiologists used their PEDs during surgery. Second, the Defendants included periods of PED usage when recording minutes of "anesthesia time" for each surgery. Third, the Defendants sought a higher level of reimbursement using a personal performance "AA" modifier code despite failing to adequately monitor their patients during surgery.

When interpreting a regulation, the court must "begin by examining the plain language of the text, giving each word its ordinary and customary meaning." <u>Scalia v. Wynnewood Ref. Co.</u>, 978 F.3d 1175, 1181 (10th Cir. 2020) (quoting <u>Mitchell v. Comm'r</u>, 775 F.3d 1243, 1249 (10th Cir. 2015)). If the regulation's meaning is clear, the court must enforce the regulation in accordance with this meaning. <u>Id.</u> The court finds that Dr. Khoury has failed to plead factual falsity here.

#### a. CPT Codes & Base Units

First, the Defendants' use of the CPT codes and corresponding base units was not false or fraudulent. The CPT code corresponds to the type of surgery. For example, anesthesia for an endovascular aneurysm repair (an upper abdomen procedure) is assigned a CPT code of 00790.

The number of base units assigned to each CPT code reflect "all activities other than anesthesia time," including "usual preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, and monitoring services." 42 C.F.R. § 414.46(a)(1). For example, a CPT code of 00790 garners seven base units. See CMS, 2022 Anesthesia Base Units by CPT Code (ZIP) (last visited Jan. 27, 2022). A higher number of base units equals a higher level of reimbursement. The function of a base unit is to identify the nature of the anesthesia service, based on the procedure's underlying difficulty and risk, and compensate the anesthesiologist for the base costs of the service.

Dr. Khoury latches onto the definition of base unit, which includes "monitoring services." § 414.46(a)(1). To be sure, monitoring the patient is part of the anesthesia service. But the complaint does not allege that the Anesthesiologist Defendants totally failed to monitor their patients, just that they did so in a distracted, inadequate way. (See Am. Compl. ¶¶ 15, 89, 153, 220, 256, ECF No. 52 (alleging a failure to "actively," "continuously," "appropriately," and "carefully" monitor).) Dr. Khoury admits that the Anesthesiologist Defendants, at minimum, "listen[ed] with one ear for beeps and blips from the monitoring machines." (Id. ¶ 94.) Even his examples of surgeries with distracted Anesthesiologist Defendants clarify that the anesthesiologists resumed fully monitoring their patients after the surgical team prompted them to do so. (Id. ¶¶ 158, 160–161.)

In short, there is no question that the amended complaint alleges that the Anesthesiologist Defendants performed <u>some</u> level of monitoring during the surgeries for which they billed the federal government.<sup>5</sup> Dr. Khoury fails to articulate how base units incorporate a standard of care

<sup>&</sup>lt;sup>4</sup> https://www.cms.gov/Center/Provider-Type/Anesthesiologists-Center.

<sup>&</sup>lt;sup>5</sup> Otherwise, Dr. Khoury would be advocating for a "worthless services" theory of falsity, where a provider seeks reimbursement for a service that is "so deficient that for all practical purposes it is the equivalent of no performance

or otherwise say anything about the quality of the care given. The court does not give credence to the expert opinions cited in Dr. Khoury's amended complaint. A plaintiff's expert cannot dictate the meaning of a law or regulation. That is the court's role. <u>United States v. Comstor Corp.</u>, 308 F. Supp. 3d 56, 69 (D.D.C. 2018). It seems clear that CPT codes and base units do not consider distractions in the operating room, so the Defendants' use of CPT codes was not false or fraudulent.

#### b. Anesthesia Time

Second, the Defendants' reporting of anesthesia time was not false or fraudulent.

Anesthesia time is "the time during which an anesthesia practitioner is present with the patient."

42 C.F.R. § 414.46(a)(3). Anesthesia time "starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary, that is, when the beneficiary may be placed safely under postoperative care." Id. It is "a continuous time period from the start of anesthesia to the end of an anesthesia service." Id.

Dr. Khoury attempts to define "presen[ce]" with the patient to mean the anesthesiologist's undivided attention. But the regulation only contemplates physical presence, not undivided attention. Anesthesia time starts at induction and ends at emergence (i.e., it lasts the whole time the patient is "under"). There is no requirement to deduct time when the anesthesiologist is not actively monitoring the patient but is still in the room. Section 414.46 mentions "interruption[s]" in anesthesia time, but its associated rulemaking supports the view that mental distractions in the operating room are not interruptions; they do not create "discontinuous anesthesia time."

at all." <u>Chesbrough v. Visiting Physicians Ass'n</u>, 655 F.3d 461, 468 (6th Cir. 2011). But Dr. Khoury disclaims this theory in his opposition. (Opp'n at 29, ECF No. 71.)

Examples of "breaks" in anesthesia time from the rulemaking include (1) when anesthesia is induced in a separate room, and the anesthesiologist leaves for the operating room; (2) when a patient is being prepared for anesthesia, but the surgery is delayed, so the anesthesiologist leaves the operating room; and (3) in facilities that use "anesthesia 'induction' rooms," where an anesthesiologist can start an IV before moving the patient to the operating room and inducing anesthesia. 64 Fed. Reg. 39608, 39624 (July 22, 1999). These are examples of interruptions in physical presence, not mental focus.

And Dr. Khoury's own authorities support the more logical reading of "presen[ce]."

Noridian, the Medicare contractor that processes the Defendants' claims, states that the "intraoperative report with anesthesia time" must note "any time spent away from beneficiary."

Noridian, Anesthesia and Pain Management (last visited Jan. 27, 2022). In other words, presence is contrasted with "time spent away." Even the American Society of Anesthesiologists (ASA), cited throughout the amended complaint, has defined a "discontinuous period[]" in anesthesia time as when an anesthesiologist is "temporarily not in attendance for direct monitoring and care of the patient." ASA, 2019 Relative Value Guide Updates Include

Anesthesia Time and Field Avoidance (last visited Jan. 27, 2022). Again, presence is contrasted with being "temporarily not in attendance." It seems clear that anesthesia time does not consider distractions in the operating room, so the Defendants' reporting of anesthesia time was not false or fraudulent.

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<sup>&</sup>lt;sup>6</sup> https://med.noridianmedicare.com/web/jeb/specialties/anesthesia-pain-management#documentation.

<sup>&</sup>lt;sup>7</sup> https://www.asahq.org/quality-and-practice-management/managing-your-practice/timely-topics-in-payment-and-practice-management/2019-relative-value-guide-updates-include-anesthesia-time-and-field-avoidance.

#### c. Personal Performance Modifier Code

Third, the Defendants' use of the "AA" personal performance modifier code was not false or fraudulent. This modifier applies when the anesthesiologist "performs the entire anesthesia service alone." 42 C.F.R. § 414.46(c)(1)(i). "Personally performed" anesthesia services can be distinguished from "medically directed" and "medically supervised" services. § 414.46(d), (f). As the names suggest, "medically directed" services are services where an anesthesiologist directs other personnel (like certified registered nurse anesthetists) in multiple procedures, and "medically supervised" services are services where an anesthesiologist supervises other personnel in multiple procedures. These modifier categories correspond to the level of anesthesiologist involvement in a surgery. Personally performed services involve the anesthesiologist conducting the whole anesthesia service, but medically directed services only require direction, and medically supervised services only require supervision. More involved services afford higher levels of reimbursement.

Dr. Khoury argues that using this modifier code is misleading because "the entire anesthesia service" includes monitoring, which he alleges the Anesthesiologist Defendants did not adequately do. But when anesthesiologists apply a personal performance modifier code to a procedure, they do not make any representations about the quality of the services provided. They simply confirm that they were the only clinician rendering those services. By affirming that they performed the entire service alone, anesthesiologists verify that they are not taking credit for others' work. And the complaint does not even allege that the Anesthesiologist Defendants totally failed to monitor their patients, just that they did so in a distracted way. If the court were to accept Dr. Khoury's interpretation of personal performance, what modifier code would he propose that the Defendants use? He does not allege that anyone other than the Anesthesiologist

Defendants monitored the patients. It seems clear that the personal performance modifier code does not consider distractions in the operating room, so the Defendants' using this code was not false or fraudulent.

Ultimately, by making these three factual falsity arguments, Dr. Khoury tries to import standards of care into benign Medicare billing regulations that simply do not exist. Applying the plain language of the regulations, the Defendants' claims were not factually false. The court dismisses all allegations of factual falsity from the complaint.

#### 2. Legal Falsity

A claim is legally false when a payee falsely certifies "compliance with a regulation or contractual provision as a condition of payment." Polukoff, 895 F.3d at 741 (quoting Thomas, 820 F.3d at 1168). A "false certification" can be express or implied. Id. "An express false certification theory applies when a government payee falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." Id. (quoting United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008), abrogated on other grounds by Universal Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176 (2016)). "By contrast, the pertinent inquiry for implied-false-certification claims is not whether a payee made an affirmative or express false statement, but whether, through the act of submitting a claim, a payee knowingly and falsely implied that it was entitled to payment." Id. (quoting Thomas, 820 F.3d at 1169).

Dr. Khoury argues that the Defendants' claims were legally false because the government will only reimburse providers for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury," and using a PED during surgery is not reasonable and necessary. He also argues that by billing for technical services that made implied claims about anesthesia,

Intermountain violated Medicare's conditions of participation. No matter if this is an express or an implied false certification theory, the court finds that Dr. Khoury has adequately pled legal falsity for MWA and the Anesthesiologist Defendants. But the conditions of participation arguments against Intermountain fail.

#### a. "Reasonable and Necessary"

The government will only pay for medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Although the parties dispute the definition of "reasonable and necessary," Dr. Khoury claims that the Tenth Circuit adopted a more expansive view in <u>United States ex rel. Polukoff v. St. Mark's Hospital</u>. There, the court said in no uncertain terms, "We thus hold that a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the [False Claims Act] if the procedure was not reasonable and necessary under the government's definition of the phrase." <u>Polukoff</u>, 895 F.3d at 743. The "government's definition" comes from the Medicare Program Integrity Manual. A procedure is "reasonable and necessary" if it is:

- Safe and effective;
- Not experimental or investigational . . . ; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
  - o <u>Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition</u> or to improve the function of a malformed body member;
  - o Furnished in a setting appropriate to the patient's medical needs and condition;
  - o Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

<u>Id.</u> at 742–43 (emphasis added). Binding Tenth Circuit precedent therefore incorporates "accepted standards of medical practice" into the meaning of "reasonable and necessary."

The Defendants, rightly realizing that <u>Polukoff</u> harms their case, argue that its holding was "dicta at best," because <u>Polukoff</u> was not about quality of services, but selection of services. (MWA & Anesthesiologist Mot. to Dismiss at 12, ECF No. 64.) But the <u>Polukoff</u> court intentionally issued a broad holding based on the Supreme Court's admonition that courts should not "adopt[] a circumscribed view of what it means for a claim to be false or fraudulent."

<u>Polukoff</u>, 895 F.3d at 743 (quoting <u>Escobar</u>, 579 U.S. at 192). The Tenth Circuit called its definition of falsity under the reasonable and necessary standard "broad," but that "strict enforcement" of the "rigorous" materiality and scienter elements would address any concerns about open-ended liability. <u>Id.</u>

As relevant here, Dr. Khoury has adequately alleged that the Anesthesiologist Defendants' use of PEDs in the operating room fell below the standard of care. The ASA has warned of the potential dangers of being distracted by PEDs in the operating room, including the risk to patient safety. ASA, Statement on Distractions (last updated Dec. 13, 2020). And the Anesthesiologist Defendants were certainly distracted by their PEDs on multiple occasions. In other words, they had a duty to monitor their patients, and their digital distractions breached that duty. By billing the government for anesthesia services that included rampant PED use, the Anesthesiologist Defendants presented legally false claims—claims that were not "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A)—for reimbursement.

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<sup>&</sup>lt;sup>8</sup> https://www.asahq.org/standards-and-guidelines/statement-on-distractions.

<sup>&</sup>lt;sup>9</sup> Dr. Khoury does not allege that Intermountain's hospital claims were not "reasonable and necessary." All he says is that "the unsafe anesthesia service compromised the quality of the surgery as a whole by elevating the risk to the patient from the surgical procedure." (Am. Compl. ¶ 187, ECF No. 52.) How an inadequately performed anesthesia service affects Intermountain's right to be reimbursed for providing the operating room, the anesthesia drugs, and other supplies is left unsaid. (See Mot. to Dismiss at 14–15, ECF No. 62.) Intermountain is therefore not affected by the court's ruling that MWA and the Anesthesiologist Defendants submitted legally false claims.

#### b. Medicare Conditions of Participation

Dr. Khoury also alleges that Intermountain violated several Medicare conditions of participation: that services "must be provided in a well-organized manner under the direction of a qualified doctor," that an "intraoperative anesthesia record" must be provided for each patient, and that "[a] hospital must protect and promote each patient's rights," including the rights "to receive care in a safe setting" and "to make informed decisions regarding his or her care."

42 C.F.R. §§ 482.52(b), 482.13, (b)(2) & (c)(2). The court finds that Dr. Khoury has failed to adequately plead violations of these conditions of participation.

First, there was no informed consent violation. "Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent." CMS, State Operations Manual Appendix A 92 (Dec. 12, 2013). The purpose of 42 C.F.R. § 482.13(b)(2) is to require that hospitals have policies to ensure patients have information on their "medical status, diagnosis, and prognosis" and that they are involved in their healthcare planning and treatment. Id. at 96. Even if patients' knowledge about anesthesiologist PED use would materially affect their decision to consent to surgery, that information would be impossible for a hospital to provide. How can a hospital know before a surgery that the anesthesiologist will be distracted by a PED?

Second, there was no safe setting violation. A "safe setting" is not an operating room free from digital distractions. Rather, Medicare guidance clarifies that the phrase "safe setting" in 42 C.F.R. § 482.13(c)(2) refers to far more foundational facility features. For example, hospitals should seek to keep patients at risk of suicide away from potentially dangerous items. Hospital

<sup>&</sup>lt;sup>10</sup> https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap a hospitals.pdf.

staff should ensure that they "follow current standards of practice for patient environmental safety, infection control, and security." Hospital units with infants or children should be armed with security features like alarms. And contaminated or unsafe materials should be moved away from patients. CMS, State Operations Manual Appendix A 107–12 (Dec. 29, 2017).

Third, there was no anesthesia service condition of participation violation. There are two relevant provisions in 42 C.F.R. § 482.52 and 482.52(b). Anesthesia services "must be provided in a well-organized manner under the direction of a qualified doctor," and an "intraoperative anesthesia record" must be "provided for each patient." Dr. Khoury argues that an anesthesia department rife with PED use cannot be well organized. But § 482.52 does not impose any requirements about the quality of anesthesia care. "Well organized" merely means that an anesthesia department is structured properly, that a physician is assigned to direct anesthesia services hospital-wide, that uniform policies exist, and that any adverse events are tracked. CMS, State Operations Manual Appendix A 450 (Dec. 2, 2011). Dr. Khoury also argues that the intraoperative anesthesia record must be accurate, and if it is not, Intermountain is liable. But the intraoperative anesthesia record guidance does not require that PED distractions be noted, but rather that the anesthesiologist document events like the "[n]ame, dosage, route and time of administration of drugs and anesthesia agents." Id. at 458 (May 21, 2010). Dr. Khoury does not allege that Intermountain's intraoperative anesthesia record policies were inadequate.

Dr. Khoury has failed to sufficiently plead that Intermountain violated Medicare conditions of participation, so this theory of legal falsity fails.

#### 3. "Causing" a False Claim To Be Presented

Dr. Khoury argues in his opposition memorandum that "Intermountain made representations about anesthesia on its claims for these surgeries" and therefore "Intermountain's

failure to assure the delivery of complete and adequate anesthesia services by the Defendant Anesthesiologists rendered those claims false." (Opp'n at 32, ECF No. 71.) Intermountain protests that Dr. Khoury did not discuss this theory in his amended complaint, so it is untimely. (Intermountain Reply at 2, ECF No. 86.) Dr. Khoury cites fourteen paragraphs from the amended complaint that purportedly discuss this "caused to be presented" theory. (Am. Compl. ¶¶ 142, 144–150, 187, 191, 193–196, ECF No. 52.) None of these paragraphs are on point. Even if Intermountain cited the CPT code, anesthesia time, and the AA modifier in its hospital claims, those elements were not factually false for MWA and the Anesthesiologist Defendants, so they are not factually false here.

Ultimately, "a court may not consider allegations or theories that are inconsistent with those pleaded in the complaint." Hayes v. Whitman, 264 F.3d 1017, 1025 (10th Cir. 2001). For this reason, Dr. Khoury's untimely argument against Intermountain fails. Even if he had alleged this in the amended complaint, this theory would still fail. Dr. Khoury at best has alleged "mere passive acquiescence"—not enough for FCA liability. United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah, 472 F.3d 702, 715 (10th Cir. 2006), abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel. Hunt, 139 S. Ct. 1507 (2019). Because (1) MWA and the Anesthesiologist Defendants' claims were not factually false, (2) Dr. Khoury failed to allege that Intermountain's hospital claims were not "reasonable and necessary," (3) Intermountain's hospital claims did not violate the Medicare Conditions of Participation, and (4) he did not allege that Intermountain "caused" MWA and the Anesthesiologist Defendants to submit legally false claims, the court dismisses the claims under subparagraphs (A) and (B) against Intermountain.

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#### **B.** Scienter

Subparagraphs (A) and (B) require that a defendant's state of mind must be "knowing[]." The False Claims Act says that a person acts "knowingly" when that person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information." § 3729(b)(1)(A). A person can act knowingly even without "specific intent to defraud." § 3729(b)(1)(B). The scienter element therefore requires that MWA and the Anesthesiologist Defendants submitted claims that were not "reasonable and necessary" (1) knowingly, (2) with deliberate ignorance, or (3) with aggravated gross negligence. United States ex rel. Burlbaw v. Orenduff, 548 F.3d 931, 945 & n.12 (10th Cir. 2008). Scienter is a "rigorous" requirement. Escobar, 579 U.S. at 192. "The proper focus of the scienter inquiry under § 3729(a) must always rest on the defendant's 'knowledge' of whether the claim is false . . . ." Burlbaw, 548 F.3d at 952–53. Dr. Khoury "must show more than a falsehood—[he] must show that [the Defendants] knowingly presented a false claim for payment." United States ex rel. Smith v. Boeing Co., 825 F.3d 1138, 1149 (10th Cir. 2016).

The court finds that Dr. Khoury has adequately pled scienter against MWA and the Anesthesiologist Defendants. The amended complaint alleges that the Anesthesiologist Defendants, as members of the ASA, knew of the dangers of using PEDs in the operating room. They knew that being distracted by PEDs in the operating room could cause patient harm. Still, they used their PEDs for personal business instead of monitoring their patients. Their conduct consistently fell below the standard of care, and yet they billed the government for monitoring

<sup>&</sup>lt;sup>11</sup> The court declines to adopt the Seventh Circuit's constrained scienter rule in <u>United States ex rel. Schutte v. SuperValu Inc.</u>, 9 F.4th 455 (7th Cir. 2021).

services that they should have known were not "reasonable and necessary." (<u>E.g.</u>, Am. Compl. ¶¶ 2–6, 96, 102, 153, 186, 212, 281.) Construing all well-pleaded facts in the light most favorable to Dr, Khoury, <u>Albers</u>, 771 F.3d at 700, the complaint contains "factual content that allows the court to draw the reasonable inference" that MWA and the Anesthesiologist Defendants acted with reckless disregard as to the falsity of their claims. <u>Burnett</u>, 706 F.3d at 1235.

#### C. Materiality

Subparagraph (B) requires that the false record or statement be "material" to a false or fraudulent claim. Likewise, false certification theories under subparagraph (A) require materiality. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." § 3729(b)(4). Like scienter, the materiality element is only relevant vis-à-vis a false claim. The only surviving false claims theory is that MWA and the Anesthesiologist Defendants submitted claims that were not "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A). Materiality is a holistic inquiry:

"[R]elevant factors include, but are not limited to (1) whether the Government consistently refuses to pay similar claims based on noncompliance with the provision at issue, or whether the Government continues to pay claims despite knowledge of the noncompliance; (2) whether the noncompliance goes to the "very essence of the bargain" or is only "minor or insubstantial"[;] and (3) whether the Government has expressly identified a provision as a condition of payment.

<u>United States ex rel. Janssen v. Lawrence Mem'l Hosp.</u>, 949 F.3d 533, 541 (10th Cir.) (quoting <u>Escobar</u>, 579 U.S. at 193–95), <u>cert. denied</u>, 141 S. Ct. 376 (2020) (mem.).

Dr. Khoury offers no evidence that the government has refused to pay for anesthesia services conducted by a distracted anesthesiologist. This weighs in favor of immateriality. See Escobar, 579 U.S. at 194–95. But by violating the regulation that all services be "reasonable and necessary," the Defendants' noncompliance "goes to the 'very essence of the bargain." This is

because Medicare will make "no payment" for services that are not reasonable and necessary.

42 U.S.C. § 1395y(a). A reasonable government payee would "attach importance" to anesthesiologist PED use because of this stringent requirement. Escobar, 579 U.S. at 193 n.5.

And the reasonable and necessary standard is an express condition of payment. See id. Taken together, Dr. Khoury has plausibly pleaded materiality for his surviving legally false claim.

#### **D. Rule 9(b)**

In a last-ditch effort to dismiss the complaint, the Defendants argue that the amended complaint fails to allege fraud with particularity. Although it provides examples of "allegedly distracted *services*," they argue, it "fails to identify representative false *claims* made to government healthcare programs." (MWA & Anesthesiologist Mot. to Dismiss at 17, ECF No. 64.) "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). But "[t]he purpose of Rule 9(b) is 'to afford defendant[s] fair notice of plaintiff's claims and the factual ground upon which [they] are based." Polukoff, 895 F.3d at 745 (quoting United States ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1172 (10th Cir. 2010)). "Rule 9(b) does not require omniscience." Id. (quoting Williams v. Duke Energy Int'l, Inc., 681 F.3d 788, 803 (6th Cir. 2012)). Therefore, "courts may consider whether any pleading deficiencies resulted from the plaintiff's inability to obtain information in the defendant's exclusive control." Id. (quoting George v. Urban Settlement Servs., 833 F.3d 1242, 1255 (10th Cir. 2016)).

All Dr. Khoury must do here is "provide enough information to describe a fraudulent scheme to support a plausible inference that false claims were submitted." <u>Lemmon</u>, 614 F.3d at 1173. And he does just that. He gives three examples of Medicare patient surgeries affected by anesthesiologist PED use. (Am. Compl. ¶¶ 162–184, ECF No. 52.) He gives examples of how

the Anesthesiologist Defendants were distracted by their PEDs during surgeries. (Id. ¶¶ 155–161.) He alleges that the Anesthesiologist Defendants often "spent the majority of their time in the operating room ignoring their patients and engrossed in their smartphones, tablets, and laptops." (Id. ¶ 152.) Sure, Dr. Khoury does not "identify any amount billed to the government, any claim number, the date on which any claim was actually submitted, or any person responsible for submitting any claim." (MWA & Anesthesiologist Mot. to Dismiss at 18, ECF No. 64.) But that is precisely the type of evidence that is "in the defendant's exclusive control." Polukoff, 895 F.3d at 745. MWA and the Anesthesiologist Defendants are surely on notice of Dr. Khoury's claims and "the factual ground upon which [they] are based." Id. The amended complaint satisfies Rule 9(b).

#### II. Retention of Overpayments

Dr. Khoury's fourth claim is for retention of overpayments. 31 U.S.C. § 3729(a)(1)(G) penalizes anyone who "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 knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." Violations of subparagraph (G) are commonly called "reverse false claims." They arise not from fraudulently seeking money from the government, but from fraudulently avoiding paying money owed to the government. See United States ex rel. Bahrani v. Conagra, Inc., 465 F.3d 1189, 1194 (10th Cir. 2006). But the "obligation" described in subparagraph (G) must have arisen before the initial false claim was made. See id. at 1195.

In other words, receiving government money for a false claim does not create an obligation to repay that money, triggering subparagraph (G). To hold otherwise would make

reverse false claims redundant with regular false claims. See United States ex rel. Tra v. Fesen, 403 F. Supp. 3d 949, 965 (D. Kan. 2019). Dr. Khoury tries to distinguish his reverse false claims theory by arguing that (1) he told the Defendants that using PEDs during surgery was a "dangerous distraction," (2) hospital administrators and other staff therefore knew about the conduct, (3) this knowledge should have led reasonably diligent hospital administrators to investigate whether they had received overpayments, and (4) the failure to do so violated subparagraph (G). (See Am. Compl. ¶¶ 241–244, ECF No. 52; Opp'n at 54–55, ECF No. 71.) But Dr. Khoury did not allege that he alerted the Defendants about false billing practices, just unsafe surgical practices. He did not tell the Defendants that he thought the anesthesiologists' conduct overcharged the government. The Defendants were simply left to connect the dots. Dr. Khoury's argument that Defendants' knowledge about PEDs created a legal duty to investigate potential overpayments is unsupported by caselaw or federal regulations. It would ultimately be a stretch to conclude that the Defendants had actual knowledge of improper claim submissions and overpayments based on Dr. Khoury's observations about cell phones during surgery. Cf. United States v. Dental Dreams, LLC, 307 F. Supp. 3d 1224, 1245 (D.N.M. 2018).

Based on the facts alleged in the complaint, the court cannot make the "reasonable inference that the [Defendants are] liable for" retention of overpayments. <u>Burnett</u>, 706 F.3d at 1235. Even though Dr. Khoury's complaint states a claim under subparagraphs (A) and (B), he cannot state a claim under subparagraph (G), so his fourth claim must be dismissed.

#### III. Conspiracy to Violate the False Claims Act

Dr. Khoury's third claim is for conspiracy to violate the False Claims Act. 31 U.S.C. § 3729(a)(1)(C) penalizes anyone who "conspires to commit a violation of subparagraph[s] (A), (B), . . . or (G)"—the subparagraphs under which Dr. Khoury's first, second, and fourth causes of

action are based. Without an attendant violation of the False Claims Act, there can be no conspiracy. United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 459 F. Supp. 2d 1081, 1091 (D. Kan. 2006) (also applying the familiar conspiracy elements to the False Claims Act). Because Dr. Khoury's first and second causes of action fail to state a claim against Intermountain, and his fourth cause of action fails to state a claim against any Defendant, his third claim for conspiracy also fails with respect to these dismissed claims.

For the surviving claim of legal falsity, the amended complaint is short on facts to support a reasonable inference that a conspiracy existed. All it says is that the Defendants "coordinat[ed] to enter inflated anesthesia time units in patient medical records, permitt[ed] the unrestrained use of PEDs in the operating room, and otherwise caus[ed] and condon[ed] the making and use of false records and statements material to false claims." (Am. Compl. ¶ 275, ECF No. 52.) And MWA and Intermountain "knew about this conduct and facilitated it to profit from the inflated bills." (Id. ¶ 229.) Other than an unsupported, one-time assertion that the Defendants "coordinated" efforts to "enter inflated anesthesia time units," the other allegations ("permitting," "condoning," "kn[owing]") are passive actions that do not show that there was ever an unlawful agreement to violate the False Claims Act. Cf. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556–57 (2007) ("Without more, parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality."). Dr. Khoury's third claim for conspiracy fails and must be dismissed.

#### IV. Nevada False Claims Act Claims

Dr. Khoury's fifth claim is for alleged violations of the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.040, which is analogous to the federal version. Because Dr. Khoury's

 $<sup>^{12}</sup>$  Nev. Rev. Stat. Ann. § 357.040(1)(a) is equivalent to 31 U.S.C. § 3729(a)(1)(A), Nev. Rev. Stat. Ann. § 357.040(1)(b) is equivalent to 31 U.S.C. § 3729(a)(1)(B), Nev. Rev. Stat. Ann. § 357.040(1)(f) & (g) are

first, second, third, and fourth causes of action fail to state a claim against Intermountain, his fifth claim for violating the Nevada False Claims Act also fails and must be dismissed. But because Dr. Khoury states a claim for legal falsity against MWA and the Anesthesiologist Defendants in his first and second causes of action, the analogous state-law claims survive dismissal.

#### **CONCLUSION**

"The False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." <u>Escobar</u>, 579 U.S. at 194 (quoting <u>Allison Engine Co. v. United States ex rel. Sanders</u>, 553 U.S. 662, 672 (2008)). But the court cannot escape <u>Polukoff</u>'s holding, which clarifies that violations of the standard of care can create False Claims Act liability. Dr. Khoury has plausibly alleged that MWA and the Anesthesiologist Defendants violated subparagraphs (A) and (B) of the False Claims Act and paragraphs (a) and (b) of the Nevada False Claims Act.

Therefore, the court orders as follows:

- 1. Intermountain's motion to dismiss (ECF No. 62) is GRANTED. All claims against Intermountain are dismissed with prejudice.
- 2. MWA and the Anesthesiologist Defendants' motion to dismiss (ECF No. 64) is GRANTED IN PART and DENIED IN PART. The court dismisses with prejudice Dr. Khoury's third and fourth claims against these Defendants, but the first, second, and fifth claims survive in part.

equivalent to 31 U.S.C. § 3729(a)(1)(G), and Nev. Rev. Stat. Ann. § 357.040(1)(i) is equivalent to 31 U.S.C. § 3729(a)(1)(C).

- 3. Dr. Khoury has failed to state a claim for factual falsity against MWA and the Anesthesiologist Defendants. The court therefore dismisses these allegations from the amended complaint. The only surviving theory of falsity in the first, second, and fifth claims is one for legal falsity under the "reasonable and necessary" standard.
- 4. Within fourteen days of the date of this order, the remaining parties shall file an attorney planning meeting report and a proposed scheduling order.

DATED this 27th day of January, 2022.

BY THE COURT:

TENA CAMPBELL

United States District Judge