IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

U.S. ex rel. Tullio Emanuele,)
)
District Polaton	(
Plaintiff/Relator,)
v.) C.A. No. 10-245 Erie
)
Medicor Associates, et al,)
)
Defendants.)
)
)

MEMORANDUM OPINION

Conti, Chief District Judge

I. Introduction

Pending before the court is a motion for reconsideration filed by defendants The Hamot Medical Center of the City of Erie ("Hamot") and Medicor Associates, Inc. ("Medicor", and together with Hamot, "defendants") (ECF No. 357). Defendants' motion challenges rulings made by this court in a memorandum opinion issued on March 15, 2017 ("Memorandum Opinion") (ECF No. 345) in which the court denied defendants' motions for summary judgment (ECF Nos. 280, 286).

The underlying action seeks damages pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(C) (the "FCA"), based upon the allegations by U.S. *ex rel*. Tullio Emanuele ("plaintiff") that defendants submitted false claims for payment to the United States. The alleged false claims were for referrals that violated the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b. To prevail on his FCA claim, plaintiff must ultimately

demonstrate that the alleged misrepresentations to the government were "material to the Government's payment decision." <u>Universal Health Servs. v. United States ex rel. Escobar</u>, 136 S.Ct. 1989, 2002 (2016). In their summary judgment motions, defendants argued, *inter alia*, that plaintiff had failed to adduce sufficient proof of materiality. The court disagreed. (Memorandum Opinion (ECF No. 345) at 32-35.) Defendants seek reconsideration of this determination in light of the Third Circuit Court of Appeals' recent decision in <u>United States ex rel. Petratos v. Genentech, Inc.</u>, 855 F.3d 481 (3d Cir. 2017).

Because defendants did not adduce a proper ground for reconsideration, defendants' motion will be denied.

II. Standard of Review

The purpose of a motion for reconsideration is "to correct manifest errors of law or fact or to present newly discovered evidence." Max's Seafood Café v. Quinteros, 176 F.3d 669, 677 (3d Cir.1999). A motion for reconsideration under Federal Rule of Civil Procedure 59(e) must therefore rely on one of three grounds: (1) an intervening change in the law; (2) the availability of new evidence; or (3) the need to correct clear error of law or prevent manifest injustice. N. River Ins. Co. v. CIGNA Reinsurance Co., 52 F.3d 1194, 1218 (3d Cir. 1995). A motion for reconsideration is not properly grounded in a request for a district court to rethink a decision it has already rightly or wrongly made. Williams v. Pittsburgh, 32 F.Supp.2d 236, 238 (W.D.Pa. 1998). Litigants are cautioned to "evaluate whether what may seem to be a clear error of law is in fact simply a point of disagreement between the Court and the litigant." Waye v. First Citizen's Nat'l Bank, 846 F.Supp. 310, 314 n.3 (M.D.Pa. 1994) (quoting Atkins v. Marathon LeTourneau Co., 130 F.R.D. 625, 626 (S.D. Miss. 1990). Motions for reconsideration should not relitigate issues already resolved by the court and should not be used to advance additional

arguments which could have been made by the movant before judgment. Reich v. Compton, 834 F.Supp. 753, 755 (E.D.Pa. 1993), aff'd in part, rev'd in part, 57 F.3d 270 (3d Cir. 1995).

III. Discussion

Defendants seek reconsideration of this court's summary judgment decision with respect to the FCA's requirement that a misrepresentation must be "material to the Government's payment decision" in order to be actionable. Escobar, 136 S.Ct. at 2002. As more fully discussed in the Memorandum Opinion, the statutes giving rise to the FCA claims in this case, the Stark Act and the Anti-Kickback Statute, each generally prohibit a health care entity from submitting payments to Medicare based upon referrals from physicians who have a "financial relationship" with the health care entity. 42 U.S.C. §§ 1395nn(a)(1); 1320a-7b(b). Each statute also contains a number of statutory exceptions (or safe harbors) that permit those referrals if certain statutory requirements are satisfied. 42 U.S.C. § 1395nn(b)-(e); 42 C.F.R. § 1001.952(d). Several of the statutory exceptions invoked in the instant case require that the pertinent financial arrangements be "in writing" and "signed by the parties." 42 C.F.R. § 411.357(l)(1); 42 C.F.R. § 411.357(d)(1); 42 C.F.R. § 1001.952(d)(1).

Plaintiff's claims in this action focus, in part, on the written documents governing the financial arrangement between Hamot and Medicor physicians, which were occasionally allowed to lapse or terminate before being renewed. (Memorandum Opinion (ECF No. 345) at 13.)

Plaintiff contends that any submissions to Medicare for payments based on referrals that occurred while those contracts had lapsed do not satisfy the writing requirements of the pertinent statutory exceptions and safe harbors. (Id.) Defendants counter that these "technical" violations of the statutory writing requirement are not "material" within the meaning of the FCA. (Id. at 32.)

At summary judgment, the parties (and the court) agreed that the United States Supreme Court's decision in <u>Escobar</u> supplied the standard for evaluating the materiality requirement in an FCA case. <u>Escobar</u>, 136 S.Ct. at 2002. The Supreme Court described the materiality standard as follows:

The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," Allison Engine, 553 U.S., at 672, 128 S.Ct. 2123 or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. See United States ex rel. Marcus v. Hess, 317 U.S. 537, 543, 63 S.Ct. 379, 87 L.Ed. 443 (1943) (contractors' misrepresentation that they satisfied a non-collusive bidding requirement for federal program contracts violated the False Claims Act because "[t]he government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive"); see also Junius Constr., 257 N.Y., at 400, 178 N.E., at 674 (an undisclosed fact was material because "[n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood" of the undisclosed fact).

In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Escobar, 136 S.Ct. at 2003-04. Based upon a careful reading of Escobar, this court deduced that the following factors warranted consideration in evaluating materiality: whether compliance with

a statute is a condition of payment; whether the violation goes to "the essence of the bargain" or is "minor or insubstantial"; and whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations. (Memorandum Opinion (ECF No. 345) at 33 (citing Escobar, 136 S.Ct. at 2003-04.) The court concluded that each of these factors favored a finding of materiality:

As an initial matter, the Stark Act expressly prohibits Medicare from paying claims that do not satisfy each of its requirements, including every element of any applicable exception. 42 U.S.C. §§1395nn(a)(1), (g)(1). The relevant exceptions expressly require that any financial arrangements that would otherwise violate the Stark Act must be set forth in writing. 42 C.F.R. § 411.357(d), (l). Although "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment," they nevertheless represent "relevant" evidence in favor of materiality. <u>Id</u>. at 2002-03.

The writing requirement is not "minor or insubstantial." Id. at 2003. The Stark Act "insist[s] on the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the remuneration to be received for those services." Kosenske, 554 F.3d at 96. Compliance with the writing requirement permits a reviewer to analyze the timeframe, rate of compensation, and the identifiable services contemplated in the arrangement to determine whether any portion is based on the volume or value of physician referrals. See 42 C.F.R. § 411.357(1). CMS guidance also requires a signature as a manifestation of the parties' assent to the arrangement, a requirement that "plays a role in preventing fraud and abuse." 80 Fed. Reg. 70886, These requirements go to the very "essence of the bargain" between the government and health care providers with respect to Stark Act compliance. Escobar, 136 S.Ct. at 2003 n. 5 (quoting Junius Contr. Co. v. Cohen, 178 N.E. 672, 674 (N.Y. 1931)).

There is no evidence in the record to suggest that "the Government consistently refuses to pay claims" based on Stark Act non-compliance (or, conversely, that "the Government pays [those claims] in full despite its actual knowledge that certain requirements were violated"). <u>Id</u>. at 2003-04. Plaintiff, however, has pointed to public records suggesting that health care providers have paid penalties after self-reporting similar violations on at least nine occasions since 2009. (ECF No. 310-12.) In the absence of any evidence to the contrary, this factor weighs slightly in favor of materiality.

(Memorandum Opinion (ECF No. 345) at 33-34.)

Defendants seek reconsideration of this conclusion in light of the Third Circuit Court of Appeal's recent decision in <u>Petratos</u>. In <u>Petratos</u>, the relator alleged that the defendant, a drug manufacturer, had concealed data showing that the side effects of a cancer drug were more severe than reported. <u>Petratos</u>, 855 F.3d at 485. The relator alleged that physicians would not have prescribed the drug had they known about the concealed data. <u>Id</u>. According to the relator, the concealment of that data caused those physicians to submit claims to Medicare for the drug that were not reasonable and necessary. <u>Id</u>. at 485-86. Critically, the relator conceded that "CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance." <u>Id</u>. at 490 (emphasis in original).

The Third Circuit Court of Appeals began its analysis by reviewing the guidance provided by the United States Supreme Court's decision in Escobar:

Just last year in <u>Universal Health Services v. United States ex rel.</u>
<u>Escobar</u>, the Supreme Court confirmed that "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." — U.S. —, 136 S.Ct. 1989, 1996, 195 L.Ed.2d 348 (2016). The Court described this standard as "demanding" and "rigorous," <u>id</u>. at 2002–03, and explained that a material misrepresentation is one that goes "to the very essence of the bargain," id at 2003 n.5 (citations omitted). This requirement helps ensure that the False Claims Act does not become "an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract." <u>Id</u>. at 2003 (citation and internal quotation marks omitted).

The Supreme Court also provided guidance as to how the materiality requirement should be enforced. It explained that a misrepresentation is not material "merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment ... [or because] the Government would have the option to decline to pay if it knew of the defendant's noncompliance." <u>Id</u>. Materiality may be found where "the Government consistently refuses to

pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." <u>Id</u>. On the other hand, it is "very strong evidence" that a requirement is not material "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated." <u>Id</u>. Finally, materiality "cannot be found where noncompliance is minor or insubstantial." <u>Id</u>.

Id. at 489.

Appling these principles, and relying heavily on the relator's concession that the government routinely paid the claims at issue despite full knowledge of the defendant's misrepresentations, the Third Circuit Court of Appeals held that the relator's allegations did not meet the "high standard" of materiality outlined by the Supreme Court:

Petratos's allegations do not meet this high standard. As the District Court noted: "there are no factual allegations showing that CMS would not have reimbursed these claims had these [alleged reporting] deficiencies been cured." App. 18. Petratos does not dispute this finding, which dooms his case. Simply put, a misrepresentation is not "material to the Government's payment decision," when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance. See Universal Health Servs., 136 S.Ct. at 1996 (emphasis added). Similarly, we think that where a relator does not plead that knowledge of the violation could influence the Government's decision to pay, the misrepresentation likely does not "have[] a natural tendency to influence ... payment," as required by the statute. See 31 U.S.C. § 3729(b)(4). At a minimum, this would be "very strong evidence" that the misrepresentation was not material. Universal Health Servs., 136 S.Ct. at 2003.

The Supreme Court's guidance in <u>Universal Health Services</u> also militates against a finding of materiality. The mere fact that § 1395y is a condition of payment, without more, does not establish materiality. <u>See id.</u> In addition, Petratos not only fails to plead that CMS "consistently refuses to pay" claims like those alleged, <u>see id.</u>, but essentially concedes that CMS would consistently reimburse these claims with full knowledge of the purported noncompliance. Nor has he cited to a single successful claim under § 1395y involving drugs prescribed for their on-label uses or a court decision upholding such a theory.

Petratos's allegations are much like the sort of "minor or insubstantial" noncompliance that the Supreme Court explained should not be litigated under the False Claims Act. See id. Petratos does not claim that Genentech's safety-related reporting violated any statute or regulation. He acknowledges that the FDA would not "have acted differently had Genentech told the truth." App. 64. And as we have explained, he does not dispute that CMS would reimburse these claims even with full knowledge of the alleged reporting deficiencies.

Id. at 490.

Defendants assert that Petratos warrants reconsideration for two reasons. First, they contend that Petratos represents "an intervening change in the law." See CIGNA Reinsurance Co., 52 F.3d at 1218. This argument, however, is contradicted by defendants' own repeated characterization of Petratos as a "reinforcement" or "clarification" of the standards derived from Escobar, rather than an alteration to the state of the law that existed at the time that this court issued the Memorandum Opinion. (Brief in Support of Motion for Reconsideration ("Brief in Support") (ECF No. 358) at 10-11.) A review of the Court of Appeals for the Third Circuit's decision confirms that Petratos utilized the same "demanding" and "rigorous" standard for materiality that this court emphasized in the Memorandum Opinion. Petratos, 855 F.3d at 489. For example, the court of appeals noted that Escobar contemplates a "'demanding' and 'rigorous' standard for materiality"; a material misrepresentation is one that goes "to the very essence of the bargain"; a misrepresentation is not material "merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment"; and materiality may be found where "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." Id. (quoting Escobar, 136 S.Ct. at 2002-03). These are the precise same factors that this court analyzed in reaching its summary judgment

decision. See Memorandum Opinion (ECF No. 345) at 33 (describing the relevant Escobar factors as whether compliance with a statute is a condition of payment; whether the violation goes to "the essence of the bargain" or is "minor or insubstantial"; and whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations). As such, defendants' attempt to characterize Petratos as an intervening change of existing law misses the mark.

Defendants next argue that, even if Petratos does not represent a change in the law, it clarifies existing law in a manner which renders the court's Memorandum Opinion clearly erroneous. Aside from the Court of Appeals for the Third Circuit's affirmation of the materiality standard set forth in Escobar, the decision in Petratos is largely inapposite. In Petratos, the court of appeals repeatedly emphasized the relator's concession that "the Government would have paid the claims with full knowledge of the alleged noncompliance" and did, in fact, "consistently reimburse those claims" despite that knowledge. Petratos, 855 F.3d at 490. In Petratos, the plaintiff also failed to allege that the defendants' misrepresentations "violated any statute or regulation." Id. Plaintiff did not make any such concessions in the instant case; to the contrary, he explicitly maintains that defendants' conduct violated the Stark Act and the Anti-Kickback Statute and the government routinely refuses to pay claims that fail to meet the statutory standards of those statutes. (Memorandum Opinion (ECF No. 345) at 33-35.) Each of the decisions cited by defendants in their motion is distinguishable on this basis. See, e.g. United States ex rel. Kelly v. Serco, Inc., 846 F.3d 325 (9th Cir. 2017) (holding that there was no evidence to support materiality because the government was fully aware of the allegedly violative conduct); Abbott v. BP Exploration & Prod., 851 F.3d 384, 387-88 (5th Cir. 2017) (affirming grant of summary judgment for lack of materiality where the government permitted

the defendant to continue with drilling activities despite knowledge of alleged regulatory violations); <u>United States ex rel. McBride v. Halliburton Co.</u>, 848 F.3d 1027, 1033-34 (D.C. Cir. 2017) (government did not disallow costs despite learning of and investigating alleged violations).

Defendants' remaining arguments represent a clear attempt to invite the court to "rethink a decision it has already rightly or wrongly made." Ins. Co. of Greater N.Y. v. Fire Fighter Sales & Service Co., No. 11-1078, 2015 WL 4531220, at * 1 (W.D. Pa. July 27, 2015) (citing Williams v. Pittsburgh, 32 F.Supp.2d 236, 238 (W.D. Pa. 1998)). For example, at summary judgment, defendants vigorously argued that the demanding standard for materiality could not be met in this case because "hyper-technical or minor non-compliance with a regulatory requirement (as the Relator has recently contended in this case) is not sufficient to establish the element of materiality." (Hamot Brief in Support of Motion for Summary Judgment (ECF No. 287) at 8.) The court rejected this position, holding that the writing requirement contained in the relevant statutory exceptions is not "minor or insubstantial" but goes to the "very 'essence of the bargain' between the government and health care providers with respect to Stark Act compliance." (Memorandum Opinion (ECF No. 345) at 34) (quoting Escobar, 136 S.Ct. at 2003 n. 5). Defendants are not entitled to seek a "second bite of the apple" by way of a motion for reconsideration. See, e.g., Boone v. Daughtery, No. 12-1333, 2013 WL 5836329, at *1 (W.D. Pa. Oct. 30, 2013) ("Motions for reconsideration are not designed to provide litigants with a second bite at the apple.") (citing Bhatnagar v. Surrendra Overseas Ltd., 52 F.3d 1220, 1231 (3d Cir. 1995)).

Defendants, again citing <u>Petratos</u>, argue that plaintiff did not adduce any evidence that the government consistently refuses to pay claims in situations where the requirements of the

Stark Act and Anti-Kickback statute exceptions are not met. As with defendants' previous assertion, the court addressed this precise issue in the course of reaching its summary judgment decision:

There is no evidence in the record to suggest that "the Government consistently refuses to pay claims" based on Stark Act non-compliance (or, conversely, that "the Government pays [those claims] in full despite its actual knowledge that certain requirements were violated"). <u>Id.</u> at 2003-04. Plaintiff, however, has pointed to public records suggesting that health care providers have paid penalties after self-reporting similar violations on at least nine occasions since 2009. (ECF No. 310-12.) In the absence of any evidence to the contrary, this factor weighs slightly in favor of materiality.

(Memorandum Opinion (ECF No. 345) at 35.) Although defendants disagree with this conclusion, a motion for reconsideration is not a vehicle for a party to reargue points of disagreement with the court. Waye v. First Citizen's Nat'l Bank, 846 F. Supp. 310, 314 n.3 (M.D.Pa. 1994); Ogden v. Keystone Residence, 226 F.Supp.2d 588, 606 (M.D. Pa. 2002) (explaining that a motion for reconsideration may not be used to reargue issues already argued or relitigate points of disagreement between the litigant and the court).

Finally, defendants attack the court's reliance on the aforementioned public records to refute the suggestion that the government pays claims even when it is aware of Stark Act non-compliance. Defendants contend that these records were not properly referenced in plaintiff's Concise Statement of Material Facts and that the court erred in the weight that it ascribed to this evidence. The former contention is simply incorrect; plaintiff explicitly cited those records in his counter-statement of material facts and attached them as an exhibit to his opposition to the defendants' summary judgment motion. (Response to Joint Concise Statement of Material Facts (ECF No. 307) ¶ 39; Appendix to Concise Statement of Material Facts (ECF No. 310) Ex. 12.) With respect to the latter contention, defendants' objection to the court's evaluation of the

summary judgment record is precisely the type of "disagreement between the Court and the litigant" that will not support a request for reconsideration. Waye, 846 F.Supp at 314 n. 3;

Williams, 32 F.Supp.2d at 238.

IV. Conclusion

For all the foregoing reasons, defendants' motion for reconsideration (ECF No. 357) will

be DENIED. An appropriate order will be entered.

By the court:

/s/ Joy Flowers Conti

Joy Flowers Conti

Chief United States District Judge

Dated: August 25, 2017

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