UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

OMNI HEALTHCARE, INC., et al., Plaintiffs,	)	
v.	)	Civil Action No. 18-cv-12558-PBS
MD SPINE SOLUTIONS LLC, et al., Defendants.	)	

MEMORANDUM AND ORDER

January 6, 2025

Saris, D.J.

INTRODUCTION

Relator OMNI Healthcare, Inc. ("Relator" or "OMNI") brings this qui tam action on behalf of the federal government, 29 states, and the District of Columbia against MD Spine Solutions LLC ("MD Labs") and its owners, Denis Grizelj and Matthew Rutledge (collectively, "Defendants"). Relator alleges that Defendants violated the federal False Claims Act ("FCA") and state law by submitting or causing the submission of false claims for medically unnecessary urinary tract infection ("UTI") tests. Relator also alleges that Defendants submitted false claims for UTI testing that resulted from violations of the federal Anti-Kickback Statute ("AKS").

Defendants move for summary judgment on all of Relator's remaining claims. Relator cross-moves for partial summary judgment, asking the Court to resolve legal questions about the FCA standard for materiality, causation, and damages.

After hearing, the Court **ALLOWS** Defendants' motion for summary judgment (Dkt. 252) and **DENIES** as moot Relator's motion for partial summary judgment (Dkt. 255).

BACKGROUND

I. Factual Background

The following facts are undisputed, except where otherwise noted. See Deaton v. Town of Barrington, 100 F.4th 348, 353 (1st Cir. 2024).

A. MD Labs' UTI Testing

MD Labs is an independent clinical laboratory founded by Grizelj and Rutledge. MD Labs began performing UTI testing around 2017. The standard test for UTIs for over 60 years has been the bacterial urine culture ("BUC"). The BUC test involves placing a urine sample on a growth medium and waiting between twenty-four and forty-eight hours to see if any bacteria grow. MD Labs used a different testing method involving polymerase chain reaction ("PCR") technology. PCR testing amplifies one or more copies of a DNA segment in the sample, which enables identification of genetic material belonging to a particular biological origin. PCR testing is more costly than BUC testing.

MD Labs used PCR technology to test for either seventeen or nineteen pathogens that could cause UTIs, depending on the time period. Some requisition forms that MD Labs used for UTI testing orders only allowed the physician to select the entire seventeen- or nineteen-pathogen panel, while others enabled physicians to customize the panel to test for specific pathogens.

Relator OMNI is a medical practice in Florida owned by Dr. Craig Deligdish. OMNI sent around 600 samples to MD Labs for PCR UTI testing between 2017 and 2019, some of which were billed to government health programs. When an OMNI provider determined that a particular laboratory test was warranted, the provider would select the test in the patient's electronic medical record, and a medical assistant would complete a requisition form for a laboratory.

Deligdish instructed his staff to order PCR UTI testing from MD Labs even when the provider had selected a BUC test for the patient.[1] He did so in order to substantiate OMNI's FCA claims against MD Labs. All the PCR UTI testing that MD Labs performed for OMNI patients resulted from this switch.

[1] The parties explained at the summary judgment hearing that the only option for UTI testing in OMNI's electronic medical record system was a BUC test.

B. MD Labs' Sales Force

During the relevant period, MD Labs used both employees and independent contractors to promote its PCR UTI testing to providers. These sales representatives received commissions based on the revenue generated from the testing ordered by providers at their accounts. MD Labs trained and managed its sales representatives identically whether they were employees or independent contractors. In 2018, Dr. Deligdish and others at OMNI discussed PCR UTI testing with multiple independent-contractor sales representatives from MD Labs. There is no evidence that any sales representative offered or paid inducements to providers.

MD Labs sought legal advice about its use of independent-contractor sales representatives in late 2016 and early 2017. Outside counsel advised MD Labs multiple times that making commission-based payments to independent-contractor sales representatives could violate the AKS. Nonetheless, Grizelj and Rutledge both testified at their depositions that they either believed the arrangement was lawful or that they were unsure of its legality. MD Labs reconfigured its sales force to use solely employees after counsel reported that a 2021 Fourth Circuit decision had upheld a jury verdict finding federal FCA liability for commissions paid to independent-contractor sales representatives. See United States v. Mallory, 988 F.3d 730, 738 (4th Cir. 2021).

C. MD Labs' Billing Practices

MD Labs advertised to providers that it did not balance bill -- i.e., bill patients for the difference between its charge and the amount paid by insurance -- for PCR UTI testing and that a patient would never pay more than $50 per test. See Mass. Med. Soc'y v. Dukakis, 815 F.2d 790, 790 (1st Cir. 1987) (defining balance billing). The $50 cap applied if the patient lacked insurance, the patient's insurer denied coverage, or the billed amount would go entirely to the patient's deductible. An MD Labs sales representative advertised the $50 self-pay price to Dr. Deligdish and OMNI.

Although the record reflects that MD Labs routinely advertised its billing practices in this manner, Grizelj claimed at his deposition that MD Labs always balance billed patients. For his part, Rutledge stated in an affidavit that only some patients benefited from the $50 cap as part of MD Labs' financial hardship policy and that MD Labs stopped charging a reduced rate to certain patients around 2020.

II. Procedural Background

Relator filed this action against MD Labs in December 2018. Relator alleged that MD Labs submitted false claims for medically unnecessary or otherwise improper UTI tests, pharmacogenetic tests, and urine drug tests in violation of the federal FCA and various state and local analogs.

In October 2021, Defendants entered into a settlement agreement with the federal government and Relator to resolve some of the claims regarding urine drug tests ("UDTs"). Defendants admitted that MD Labs simultaneously performed presumptive and confirmatory UDTs even though Defendants knew that, in certain situations, providers would not use the result of the presumptive test because the more precise confirmatory result was available at the same time. Relator retained the right to pursue other claims relating to the "submission or causing the submission of false claims for [UTI] testing." Dkt. 85-1 at 9. The United States has not intervened in the non-settled claims.

Defendants moved to dismiss in May 2022. The Court denied the motion, holding that Relator had adequately pled claims under the federal FCA and state and local analogs with regard to medically unnecessary UTI testing. Relator subsequently amended its complaint to add claims under the AKS and the Eliminating Kickbacks in Recovery Act ("EKRA"). Relator also advanced three new sets of factual allegations in support of its FCA claims: 1) that MD Labs entered into independent-contractor service agreements in which it paid compensation for referrals; 2) that MD Labs routinely did not balance bill patients; and 3) that MD Labs submitted claim forms to health care programs listing diagnosis codes that differed from those on the requisition forms from the ordering physicians. Defendants moved to dismiss these new claims and allegations. The

Court allowed the motion with respect to the new AKS and EKRA claims and the allegation that Defendants submitted claim forms with false diagnosis codes but otherwise denied the motion.

In due course, Defendants moved for summary judgment on all of Relator's remaining claims. Relator cross-moved for summary judgment on three questions of law related to the federal FCA standard.[2]

LEGAL STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A genuine dispute is one which 'a reasonable jury could resolve . . . in the favor of the non-moving party,' and a material issue is one with the 'potential to affect the outcome . . . under the applicable law.'" Kinzer v. Whole Foods Mkt., Inc., 99 F.4th 105, 108 (1st Cir. 2024) (alterations in original) (quoting Cherkaoui v. City of Quincy, 877 F.3d 14, 23-24 (1st Cir. 2017)). In determining whether to grant summary judgment, a court must construe "the facts in the light most favorable to the non-moving party" and "draw[] all reasonable inferences" in its favor. Id.

[2] After the deadline for summary judgment motions, Defendants sought leave to file a supplemental motion arguing that the FCA's qui tam provision is unconstitutional. Because the Court grants summary judgment to Defendants on all of Relator's remaining claims for other reasons, there is no need to address the constitutional issue.

(quoting Harley-Davidson Credit Corp. v. Galvin, 807 F.3d 407, 408 (1st Cir. 2015)).

The party seeking summary judgment "must [first] adumbrate 'an absence of evidence to support the nonmoving party's case.'" Pleasantdale Condos., LLC v. Wakefield, 37 F.4th 728, 733 (1st Cir. 2022) (alteration in original) (quoting Brennan v. Hendrigan, 888 F.2d 189, 191 (1st Cir. 1989)). Once the movant does so, "[t]he burden then shifts to the nonmovant to establish the existence of a genuine issue of material fact." Id. To satisfy this burden, the nonmovant "must present definite, competent evidence" demonstrating that a trialworthy issue exists. Id. (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991)). "[C]onclusory allegations, improbable inferences, and unsupported speculation" do not suffice. Kinzer, 99 F.4th at 108 (quoting Ellis v. Fid. Mgmt. Tr. Co., 883 F.3d 1, 7 (1st Cir. 2018)).

DISCUSSION

I. Federal FCA Standard

A. General Standard

Relator's primary argument is that Defendants "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A). Liability under this presentment provision has multiple elements. "Evidence of an actual false claim is 'the sine qua non of [an FCA] violation.'" United States ex rel. Booker v.

Pfizer, Inc., 847 F.3d 52, 57 (1st Cir. 2017) (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004)). The plaintiff also must prove that the defendant either "present[ed]" or "cause[d] to be presented" the false claim to the federal government, 31 U.S.C. § 3729(a)(1)(A), and that the claim's falsity was material to the government's payment decision, see Guilfoile v. Shields, 913 F.3d 178, 187 (1st Cir. 2019). Lastly, "[t]he FCA includes a scienter requirement that the false claim be submitted 'knowingly.'" Id. (quoting 31 U.S.C. § 3729(a)(1)(A), (b)(1)). The FCA defines "knowingly" to mean that the defendant "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). "[P]roof of specific intent to defraud," however, is not required. Id. § 3729(b)(1)(B).

B. FCA Claims Premised on an AKS Violation

Two of Relator's theories of FCA liability are premised on alleged AKS violations. The AKS makes it a criminal offense to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person":

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . .

42 U.S.C. § 1320a-7b(b)(2). Congress enacted the AKS "to prevent medical providers from making decisions based on improper financial incentives rather than medical necessity and to ensure that federal health care programs do not bear the costs of such decisions." United States ex rel. Banigan v. PharMerica, Inc., 950 F.3d 134, 137 (1st Cir. 2020). "[T]he heartland of what the AKS is intended to prevent" is "the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal health care programs." Guilfoile, 913 F.3d at 192-93. "Essentially, the AKS targets any remunerative scheme through which a person is 'paid "in return for" referrals' to a program under which payments may be made from federal funds." Id. at 189 (quoting United States v. Patel, 778 F.3d 607, 618 (7th Cir. 2015)).

For purposes of the FCA, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim." 42 U.S.C. § 1320a-7b(g). In other words, "[a]n AKS violation that results in a federal health care

payment is a per se false claim under the FCA." Guilfoile, 913 F.3d at 190 (alteration in original) (quoting United States ex rel. Lutz v. United States, 853 F.3d 131, 135 (4th Cir. 2017)).

Certain legal principles come into play when an FCA claim is premised on an underlying AKS violation. For starters, the plaintiff need not prove that "compliance with the AKS was material to the government's decision to pay any specific claim." Id. The plaintiff must show, however, "a sufficient causal connection between [the] AKS violation and a claim submitted to the federal government." Id. Finally, establishing a violation of the AKS requires proof that the defendant acted "knowingly and willfully." 42 U.S.C. § 1320a-7b(b)(2). In this context, the term "willfully" refers to knowledge that the conduct was unlawful. See United States ex rel. Langer v. Zimmer Biomet Holdings, Inc., __ F. Supp. 3d __, __ (D. Mass. 2024) [2024 WL 3633536, at *5]; United States v. Teva Pharms. USA, Inc., 560 F. Supp. 3d 412, 421 (D. Mass. 2021); see also United States ex rel. Hart v. McKesson Corp., 96 F.4th 145, 154-55, 157 (2d Cir.) (adopting this construction and collecting cases from other circuits doing the same), cert. denied, __ S. Ct. __ (2024) [2024 WL 4426646].

II. Medically Unnecessary PCR Testing

Relator's main theory of FCA liability posits that Defendants submitted claims for medically unnecessary PCR testing for UTIs. Medicare is statutorily prohibited from covering "items or

services" that "are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A); see D'Agostino v. ev3, Inc., 845 F.3d 1, 10 (1st Cir. 2016). And the Medicare claim form requires the submitting entity to certify that the listed items or services were medically necessary. See United States ex rel. Riedel v. Bos. Heart Diagnostics Corp., 332 F. Supp. 3d 48, 57 (D.D.C. 2018). Thus, "claims for medically unnecessary treatment are actionable under the FCA." United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730, 742 (10th Cir. 2018) (quoting United States ex rel. Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370, 376 (5th Cir. 2004)).

Defendants seek summary judgment on this theory of liability on three grounds: 1) the claims for PCR UTI testing were not false because the tests were not medically unnecessary; 2) Relator cannot prove that Defendants caused the submission of false claims because Dr. Deligdish's direction to his staff to order PCR testing from MD Labs was an intervening cause that broke any causal chain with regard to OMNI-related claims; and 3) Defendants did not know that MD Labs was performing medically unnecessary tests. The Court agrees with Defendants' scienter argument and, therefore, need not address their other arguments.

"[A] laboratory generally may rely on [a] doctor's order in submitting a claim for reimbursement as medically necessary." United States v. Bertram, 900 F.3d 743, 750 (6th Cir. 2018); cf.

United States ex rel. Allen v. Alere Home Monitoring, Inc., 334 F. Supp. 3d 349, 365 (D. Mass. 2018) (explaining that the seller of an at-home testing kit was "generally entitled to rely on the independent judgment of a medical provider" regarding medical necessity). A laboratory violates the FCA, however, if it knows that it is submitting claims for medically unnecessary tests. See, e.g., Bertram, 900 F.3d at 750; Allen, 334 F. Supp. 3d at 357, 365; United States ex rel. Groat v. Bos. Heart Diagnostics Corp., 296 F. Supp. 3d 155, 165 (D.D.C. 2017). To satisfy the FCA's scienter requirement, Relator must show one of the following: 1) Defendants were aware they were submitting claims for medically unnecessary tests (actual knowledge); 2) they were aware of a substantial risk that they were submitting claims for medically unnecessary tests but intentionally avoided confirming that fact (deliberate ignorance); or 3) they were conscious of a substantial and unjustifiable risk that the tests were medically unnecessary but submitted the claims anyway (reckless disregard). See 31 U.S.C. § 3729(b)(1)(A); United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739, 751 (2023).

Defendants offer evidence indicating that they believed that PCR testing was superior to BUC testing for diagnosing UTIs. See Dkt. 254-3 ¶ 6; Dkt. 254-7 at 10, 14-15. The evidence Relator puts forth in response is not sufficient to raise a triable issue that

Defendants submitted claims for PCR UTI tests knowing that the performance of the PCR testing was medically unnecessary.

Relator first argues that a reasonable jury could infer that Defendant acted knowingly from the absence of government authorization for coverage for PCR UTI testing. There was no national coverage determination ("NCD") or local coverage determination ("LCD") governing Medicare's coverage of PCR UTI testing during the relevant period, although half of Medicare administrative contractors have since adopted an applicable LCD that took effect in June 2022. See Odell v. U.S. Dep't of Health & Hum. Servs., 995 F.3d 718, 720 (9th Cir. 2021) (describing NCDs and LCDs). This argument fails because Relator concedes that "an NCD or LCD may not be specifically required in all cases for a particular service" to be deemed medically necessary. Dkt. 269 at 7. "Absent a regulation, [an NCD], or an LCD, the Medicare contractor proceeds on a case-by-case basis to determine whether a service is reasonable and necessary." Odell, 995 F.3d at 720; see Banks v. Sec'y, Dep't of Health & Hum. Servs., 38 F.4th 86, 90 (11th Cir. 2022) ("[A]pplying [the medical necessity] standard often entails case-by-case adjudication."); Polukoff, 895 F.3d at 735 (noting that Medicare contractors may "make individual claim determinations, even in the absence of [a national or local coverage determination], . . . based on the individual's particular factual situation" (alterations in original) (quoting

Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003))). Knowledge of the absence of an applicable NCD or LCD would not have made Defendants aware of a substantial risk that the PCR UTI tests were medically unnecessary.

Relator's reliance on a set of guidelines from the American Urological Association ("AUA") is similarly unconvincing. The AUA guidelines -- which were "published" in 2019 and had their "validity confirmed" in 2022 -- state that "the impact of [PCR] tests on the accuracy of diagnosis [of UTIs] is not documented and cannot yet be recommended for incorporation into clinical practice." Dkt. 259-4 at 2, 6-7. The only specific claims for payment documented in the record, however, occurred in 2018 and early 2019. See Dkt. 259-8 at 3-4. Even assuming the AUA guidelines did not change in relevant part between 2019 and 2022, Relator has not shown that their original publication in 2019 pre-dated submission of any claim for payments. Nor has Relator provided guidelines with similar language about PCR testing that were published before MD Labs' submission of claims.

Relator also highlights an analysis examining fifty-seven PCR tests that MD Labs performed for OMNI patients. Of the requisition forms sent to MD Labs for these patients, the box for the PCR UTI panel was unchecked on twenty-one forms, and the provider failed to sign twenty-three forms. See id. at 4. Under the circumstances,

the absence of checkmarks and provider signatures on certain requisition forms would not have suggested a substantial risk that the ordered tests were medically unnecessary. See Allen, 334 F. Supp. 3d at 365 (asking whether the defendant "had a specific basis to second-guess" the physician's certification of medical necessity). As the form at issue was specific to MD Labs' PCR UTI testing, see Dkt. 259-15 at 2, MD Labs had no reason to doubt that the provider intended to order such a test. And the form expressly stated that a provider signature was "optional." Id.

Moreover, Relator offers no reason to believe that this sample of fifty-seven tests -- which was selected by counsel, see Dkt. 254-18 at 5 -- is representative of the PCR UTI tests performed for OMNI patients, let alone of the tests MD Labs performed for all patients. With no proof of the representativeness of this sample, all that is left is missing checkmarks and signatures on a small percentage of the requisition forms submitted to MD Labs. At best, this evidence may support a reasonable finding that Defendants negligently performed PCR tests that providers did not intend to order. But "innocent mistakes and negligence are not offenses under the [FCA]." United States v. President & Fellows of Harvard Coll., 323 F. Supp. 2d 151, 189 (D. Mass. 2004) (alteration in original) (quoting United States v. Taber Extrusions, LP, 341 F.3d 843, 845 (8th Cir. 2003)).

Finally, Relator points to a January 2018 email in which Grizelj recommended to Rutledge that they ask a Medicare administrative contractor for "guidance on medical necessity" regarding the PCR UTI tests. Dkt. 259-25 at 2. Relator does not, however, offer evidence indicating that Defendants were ever advised that they were conducting medically unnecessary tests or aware of a substantial risk that the tests were medically unnecessary when a doctor orders them.

In addition to arguing that the performance of PCR UTI testing was generally medically unnecessary, Relator advances a separate theory regarding the make-up of MD Labs' PCR testing panels. Relator notes that MD Labs' default PCR panel tested for either seventeen or nineteen pathogens and argues that use of these overly broad panels resulted in the performance of medically unnecessary tests. It is true that "bundled tests, ordered via a pre-printed form, can create FCA liability, provided the certifying entity is aware that one or more of the tests is medically unnecessary, or recklessly disregards such a risk." Allen, 334 F. Supp. 3d at 357 (collecting cases). But a medical expert for Defendants opined based on peer-reviewed literature that the make-up of MD Labs' panels of seventeen and nineteen pathogens was appropriate for UTI testing. See Dkt. 254-5 at 6. Relator does not respond with any record evidence indicating that the make-up of the panels was unnecessarily broad.

In sum, no reasonable jury could conclude on this record that Defendants knew that they were submitting claims for PCR UTI testing that was medically unnecessary. Summary judgment is therefore warranted for Defendants on this theory of liability.

III. Independent-Contractor Sales Representatives

Relator's second theory of FCA liability is premised on Defendants' purported violation of the AKS via MD Labs' commission-based payments to independent-contractor sales representatives.[3] The AKS prohibits individuals from paying remuneration to induce a person to "arrange for or recommend purchasing . . . or ordering" healthcare items or services. 42 U.S.C. § 1320a-7b(b)(2)(B). The AKS includes a safe harbor for payments "by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services," id. § 1320a-7b(b)(3)(B); see 42 C.F.R. § 1001.952(i), but this safe harbor does not protect payments to independent contractors, see Mallory, 988 F.3d at 738; Langer, __ F. Supp. 3d at __ [2024 WL 3633536, at *4].

[3] Relator asserts that these payments also violated the EKRA, which criminalizes the knowing and willful payment of "any remuneration . . . to induce a referral of an individual to a . . laboratory" for "services covered by a health care benefit program." 18 U.S.C. § 220(a)(2). Relator frames its arguments solely in terms of the AKS, however, and does not contend that the analysis would differ under the EKRA.

The plain language of the AKS's broad prohibition covers payments to independent contractors who were hired to influence those who make healthcare decisions on behalf of providers by promoting a company's product or service. See Mallory, 988 F.3d at 738; Langer, __ F. Supp. 3d at __ [2024 WL 3633536, at *3-4]. At the hearing, the government stated: "The law is that paying independent contractors commission-based fees is not per se unlawful, but it does bring the conduct within the confines of the [AKS]." Dkt. 277 at 30.[4] While Relator does not dispute that MD

[4] The Department of Health and Human Services' Office of Inspector General ("OIG") has twice outlined factors relevant for determining whether an independent-contractor sales arrangement falls afoul of the AKS. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,739 (May 5, 2003) (advising consideration of 1) "[t]he amount of compensation"; 2) "[t]he identity of the sales agent engaged in the marketing or promotional activity (e.g., is the agent a 'white coat' marketer or otherwise in a position of exceptional influence)"; 3) "[t]he sales agent's relationship with his or her audience"; 4) "[t]he nature of the marketing or promotional activity"; 5) "[t]he item or service being promoted or marketed"; and 6) "[t]he composition of the target audience"); OIG Advisory Opinion No. 98-10, 1998 WL 35287765, at *3-4 (Aug. 31, 1998) (listing the following "suspect characteristics": 1) "compensation based on percentage of sales"; 2) "direct billing of a Federal health care program by the Seller for the item or service sold by the sales agent"; 3) "direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program"; 4) "direct contact between the sales agent and Federal health care program beneficiaries"; 5) "use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients"; and 6) "marketing of items or services that are separately reimbursable by a Federal health care program"); see also Langer, __ F. Supp. 3d at __ [2024 WL 3633536, at *4] (discussing these OIG factors).

Labs' payments to sales representatives who were employees fall within the bona fide employee safe harbor, it alleges that the payments to independent-contractor sales representatives violated the AKS and that this violation resulted in the submission of claims for payment for PCR UTI testing.[5]

Again, Defendants seek summary judgment on this theory of liability on three alternative grounds: 1) no underlying AKS violation occurred because Defendants did not pay the sales representatives with an unlawful intent to induce referrals; 2) no underlying AKS violation occurred because Defendants did not know that the payments at issue were unlawful; and 3) even if an underlying AKS violation occurred, it did not result in the submission of claims.

The Court begins and ends its analysis with Defendants' causation argument. Under 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA. The First Circuit has interpreted the "resulting from" language in this provision as requiring "a sufficient causal connection

[5] Relator asserts that MD Labs paid sales representatives a fee for collecting specimens from providers. It is not clear from the record whether these payments are different from the commission-based payments that the parties otherwise discuss. The characterization of the payments as a specimen collection fee rather than a commission does not affect the legal analysis.

between an AKS violation and a claim submitted to the federal government." Guilfoile, 913 F.3d at 190.

The parties dispute the relevant standard for determining whether this "sufficient causal connection" exists. Defendants urge the Court to apply the "but-for" causation standard adopted by the Sixth and Eighth Circuits. See United States ex rel. Martin v. Hathaway, 63 F.4th 1043, 1052-55 (6th Cir.), cert. denied, 144 S. Ct. 224 (2023); United States ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 834-36 (8th Cir. 2022). Under this standard, the plaintiff must show "that the defendants would not have included particular 'items or services' [in claims for payment] absent the illegal kickbacks." Cairns, 42 F.4th at 835 (quoting 42 U.S.C. § 1320a-7b(g)). Relator responds that proof of but-for causation is not necessary. The Third Circuit has held that a claim results from an AKS violation if the plaintiff shows "that at least one of [the] claims sought reimbursement for medical care that was provided in violation of the [AKS]." United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 98 (3d Cir. 2018). In other words, a court must ask whether "a particular patient [was] exposed to an illegal recommendation or referral and a provider submit[ted] a claim for reimbursement pertaining to that patient." Id. at 100. Courts within this district are split on whether but-for causation is required in this context. Compare United States v. Regeneron Pharms., Inc.,

No. 20-11217-FDS, 2023 WL 6296393, at *11 (D. Mass. Sept. 27, 2023) (adopting the but-for causation standard), perm. app. granted, No. 23-8036, 2023 WL 8599986 (1st Cir. Dec. 11, 2023), with United States ex rel. Witkin v. Medtronic, Inc., No. 1:11-cv-10790-IT, 2024 WL 1892405, at *18-19 (D. Mass. Mar. 31, 2024) (rejecting but-for causation), and United States v. Teva Pharms. USA, Inc., 682 F. Supp. 3d 142, 148 (D. Mass. 2023) (same).

The Court holds that the "resulting from" language in § 1320a-7b(g) requires a plaintiff to show that the AKS violation was a but-for cause of the inclusion of the item or service in a claim for payment. To begin, I do not read the First Circuit's decision in Guilfoile to have reached a binding holding adopting the Third Circuit's approach. While the First Circuit stated that a "sufficient causal connection" is required and then cited to the Third Circuit's opinion in Greenfield, it did not define what type of causal connection is "sufficient." Guilfoile, 913 F.3d at 190. The First Circuit also expressly warned that it was "not attempt[ing] to assess the full implications of" § 1320a-7b(g) because it was addressing "not the standard for proving an FCA violation based on the AKS, but rather the requirements for pleading an FCA retaliation claim." Id.

Moreover, construing "resulting from" to mandate a showing of but-for causation is consistent with basic principles of statutory interpretation. When, as here, "Congress uses a term in a statute

and does not define it," courts "generally assume that the term carries its plain and ordinary meaning." United States v. Saemisch, 70 F.4th 1, 7 (1st Cir. 2023) (quoting City of Providence v. Barr, 954 F.3d 23, 31 (1st Cir. 2020)). The Supreme Court has explained that the "ordinary meaning" of a nearly identical phrase -- "results from" -- entails "a requirement of actual causality," i.e. but-for causation. Burrage v. United States, 571 U.S. 204, 210-11 (2014). There is "no textual or contextual indication" that Congress intended to give a different meaning to the phrase "resulting from" in § 1320a-7b(g). Id. at 212. While the congressional record suggests that § 1320a-7b(g) was enacted to "strengthen[] whistleblower actions," Guilfoile, 913 F.3d at 190 (alteration in original) (quoting 155 Cong. Rec. S10,852, S10,853 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman)), that legislative history cannot "be used to 'muddy' the meaning of 'clear statutory language.'" Food Mktg. Inst. v. Argus Leader Media, 588 U.S. 427, 436 (2019) (quoting Milner v. Dep't of Navy, 562 U.S. 562, 572 (2011)). Relator emphasizes the First Circuit's decision in United States ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377 (1st Cir. 2011), in support of its argument that it need not prove but-for causation. The court in Hutcheson expressly declined to address the then-recently enacted language in § 1320a-7b(g), see id. at 392 & n.17, so that decision does not help Relator's case.

Applying this but-for causation standard, the Court concludes that no reasonable jury could find on this record that the submission of claims for PCR UTI testing resulted from the alleged AKS violation, i.e., Defendants' commission-based payments to independent-contractor sales representatives. For one, Relator has offered no evidence that the independent-contractor status of some of its sales representatives unduly influenced any provider's decision to order PCR UTI testing from MD Labs. As previously noted, the AKS includes a safe harbor for payments made to bona fide employees. See 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i). Defendants submitted unrebutted evidence that MD Labs trained, managed, disciplined, and paid its sales representatives identically whether they were employees or independent contractors. See Dkt. 254-3 ¶¶ 15-17. Plainly, the sales representatives, whether employee or independent contractor, sought to influence referral of testing to MD Labs -- that's why they were hired. But there is no evidence that MD Labs' independent-contractor sales representatives acted any differently than the employees receiving commission-based payments from MD Lab.

Nor does the record support a reasonable finding that any independent-contractor sales representative engaged in conduct that improperly or unduly influenced a provider's decision to purchase the product. It is true that sales representatives

participated in discussions with OMNI about an arrangement in which OMNI would share in the profits from PCR UTI tests ordered from MD Labs. See Dkt. 259-22 at 2; Dkt. 259-23 at 2. While Defendants insist that these troubling discussions concerned the negotiation of a lawful reference laboratory agreement, they have not adequately explained when that type of arrangement is permissible. Nonetheless, the record reflects that the parties never executed any such agreement, and Relator offers no evidence that the profit-sharing proposal ever came to fruition. Thus, any potentially improper conduct by the independent-contractor sales representatives did not cause the submission of claims for MD Labs' PCR UTI testing.

Finally, Dr. Deligdish admitted at his deposition that OMNI chose to order PCR UTI testing from MD Labs in every instance in order to substantiate FCA allegations against Defendants. See Dkt. 254-12 at 22-23; Dkt. 260 ¶¶ 60-61. In other words, Dr. Deligdish caused submission of false claims for PCR testing which he knew were not medically necessary. Relator cites no evidence that the commission-based payments to independent-contractor sales representatives played any role in OMNI's decision to order PCR UTI tests from MD Labs. Accordingly, no reasonable jury could find that the alleged AKS violation arising from these payments was a but-for cause of the submission of claims for payment to the federal government.

IV. Billing Practices

That leaves Relator's final theory of FCA liability, which concerns Defendants' purported failure to balance bill patients and capping of out-of-pocket costs for patients at $50. Relator asserts that these billing practices violated the AKS and that Defendants submitted claims for payment to the federal government that resulted from these AKS violations. Defendants have submitted evidence that they never engaged in these practices. The matter is disputed.

Even assuming that the record suffices to show that MD Labs declined to balance bill and capped out-of-pocket costs for certain patients, Relator has put forth no proof that MD Labs submitted a claim for PCR UTI testing to a government health care program for a patient that received either of these financial benefits. The only evidence in the record of specific claims for MD Labs' PCR UTI testing is a summary chart that describes fifty-seven tests conducted by MD Labs for OMNI patients (only some of which involved claims submitted to a government health care program). See Dkt. 259-8 at 3-4. The chart does not state whether MD Labs declined to balance bill or capped out-of-pocket costs for any of the patients for whom the claims were submitted. Without such evidence, a reasonable jury could not conclude that, absent the allegedly

unlawful kickbacks, Defendants would not have submitted the claims for payment for PCR UTI testing. See Cairns, 42 F.4th at 835.[6]

V. Texas Law Claims

Finally, Defendants assert that Relator's claims under various state and local analogs of the federal FCA fail as a matter of law for the same reasons as its federal claims. Relator responds that even if summary judgment is warranted for Defendants on its federal claims, its claim under Texas law (Count XXVIII) survives. Relator points to three purported differences between Texas law and federal law: 1) liability under the Texas Medicaid Fraud Prevention Act ("TMFPA") does not require proof either of the submission of false claims or of materiality; 2) the TMFPA defines "materiality" differently than the federal FCA in that it "reaches conduct beyond influencing the payment of money"; and 3) unlike the federal AKS, neither the TMFPA nor the Texas Anti-Kickback Statute requires that a defendant act "willfully." Dkt. 259 at 30-31.

Relator's arguments about Texas law are unconvincing. Because the Court's grant of summary judgment to Defendants on the federal

[6] This evidentiary gap would be fatal to this theory of liability even under the looser causation standard employed by the Third Circuit. See Greenfield, 880 F.3d at 98, 100 (requiring a plaintiff to "prove that at least one of [the] claims sought reimbursement for medical care that was provided in violation of the [AKS]," i.e., that "a particular patient [was] exposed to an illegal recommendation or referral and a provider submit[ted] a claim for reimbursement pertaining to that patient").

claims does not turn either on the federal FCA's materiality element or on the willfulness requirement for a federal FCA claim premised on an AKS violation, any distinctions in those elements between federal and Texas law are beside the point. And insofar as Relator wishes to advance theories of liability under Texas law that differ from those it presses under federal law -- i.e., that do not involve the submission of false claims -- it does not articulate those theories with any specificity. Relator's allusion to other possible theories of liability cannot save its case at this juncture.

ORDER

For the reasons stated above, Defendants' motion for summary judgment (Dkt. 252) is **ALLOWED**, and Relator's motion for partial summary judgment (Dkt. 255) is **DENIED** as moot.

SO ORDERED.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
United States District Judge