UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* LAURIE SIMPSON, Plaintiff–Relator, v. BAYER CORP., *et al.*, Defendants.	Civil Action No.: 05-3895 (JLL) (JAD) **OPINION**

LINARES, Chief District Judge.

This matter comes before the Court by way of cross-motions for partial summary judgment by Plaintiff–Relator Laurie Simpson, (ECF No. 324), and Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare, LLC (collectively, "Bayer"), (ECF No. 323). Bayer has opposed Relator's motion, (ECF No. 329), and Relator has opposed Bayer's motion, (ECF No. 330). The United States (the "Government"), though declining to intervene in this matter, (ECF No. 16), has filed a statement of interest. (ECF No. 338). The Court held oral argument on the cross-motions on March 11, 2019. (ECF No. 344). For the following reasons, the Court denies both motions.

I. BACKGROUND[1]

Relator, a former Bayer employee, filed this *qui tam* action under the whistleblower provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, on August 5, 2005. (ECF No. 1). The Government declined to intervene. (ECF No. 16). As relevant to the present motions, Relator alleges that Bayer caused the submission of false claims to federal health programs related to a Bayer pharmaceutical, Trasylol, (1) by marketing Trasylol for off-label uses that were not reasonable and necessary, and (2) by paying kickbacks to physicians and other healthcare professionals to induce increased use of Trasylol. (*See* ECF No. 324-1 ("Rel. Br.") at 19–20; 10AC ¶¶ 187–214). The allegations underlying this dispute have been described on several occasions, most recently in the Court's March 16, 2015 Opinion granting in part and denying in part Bayer's motion to dismiss the Ninth Amended Complaint. (ECF No. 208). Accordingly, and in the interest of judicial economy, the Court includes an abbreviated statement of the factual and procedural history to the extent such background is relevant to the instant motions.

A. Medicare Payment System

The present dispute arises in the context of the reimbursement system used by Medicare. Medicare is a federal health insurance program for individuals with disabilities and the elderly. 42

[1] This background draws from the parties' statements of material facts pursuant to Local Civil Rule 56.1, (ECF No. 324-2 ("Rel. 56.1"), ECF No. 323-2 ("Bayer 56.1"), ECF No. 330-1 ("Rel. Reply 56.1"), and ECF No. 329-1 ("Bayer Reply 56.1")), as well as from Relator's Tenth Amended Complaint, (ECF No. 213 ("10AC")), and the broader legal landscape in which this dispute arises. To the extent that Relator admits to any material facts as stated by Bayer, the Court will cite only to "Bayer 56.1" and the relevant paragraph numbers. Likewise, to the extent Bayer admits to any material facts as stated by Relator, the Court will cite only to "Rel. 56.1" and the relevant paragraph numbers. The Court will "disregard all factual and legal arguments, opinions and any other portions of the 56.1 Statement[s] which extend beyond statements of fact." *Globespanvirata, Inc. v. Tex. Instrument, Inc.*, No. 03-2854, 2005 WL 3077915, at *2 (D.N.J. Nov. 15, 2005); *see also* L. Civ. R. 56.1 ("Each statement of material facts . . . shall not contain legal argument or conclusions of law.").

U.S.C. § 1395 *et seq.* Medicare Part A covers inpatient hospital services and items used during inpatient stays. *See* 42 U.S.C. § 1395c; 42 C.F.R. § 409.10(a)(5). With certain exceptions not applicable here, Medicare reimburses hospitals for items and services provided to beneficiaries during inpatient stays "through fixed, bundled payments on a per discharge basis under the Inpatient Prospective Payment System ('IPPS')." (Rel. 56.1 ¶ 5); *see also* 42 U.S.C. § 1395ww(d); 42 C.F.R. §§ 412.1, 412.60. Under the IPPS, "inpatient services are reimbursed a fixed amount based upon the Diagnosis Related Group ('DRG') classification of the inpatient stay." (Rel. 56.1 ¶ 6); *see also* 42 C.F.R. §§ 412.1, 412.2, 412.60. DRG classifications and payment rates are created by the Centers for Medicare and Medicaid Services ("CMS") based on the aggregation of weighted factors and average costs over time. *See* 42 C.F.R. § 412.60. Congress adopted the IPPS in order to incentivize hospitals to manage operating costs efficiently, as costs above the fixed payment are borne by the hospital. *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 49 (D.C. Cir. 2015).

Hospitals submit requests for reimbursement to the Government using a HCFA/CMS-1450 form, also called a UB-92/UB-04 ("UB form"). (Rel. 56.1 ¶ 10). During the Relevant Time Period,[2] hospital providers submitted claims for reimbursement for inpatient stays using the UB form or its electronic equivalent. (Rel. 56.1 ¶ 10). Such claims were based on the assigned DRG classification for the Medicare beneficiary during a given inpatient stay, and reimbursements in turn depended on the DRG classification, "rather than on the costs of the specific items and services provided to the particular patient." (Rel. 56.1 ¶ 6); *see also* 42 C.F.R. § 412.60. Nevertheless, the parties agree that DRG payments constitute "payment in full for all inpatient items and services provided" to patients. (Rel. 56.1 ¶ 8); *see also* 42 C.F.R. §§ 412.2(b), 412.50(a).

Certain items and services are not reimbursable by Medicare. The Medicare statute

[2] The Relevant Time Period refers to the period on or after August 5, 1999. (*See* ECF No. 147 at 23).

provides that "no payment may be made . . . for any expenses incurred for items or services" which "are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). In order to participate in Medicare, hospital providers submit an enrollment application to CMS called a form CMS-855A. (Rel. 56.1 ¶ 4; Bayer Reply 56.1 ¶ 4). The form CMS-855A includes the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

(Rel. 56.1 ¶ 4); *see also* CMS-855A § 15 ¶ 3, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf. Hospitals also submit annual reports to CMS called forms CMS-2552, *see* 42 C.F.R. § 413.20(b), which require a mandatory certificate of compliance, which includes the following certification:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

CMS-2552-10, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3P240f.pdf. The CMS-2552 also requires certification from an officer or administrator of the provider: "I further certify that I am familiar with the laws and regulations regarding the provision of health

care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." *Id.*

B. Trasylol

Trasylol is Bayer's trade name for aprotinin, a drug that was approved by the Food and Drug Administration ("FDA") for intravenous administration to reduce blood loss in patients undergoing cardiopulmonary bypass during the course of coronary artery bypass graft ("CABG") surgery. (Rel. 56.1 ¶ 1). Trasylol was among the items and services administered during inpatient stays that were reimbursed through bundled DRG payments. (Bayer Reply 56.1 ¶ 9). Beyond this basic background, many facts concerning Trasylol remain disputed by the parties and subject to ongoing discovery.

Relator alleges that "Bayer engaged in unlawful marketing, including off-label marketing and payment of kickbacks, in order to increase the market share" of Trasylol, and "engaged in a campaign of concealment and disinformation concerning Trasylol's safety and efficacy that continued at least until May 2008, when Bayer recalled Trasylol from the market." (10AC ¶ 9). Specifically, Relator alleges that Bayer knowingly promoted Trasylol to physicians and hospitals for potentially harmful off-label uses that lacked sufficient medical support and were not reasonable and necessary. (10AC ¶ 394). Furthermore, Relator raises detailed allegations of a far-reaching kickback scheme through which Bayer invited physicians and other healthcare professionals to attend all-expenses-paid "consulting" trips throughout the United States, paid them "consulting" fees, and lavished them with grants and other gifts in exchange for increased promotion and use of Trasylol. (10AC ¶¶ 15, 187–214). As a consequence of Bayer's alleged conduct, Trasylol's market share grew, resulting in considerable profit to Bayer. (10AC ¶¶ 13,

118–19). Bayer denies many of Relator's factual allegations concerning the kickback scheme and the promotion of Trasylol for off-label uses, (*see generally* ECF No. 222), but the parties do not raise those underlying factual disputes for purposes of the instant motions, which focus instead on the DRG reimbursement mechanism, (*see generally* Rel. 56.1; Bayer 56.1).

C. The False Claims Act and the Anti-Kickback Statute

"The False Claims Act is meant 'to reach all types of fraud . . . that might result in financial loss to the Government.'" *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 486 (3d Cir. 2017) (quoting *Cook Cty. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003)). The FCA imposes liability on any person who: "(A) knowingly presents, or causes to be presented [to the United States Government], a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[3] 31 U.S.C. § 3729(a)(1)(A)–(B). "A [FCA] violation includes four elements: falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487.

With respect to the falsity element, "[a] false or fraudulent claim may be either factually false or legally false." *Greenfield*, 880 F.3d at 94. "A claim is factually false when the claimant misrepresents what goods or services . . . it provided to the Government." *Id.* (quoting *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)). A claim is legally false when the claimant misrepresents "its compliance with a statutory, regulatory, or contractual requirement." *Id.* Relator argues here that Bayer caused the submission of claims that were legally false. (Rel. Br. at 28 n.28).

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[3] "Although Congress amended the False Claims Act in 2009 by enacting the Fraud Enforcement and Recovery Act ('FERA'), it did not substantially alter the provisions of the pre-FERA version of the False Claims Act." *U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 94 n.5 (3d Cir. 2018).

Two statutory requirements are relevant to Relator's claims of legal falsity. First, if a claim "does not comply with statutory conditions for payment," including that the items and services claimed are "'reasonable and necessary for the diagnosis and treatment of illness or injury,'" as required by the Medicare statute, it is a false claim. *Petratos*, 855 F.3d at 487 (quoting 42 U.S.C. § 1395y(a)(1)(A)). Second, a claim may be legally false where there is an underlying violation of the Anti-Kickback Statute ("AKS"). *Greenfield*, 880 F.3d at 95. The AKS prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to refer an individual to a person 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." 42 U.S.C. § 1320a-7b(b)(2)(A). It is well-settled that "claims for payment made pursuant to illegal kickbacks are false under the [FCA]," *Greenfield*, 880 F.3d at 95 (quoting *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 (D. Mass. 2011)). In 2010, Congress amended the AKS to clarify existing law, expressly providing that "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]." 42 U.S.C. § 1320a-7b(g).

D. Relevant Procedural History

Since the initiation of this lawsuit, the Court has decided three motions to dismiss, narrowing Relator's claims and legal theories in the process. (*See* ECF Nos. 130, 147, 208). In the causes of action that remain in the now-operative Tenth Amended Complaint and that are relevant to the present motions, Relator alleges that Bayer caused the submission of false claims in two ways: (1) by unlawfully promoting Trasylol for off-label uses that were not "reasonable and necessary" under the Medicare statute, and (2) by paying kickbacks to physicians and other

healthcare professionals to induce increased use of Trasylol, in violation of the AKS. (10AC ¶¶ 1–2, 9–21). Discovery has been and remains ongoing as of 2016. (*See* ECF No. 320).

At a settlement conference held on September 5, 2018, (ECF No. 319), the parties agreed that one of Bayer's defenses—that surgeries in which Trasylol was administered were reimbursed through the bundled DRG payment system, thereby preventing FCA liability—presented a narrow legal issue that was ripe for the Court's decision on summary judgment. (*See* Rel. Reply 56.1 ¶ 19 ("[Relator] agrees that Bayer's DRG defense presents a narrow legal issue . . . that the Court can and should decide . . . without considering" factual arguments about the record.); ECF No. 323-1 ("Bayer Br.") at 6 ("With respect to [the issue before the Court], no material facts are in dispute, and the parties have agreed that the Government's fixed-fee system presents a pure legal issue that is ripe for this Court's resolution.")). Thereafter, the Court directed the parties to submit cross-motions for partial summary judgment on "the narrow issue of whether [Bayer] may be liable under the False Claims Act . . . for claims for Medicare and Medicaid reimbursement for surgical procedures in which Trasylol was administered, regardless of whether the relevant requests for reimbursement were 'bundled' rather than itemized, and regardless of whether the administration of Trasylol in said procedures affected the total amounts of the corresponding reimbursements." (ECF No. 321).[4] The instant motions followed.

II. LEGAL STANDARD

Summary judgment is appropriate when, drawing all reasonable inferences in the

[4] Because the parties jointly represent that this issue is ripe for summary judgment based upon currently undisputed facts, and pursuant to the Court's Order, (ECF No. 321), the Court limits its consideration to this "narrow issue" only, and disregards at this stage arguments made on either side that raise disputes concerning facts outside the parties' Rule 56.1 Statements, including Relator's alternative theories based on exceptions to the DRG system, as well as Bayer's defenses to those theories. (*See* ECF No. 330 at 31–35; ECF No. 329 at 22–26).

non-movant's favor, there exists 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). "[T]he moving party must show that the non-moving party has failed to establish one or more essential elements of its case on which the non-moving party has the burden of proof at trial." *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 424 (3d Cir. 2007) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986)).

The Court must consider all facts and their reasonable inferences in the light most favorable to the non-moving party. *See Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). If a reasonable juror could return a verdict for the non-moving party regarding disputed issues of material fact, summary judgment is not appropriate. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id.* at 249.

III. ANALYSIS

Bayer presently raises a threefold defense to liability under the FCA for claims for surgeries during which Trasylol was administered. First, Bayer argues that Relator fails to identify any claim for payment for Trasylol because Trasylol is not identified on any claim form. (Bayer Br. at 7, 20–21). Second, Bayer argues that, even assuming Relator could identify claims for Trasylol, those claims are not false claims under either an express or implied false certification theory. (Bayer Br. at 21–22). Third, Bayer argues that Relator cannot show that any alleged fraud related to Trasylol was material to the Government's decision to pay claims for those surgeries—a requirement for FCA claims of legal falsity—because DRG payment amounts do not change based on whether Trasylol was or was not administered. (Bayer Br. at 23–30). Relator responds that

FCA liability may still attach under these circumstances, notwithstanding the absence of a Trasylol line item on the claim forms or the absence of a financial impact of the use or non-use of Trasylol on reimbursement amounts. (ECF No. 330 at 8–9). Indeed, Relator argues that the FCA may impose liability in such circumstances as a matter of law, and therefore that she is entitled to summary judgment on this narrow issue. (Rel. Br. at 9–10).

A. Bayer's Motion

1. Claims for Trasylol

Bayer first argues that it is entitled to judgment as a matter of law because "Relator has not identified any claims for Trasylol." (Bayer Br. at 8). Bayer acknowledges that UB forms submitted to Medicare constitute claims for payment under the FCA,[5] (ECF No. 329 at 10), but in Bayer's view, claims for surgeries in which Trasylol was used are not claims *for Trasylol* because Trasylol is not identified on the claim forms. (Bayer Br. at 20–21). Bayer maintains instead that UBs represent only "claims for surgeries." (ECF No. 329 at 10). However, Bayer does not dispute that a "DRG payment constitutes payment in full *for all inpatient items* and services provided to the patient." (Bayer Reply 56.1 ¶ 8 (emphasis added)). The governing regulation states that "payments made under the prospective payment systems . . . are payment in full for all inpatient hospital services, as defined in § 409.10 of this chapter," 42 C.F.R. § 412.50(a), a definition that includes "[d]rugs, biologicals, supplies, and equipment" furnished to an inpatient, *id.* § 409.10. Logically, then, a request for DRG payment for a surgery in which Trasylol was used "constitutes a claim for the bundle of items and services provided" during the inpatient stay, including Trasylol.

[5] *See U.S. v. Rogan*, No. 02-3310, 2006 WL 8427270, at *19 (N.D. Ill. Oct. 2, 2006) ("False claims to Medicare, including Medicare cost reports and UB-92s . . . are actionable under the civil FCA."), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

(ECF No. 330 at 11). Surely Bayer is not suggesting that Medicare pays for "surgeries" in the abstract. Therefore, Bayer's insistence that UB forms "are not claims for Trasylol; they are claims for surgeries," (ECF No. 329 at 10), while rhetorically cunning, is unpersuasive.

Courts have found claims for fixed payments and related cost reports to constitute claims under the FCA for medical care provided in connection with the procedures for which reimbursement is sought. *See, e.g.*, *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 343–44 (D. Conn. 2004) (holding that "defendants' submission of Form HCFA-1450 (UB-82 and UB-92)" for procedures in which non-reimbursable cardiac devices were administered "clearly constituted the submission of a 'claim' to the United States government," since the forms represented "the hospitals' requests for payments for the services provided to the Medicare beneficiary"); *U.S. ex rel. Morris v. Crist*, No. 97-1395, 2000 WL 432781, at *5 (S.D. Ohio Mar. 29, 2000) (rejecting a hospital's DRG defense to an FCA claim arising from non-allowable for-profit research costs, finding the argument "fail[ed] to take into account the contents of the entire bill sent to Medicare," and concluding that "the entire bill represents a claim against the United States to be paid or approved"); *see also U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015) (finding that, for purposes of calculating damages, each UB "can constitute a discrete fraudulent claim under the FCA," because "each time [defendant] submitted to Medicare a UB-92/04 form asking for reimbursement for a prohibited referral, it was knowingly asking the government to pay an amount that, by law, it could not pay"); *U.S. ex rel. Bahnsen v. Boston Sci. Neuromodulation Corp.*, No. 11-1210, 2018 WL 4604307, at *5 (D.N.J. Sept. 24, 2018) (holding that the "claim" for purposes of FCA liability was the form submitted for payment, noting that, "in determining whether a submission constitutes a claim, the Court reviews the issue based on the action of a [claimant] and does not consider how the government processed the information").

Bayer's reliance on *U.S. ex rel. Portilla v. Riverview Post Acute Care Ctr.*, No. 12-1842, 2014 WL 1293882 (D.N.J. Mar. 31, 2014) to argue otherwise is unavailing.[6] Bayer correctly notes that the Court in *Portilla* dismissed an FCA claim that arose in the context of a prospective payment system arguably analogous to the DRG system. 2014 WL 1293882, at *15–16. However, that court relied on the bundled reimbursement mechanism to reject a claim of *factual* falsity, *id.*, whereas here, the FCA claim at issue is one of *legal* falsity.[7] The bundled payment defense makes more sense in the factual falsity context: where a claim does not list individual items provided to a patient, the claim does not make a factual misrepresentation about those items that could impact the corresponding reimbursement. By contrast, Relator's FCA claim depends not on factual representations made *about Trasylol* (of which, for purposes of these motions, there are none), but rather on hospitals' allegedly false certifications of compliance (or failures to disclose non-compliance) with applicable statutory requirements in connection with surgeries using Trasylol. *Portilla*'s reasoning therefore provides little support for rejecting Relator's legal falsity claim here.

Similarly, the decision in *U.S. ex rel. Magid v. Wilderman*, No. 96-4346, 2004 WL 945153 (E.D. Pa. Apr. 29, 2004) does not convince this Court that summary judgment is warranted under these circumstances. There, the relator alleged that the defendant hospital billed Medicare for lab tests that were not medically necessary. 2004 WL 945153, at *8. The hospital argued that, by virtue of the DRG payment system, "Medicare did not specifically reimburse [the hospital] for those tests." *Id.* The Court granted summary judgment for the hospital, noting that the relator failed to explain how the hospital "could have overcharged Medicare for [the lab] tests given the [DRG] payment schedule." *Id.* at *9. However, discovery in *Magid* had closed, *id.* at *3, and the

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[6] Bayer cites to *Portilla* in support of its argument that the materiality element is not met, *see infra* Part III.A.3. However, the Court in *Portilla* dismissed the relator's claims without reaching materiality, so discussion of that case is more appropriate here.

[7] The *Portilla* Court also rejected a claim of legal falsity on other grounds not relevant here. *Id.* at *16–17.

relator had failed to introduce any UB form "or any other evidence that might have shown that Medicare reimbursed" the hospital for the lab tests at issue, *id.* at *9. The court therefore concluded that the relator had not met her burden of demonstrating a material issue of fact. *Id.* Here, by contrast, discovery remains ongoing, and Relator has indicated that a combination of UB forms and hospital records will show that Medicare paid reimbursements to hospitals covering procedures involving Trasylol. (ECF No. 346 ("Hearing Tr.") 16:24–18:5).

Bayer protests that acknowledgement of UB forms as "claims" for items and services provided during the claimed procedures would lead to "extreme and absurd results" in which even "surgical gloves or light bulbs in the operating room" that were tainted by kickbacks "could trigger billions in dollars of FCA liability—even though those products are not identified on the claim form." (Bayer Br. at 22). The Court disagrees. First, given the policy behind the AKS, the Court rejects the suggestion that the Government would find it "extreme and absurd" to prohibit the knowing submission of claims involving unlisted kickback-tainted items. Indeed, Relator cites to over ten FCA actions resulting in settlements that arose from claims for procedures including items like surgical supplies and medical devices tainted by kickbacks that, like Trasylol, were not "specifically referenced on claims submissions." (ECF No. 330 at 19–20 & n.13).[8] Second, Bayer's equation of Trasylol with light bulbs and surgical gloves is not only unpersuasive in the context of other FCA actions, but it also underscores the gravity of Relator's allegations. Trasylol is far from an "inexpensive commodity product," (ECF No. 330 at 21); rather, at nearly $1,300 per

[8] *See also Wilkins*, 659 F.3d at 314 ("consider[ing] but reject[ing]" a defendant's argument that permitting FCA liability based on an implied false certification of compliance with the AKS would "transform the FCA into a strict liability statute in which 'every participant in the Medicare program impliedly certifies each time it submits a claim for payment to the program that the claim does not arise from some payment arrangement that—however attenuated, immaterial, and unknowing—could be characterized as a violation of the AKS,'" noting that the AKS and the FCA contain protections against such an outcome, including the knowledge and materiality requirements).

dose, (*see* Bayer Br. at 31), Trasylol is a powerful intravenous drug that was ultimately withdrawn from the U.S. market as a result of serious adverse side effects, which Relator alleges that Bayer concealed and misrepresented to its own benefit. (ECF No. 330 at 21 & n.15).

Finally, to the extent Bayer argues that summary judgment is appropriate because Relator has not yet identified *which* UB forms represent claims for Trasylol, the Court notes that "discovery remains substantially incomplete." (ECF No. 330 at 9). Ongoing discovery may uncover evidence showing which procedures involved use of Trasylol and, consequently, which claims for reimbursement comprised claims for Trasylol. Trasylol's express identification on the claim form itself is not the only way of proving the existence of a claim for a surgery involving Trasylol. Indeed, Relator indicated at a hearing on the instant cross-motions that she has produced hospital records indicating that Trasylol was used in particular surgeries which were then billed to Medicare, noting that participating hospitals maintain records of drug administration. (Hearing Tr. 16:24–18:5). Relator's failure to match those records to the relevant UB forms at this stage in the litigation does not preclude the possibility of Relator's success in the future.[9]

2. Falsity

Where a claim of legal falsity is based on a certification of compliance with a legal provision, such certification may be express or implied. *Wilkins*, 659 F.3d at 306. "'Under the 'express false certification' theory, [a claimant] is liable under the FCA for falsely certifying that it is in compliance with' a material statute, regulation, or contractual provision." *U.S. v. Eastwick Coll.*, 657 F. App'x 89, 94 (3d Cir. 2016) (quoting *Wilkins*, 659 F.3d at 305). In addition to express misrepresentations, the FCA also "encompasses claims that make . . . certain misleading

[9] However, the existence of this and other material factual disputes does preclude judgment as a matter of law in favor Relator at this stage, *see infra* Part III.B.

omissions." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016). Under the implied false certification theory, a submitted claim "*impliedly* certifies compliance with all conditions of payment[, b]ut if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the [claimant] has made a misrepresentation that renders the claim 'false or fraudulent' under [the FCA]." *Id.* at 1995 (emphasis added).

a. Express False Certification

Relator's theory of liability relies on both express and implied certifications. (*See* Hearing Tr. 7:10–24). First, Relator points to the express certifications that hospitals submit to Medicare on forms CMS-855A and CMS-2552. (Rel. Br. at 12, 16). To restate, in relevant part: on form CMS-855A, hospitals acknowledge that "Medicare is conditioned upon the claim and the underlying transaction complying with [the Medicare] laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute[])," (Rel. Br. at 12), and on form CMS-2552, hospitals acknowledge that, "if services identified in this report were provided or procured through the payment directly or indirectly of a kickback . . . criminal, civil, and administrative action, fines, and/or imprisonment may result," and certify that "the services identified in this cost report were provided in compliance with [the] laws and regulations" regarding the provision of health care, (Rel. Br. at 16). Relator therefore argues that, "if the use of Trasylol in an inpatient surgery was tainted by a kickback from Bayer (or was for a use that was not reasonable and necessary), the transaction represented on the inpatient claim form violates this certification, and constitutes a false claim." (ECF No. 330 at 13–14).

Bayer urges the Court to reject Relator's express false certification theory because hospitals

made no express certifications specifically about Trasylol. (Bayer Br. at 21). In other words, because the Medicare forms require hospitals to certify only that the "services identified" were provided in compliance with legal requirements, those certifications do not apply to items, like Trasylol, that are not "identified." (Bayer Br. at 21). Relator responds, and the Court agrees, that the plain language of the CMS-855A requires certification of hospitals' understanding that "payment of a claim by Medicare is conditioned on the claim *and the underlying transaction* complying with" applicable laws and regulations, including the AKS. (ECF No. 330 at 13). That "underlying transaction" includes the bundle of items and services provided to a Medicare beneficiary during a claimed procedure. The certification's language is "more than specific enough to make clear that the claims submitted by hospitals represented that any underlying transactions had not involved third party kickbacks prohibited by the AKS." *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 393 (1st Cir. 2011) (holding that similar language in a provider agreement was sufficient to state a claim that subsequently submitted Medicare claims were false under the FCA).

Indeed, in reaffirming a prior holding that "a participant in a federal healthcare program complies with the [FCA] by 'refrain[ing] from offering or entering into payment arrangements which violate the [AKS], while making claims for payment to the Government under that program,'" the Third Circuit emphasized that such a reading of the FCA is "consistent with the language in CMS Form 855s, which requires providers to certify that 'the claim and the underlying transaction' (*i.e.*, the medical care being reimbursed) comply with the [AKS]." *Greenfield*, 880 F.3d at 97 (first quoting *Wilkins*, 659 F.3d at 314, then quoting form CMS-855); *see also Wilkins*, 659 F.3d at 312 (concluding in dicta that a complaint alleging a kickback scheme, coupled with certifications of compliance with applicable Medicare regulations, "[a]rguably . . . state[s] a claim

for relief under an express false certification theory inasmuch as [relators] allege that [defendants] falsely certified compliance with the AKS in order to receive monthly payments from the Government"); *In re Cardiac Devices*, 221 F.R.D. at 346–47 ("To the extent that defendants included in their [Medicare Form HCFA-2552] Cost Reports payments for non-covered items, this would render their certifications [that the Cost Reports were 'true, correct, and complete' and 'prepared . . . in accordance with applicable instructions, except as noted'] false, [and t]hus, as pled, these claims would be legally false under an express certification theory.").

Furthermore, the statutory text of the AKS makes clear that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." 42. U.S.C. § 1320a-7b(g). This language supports Relator's view that certifications of compliance with the AKS are expressly false where claims are submitted for payment covering "items or services resulting from" a kickback, as Relator alleges Trasylol to be. Accordingly, the Court is unable to hold, as a matter of law, that these express certifications reach only items and services that are itemized on claim forms.

b. Implied False Certification

Even assuming, *arguendo*, that the express certifications on the CMS forms do not apply to Trasylol, Relator's claims may nevertheless succeed under an implied false certification theory. (ECF No. 330 at 27). The logic of Relator's implied false certification theory is this: Every time a hospital submits a claim for a surgery, it implies that the claimed procedure is eligible for reimbursement (*i.e.*, compliant with all material requirements for payment), even absent express certifications of compliance. If a drug provided as part of that surgery violated a material condition of payment, and such noncompliance was not disclosed, that would render the claim false. *See*

Escobar, 136 S. Ct. at 1995. Bayer argues, relying on the Supreme Court's decision in *Escobar*, that Relator's theory fails because implied false certification liability attaches only where the claims for payment also make "specific representations about the goods or services provided" that, given the implication that those goods or services are eligible for reimbursement, rise to the level of "misleading half-truths," *id.* at 2001, and the claims at issue here contain no specific representations about Trasylol. (Bayer Br. at 22). Relator responds, and the Court agrees, that *Escobar* held that such specific misrepresentations were *sufficient* to render a claim false under the implied false certification theory—but declined to address whether they were *necessary*. (ECF No. 330 at 15–16).

The *Escobar* decision was the Supreme Court's first endorsement of the implied false certification theory under limited circumstances. In that case, the defendant, a mental health services provider, allegedly permitted the treatment of patients by staff who were "unqualified, unlicensed, and unsupervised." *Escobar*, 136 S. Ct. at 1998. The defendant then "submitted [to Medicaid] reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of [Massachusetts Medicaid] regulations pertaining to staff qualifications and licensing requirements for these services." *Id.* at 1997–98. The relators alleged that those claims violated the FCA under the implied false certification theory, arguing that "every submission of a claim for payment implicitly represents that the claimant is legally entitled to payment, and that failing to disclose violations of material legal requirements renders the claim misleading." *Id.* at 1999–2000.

Neither embracing nor rejecting the relators' broad implied false certification theory, the Court held narrowly that, as pled, the defendant's claims for payment rose to the level of misrepresentations sufficient to trigger FCA liability. *Id.* at 2000. The Court reasoned that the

claims at issue, which included "payment codes that corresponded to specific counseling services" and staff "[i]dentification numbers corresponding to specific job titles," would lead to the incorrect conclusion "that the clinic had complied with core Massachusetts Medicaid requirements" regarding staff training and qualifications. *Id.* "By using payment and other codes that conveyed this information without disclosing [the facility's] many violations of basic staff and licensing requirements for mental health facilities, [defendant's] claims constituted misrepresentations." *Id.* at 2000–01. Accordingly, the Court held that "the implied false certification theory can be a basis for liability, *at least* where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001 (emphasis added).

Contrary to Bayer's argument, then, the Supreme Court did not hold that the absence of specific representations about the items and services provided is necessarily fatal to an implied false certification claim. Indeed, the Court explicitly declined to reach the question of "whether *all* claims for payment implicitly represent that the billing party is legally entitled to payment," since the claims before the Court did "more than merely demand payment." *Id.* at 2000 (emphasis added). In other words, "[t]he Supreme Court left open the question of whether a claim that 'merely demand[s] payment,' as opposed to one that makes specific representations about the goods or services provided, can count as the requisite misleading representation." *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1031 n.4 (D.C. Cir. 2017) (quoting *Escobar*, 136 S. Ct. at 2000). Therefore, to the extent Bayer argues that Relator's implied false certification theory fails as a matter of law under *Escobar* because the claims at issue make "no 'specific

representation' about Trasylol," (Bayer Br. at 22), Bayer misreads *Escobar*.

The Third Circuit has, before *Escobar*, recognized the possibility of FCA liability under the implied false certification theory arising from claims for payment that did not make the kinds of specific representations about the noncompliant items or services that were present in *Escobar*. *See Wilkins*, 659 F.3d at 313 (holding that relators "clearly state[d] a claim for relief under an implied false certification theory of liability" where they alleged that defendants paid kickbacks to physicians in exchange for names of potential new Medicare enrollees and then "submitted claims for payment to the Government at a time that they knowingly violated" the AKS, without requiring allegations that the defendants made specific representations to the Government concerning the referred patients or the items or services provided to them).[10] Furthermore, in a post-*Escobar* case involving allegations of both express and implied false certifications, the Third Circuit took an especially expansive view of FCA liability in the context of noncompliance with the AKS. *Greenfield*, 880 F.3d at 96–98 (affirming summary judgment for defendant on causation grounds). The Circuit emphasized that that Congress expressly made AKS violations actionable under the FCA in 2010 "as part of an overall effort 'to strengthen[] whistleblower actions based on medical care kickbacks' and 'to ensure that *all* claims resulting from illegal kickbacks are considered false

[10] *Escobar* abrogated *Wilkins* only insofar as the Supreme Court rejected *Wilkins*'s limitation of the implied false certification theory to FCA claims arising from noncompliance with expressly designated conditions of payment. *Escobar*, 136 S. Ct. at 1996 ("Defendants can be liable for violating requirements even if they were not expressly designated as conditions of payment. Conversely, even when a requirement is expressly designated a condition of payment, not every violation of such a requirement gives rise to liability."); *see also U.S. ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh, Pa.*, 728 F. App'x 101, 106 (3d Cir. 2018) ("[E]ven though *Escobar* reaffirmed *Wilkins*'s holding that a defendant's failure to comply with certain statutory, regulatory, or contractual requirements may violate the FCA, the Supreme Court made clear that those requirements need not be express 'conditions of payment' to trigger FCA liability."). The Supreme Court eschewed *Wilkins*'s distinction between a condition of payment and a condition of participation in favor of the multi-factor materiality standard, *see infra* Part III.A.3. Accordingly, after *Escobar*, *Wilkins* supports the application of the implied false certification theory where "the defendant's non-compliance, if discovered, would have been 'material to the Government's payment decision,'" *Freedom Unlimited*, 728 F. App'x at 106 (quoting *Escobar*, 136 S. Ct. at 2002).

claims for the purpose of civil action[s] under the [FCA].'" *Id.* at 96 (quoting 155 Cong. Rec. S10852, S10853–54 (daily ed. Oct. 28, 2009) (Sen. Kaufman)). "The [AKS] and [FCA] were not drafted to cabin healthcare providers' liability for certain types of false claims or for certain types of illegal kickbacks. Instead, Congress intended both statutes to reach a broad swath of 'fraud and abuse' in the federal healthcare system." *Id.* (quoting H.R. Rep. No. 95-393, at 47 (1977)). Therefore, at least in a case involving alleged AKS violations, this Court cannot conclude that implied false certification liability in the Third Circuit is limited to claims involving the kind of suggestive and misleading representations that were before the Supreme Court in *Escobar*.[11]

Other courts in this District have permitted implied false certification claims to proceed without requiring specific representations that rose to the level of those in *Escobar*. *See, e.g.*, *U.S. ex rel. Jersey Strong Pediatrics, LLC v. Wanaque Convalescent Ctr.*, No. 14-6651, 2017 WL 4122598, at *4 (D.N.J. Sept. 18, 2017) (allowing implied false certification claim to proceed where relator alleged that defendants "fraudulently billed Medicare and Medicaid instead of patients' private health insurance policies" in violation of the Medicare Secondary Payer Act, despite the fact that the claims "[did] not contain patient names, dates of treatment, or primary insurance policy numbers"); *U.S. ex rel. Laporte v. Premiere Educ. Grp.*, L.P., No. 11-3523, 2017 WL 3471163, at *3 (D.N.J. Aug. 11, 2017) (finding falsity met where defendants' alleged noncompliance with Higher Education Act regulations rendered them ineligible for Title IV funding, reasoning that the defendants' mere representations of eligibility for payment were

[11] The Third Circuit's mere invocation in *U.S. v. Eastwick Coll.*, 657 F. App'x 89 (3d Cir. 2016) of *Escobar*'s language that "implied false certification liability attaches when a claimant 'makes specific representations about the goods or services provided' and the claimant's 'failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths,'" is insufficient for this Court to conclude that the Circuit categorically prohibits FCA liability in the absence of such representations, as the Circuit in that case affirmed dismissal of the complaint on other grounds, and because the panel's disposition of the case was non-precedential. 657 F. App'x at 94 (quoting *Escobar*, 136 S. Ct. at 2001).

sufficiently "specific" as to constitute "misleading half-truths");[12] *see also In re Cardiac Devices*, 221 F.R.D. at 346–47 (endorsing implied false certification theory arising from Medicare claims for procedures involving non-reimbursable cardiac devices, reasoning that, "in submitting their claims, defendants were obligated to seek payment only for those services that were covered[, and t]o the extent that they sought payment for services that were not covered, the claims were legally false"). Bayer cites no authority to the contrary, other than *Escobar* itself, which Bayer misconstrues. (*See* Bayer Br. at 22; ECF No. 329 at 14–15).

Relator's ability to prove that Bayer caused the submission of false claims related to Trasylol, premised on both express certifications of compliance with the AKS on mandatory CMS forms, as well as on certifications that are implied in the submission of claims for reimbursement, hinges on facts that remain in dispute. Because the case law does not foreclose Relator's success in proving the submission of false claims for Trasylol under either an express or implied false certification theory, and because discovery remains open, Bayer is not entitled to summary judgment on this issue.

3. Materiality

"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

[12] In *Druding v. Care Alternatives, Inc.*, 346 F. Supp. 3d 669 (D.N.J. 2018), the court suggested, in setting forth the FCA standard, that "[u]nder the so-called 'implied false certification theory,' . . . a plaintiff must demonstrate that the defendant submit[ted] a claim that includes 'specific representations about goods or services provided' which are rendered 'misleading half-truths' through 'the defendant's failure to disclose noncompliance'" with an applicable requirement. 346 F. Supp. 3d at 682–83 (quoting *Escobar*, 136 S. Ct. at 2001). Because the court granted summary judgment for the defendant on grounds unrelated to the presence or absence of specific representations, that language is dicta. To the extent the *Druding* court relied on its reading of *Escobar*'s "specific representations" language, this Court disagrees with that reading. *See McBride*, 848 F.3d at 1031 n.4.

under the [FCA]." *Escobar*, 136 S. Ct. 1996. In other words, all FCA claims of legal falsity must also meet the FCA's materiality standard, "as falsity and materiality are distinct requirements." *Greenfield*, 880 F.3d at 98 n.8.[13] The FCA "defines 'material' to mean 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" *Escobar*, 136 S. Ct. 1996 (quoting 31 U.S.C. § 3729(b)(4)). Accordingly, "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Id.* at 2002 (citations omitted). The Supreme Court has clarified that the FCA's "materiality standard is demanding," *id.* at 2003, and has set forth the following multi-factor test:

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

Id. at 2003–04. In setting forth this approach, the Supreme Court rejected a materiality standard that would rely exclusively on whether the fraud at issue disguised noncompliance with a provision that the Government has expressly designated a condition of payment: "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

[13] The materiality requirement applies to conduct occurring both before and after the 2009 FCA amendment. *U.S. ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 763 (3d Cir. 2017).

if it knew of the defendant's noncompliance." *Id.* at 2003. Rather, courts must include in the materiality analysis evidence of the Government's "likely or actual" conduct with respect to the payment of claims that were not compliant with the relevant provision. *Id.* at 2002.

Bayer argues that Relator has not shown—and cannot show as a matter of law—that the alleged false certifications about Trasylol were material to the Government's payment decision by virtue of the operation of the DRG system. (Bayer Br. at 23–24). The crux of Bayer's argument is that "neither the use of Trasylol nor any associated misrepresentations affected the Government's decision to pay the DRG claims . . . because the Government paid a fixed fee and Trasylol did not even appear on the claim form." (ECF No. 329 at 15, 17). In Bayer's view, because the use or non-use of Trasylol did not change the reimbursement amount for a given surgery, the alleged violations had "no effect on the Government fisc," (ECF No. 329 at 17), and as a result, the Government "would not care" whether a kickback-tainted item such as Trasylol was used, (Bayer Br. at 24).

The Court rejects Bayer's argument that the Government's payment amount is dispositive on the question of materiality. The clear focus of the materiality inquiry under *Escobar* is not the *amount* of payment, but rather the "Government's payment *decision*." 136 S. Ct. at 2002 (emphasis added). Put differently, the materiality inquiry does not ask whether *the cost* of a noncompliant item would have affected the Government's payment decision; it asks whether *the noncompliance itself* would have affected that decision. *See Portilla*, 2014 WL 1293882, at *8 ("The falsity or fraud . . . must be material; that is, it must have the potential to affect the payment decision-making process."). The Government considers factors other than the bald dollar amount of a reimbursement request when deciding whether to pay a claim, including the claimant's compliance with applicable statutory requirements. *See Escobar*, 136 S. Ct. at 2003; *see also U.S.*

ex rel. Hayes v. CMC Elecs., Inc., 297 F. Supp. 2d 734, 738 (D.N.J. 2003) (rejecting defendant's argument that an FCA claim requires a showing of "an actual and quantifiable monetary loss" to the Government). Therefore, just because a noncompliant claim would not cost the Government *more* than a compliant claim does not mean the Government is "indifferent" to underlying compliance violations.[14] (ECF No. 329 at 18).

Indeed, the Court agrees with Relator that the Government suffers a loss every time it pays a noncompliant claim that it need not pay. (ECF No. 330 at 14). The Court is guided by the Third Circuit's recently reaffirmed principle that, at least in the context of an underlying AKS violation, "[t]he Government does not get what it bargained for when a defendant is paid . . . for services tainted by a kickback." *Greenfield*, 880 F.3d at 97 (quoting *Wilkins*, 659 F.3d at 314); *see also U.S. ex rel. Int'l Bhd. of Elec. Workers, Local Union No. 98 v. Fairfield Co.*, No. 09-4230, 2013 WL 3327505, at *4 (E.D. Pa. July 2, 2013) (finding falsity satisfied where, "even though the government paid less than it would have had it paid the fair market value, the Federal Treasury still paid the amount, which could be considered a 'loss,'" noting that "[a] party can be subject to FCA liability even where the government suffers no monetary injury"); *U.S. v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 443 (E.D. Pa. 2004) ("Whether or not the . . . Government would be out *additional* money beyond that already appropriated for [a claimant], it

[14] Bayer cites to *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 184 (3d Cir. 2001) for the principle that "the submission of false claims to the United States government for approval which do not or would not cause financial loss to the Government are not within the purview of the [FCA]," and that, "[u]nless these claims would result in economic loss to the United States government, liability under the [FCA] does not attach." (*See* Bayer Br. at 34). But the facts of *Hutchins* have no bearing on the present dispute, and Bayer relies on this language entirely out of context. In *Hutchins*, the Third Circuit held that the submission of inflated legal bills for approval by a U.S. bankruptcy court did not constitute FCA violations because the bankruptcy court's approval of the bills would not cause financial loss to the Government. 253 F.3d at 184. That reasoning made sense in *Hutchins*: the Government (*i.e.*, the bankruptcy court) was only *approving* bills that were to be paid by a bankruptcy estate. Here, by contrast, Bayer does not dispute that the Government (*i.e.*, CMS) was *paying* the claims, thereby "result[ing] in economic loss," *id.* *See Hayes*, 297 F. Supp. 2d at 738–39 (distinguishing *Hutchins* on same grounds).

would suffer a loss if the money appropriated for legitimate purposes were instead wasted on a false claim.") (quoting *U.S. ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 739 (D.C. Cir. 1998)). And, although the Government's entitlement to refuse payment in the event of noncompliance with a particular statutory requirement is not dispositive on the question of materiality as a whole, *see Escobar*, 136 S. Ct. at 2004, the Court notes, for the purposes of rejecting Bayer's argument that noncompliance in this case would be effectively valueless to the Government, that CMS can deny (and therefore incur no loss for) claims that are tainted by kickbacks. *See Greenfield*, 880 F.3d at 98 ("[A] kickback renders a subsequent claim ineligible for payment.").

The Court acknowledges that there is a split among district courts on this issue. In declining to hold as a matter of law that materiality cannot be established where the Government reimburses claims on a fixed basis, the Court follows several other districts that have considered and rejected similar arguments, as the Court finds the reasoning of those decisions persuasive for the reasons explained in this section. *See, e.g.*, *Commonwealth ex rel. Martino-Fleming v. S. Bay Mental Health Ctr.*, 334 F. Supp. 3d 394, 408–09 (D. Mass. 2018) (holding that Massachusetts sufficiently alleged a state law FCA claim against health care provider, despite the fact that false claims did not increase the reimbursement amount, noting that, "[a]lthough the contractors are paid a fixed rate . . . , the claims . . . are paid with government money"); *U.S. v. Visiting Nurse Serv. of N.Y.*, No. 14-5739, 2017 WL 5515860, at *12 (S.D.N.Y. Sept. 26, 2017) (rejecting argument that fixed reimbursement amounts defeated materiality under *Escobar*, noting that "the question is not whether the false nursing visits caused CMS to pay extra but whether, had CMS known that [defendant] was not making the number of visits it reported . . . , it would have naturally tended to not pay those claims"); *U.S. ex rel. Dan Abrams Co. v. Medtronic, Inc.*, No. 15-1212, 2017 WL 4023092, at *9–10 (C.D. Cal. Sept. 11, 2017) (the fact that "the amount paid by the government

for a spinal surgery is not affected by whether one or more of the [noncompliant devices] . . . are used" does not defeat FCA liability, reasoning that the DRG system "does not mean that the government . . ., in establishing general payment policies, has assigned no value to" those devices); *Merck-Medco*, 336 F. Supp. 2d at 442 (concluding that the Government stated an FCA claim despite the fact that the false claim did not increase the payment amount, reasoning that "[defendant's] argument would mean that any government program that involved a fixed . . . contribution . . . would be completely immune from claims of abuse; that Congress would have the FCA turn a blind eye to such behavior is simply inconceivable to this Court"); *see also Hutcheson*, 647 F.3d at 394–95 (rejecting DRG defense pre-*Escobar* but applying similar materiality standard, concluding that "[t]he intricacies of the DRG system do not alter the clear language" of providers' certifications of compliance with the AKS, and reasoning that the defendant's "argument that Medicare would excuse these violations because of a bureaucratic mechanism . . . impermissibly cabins what the government may consider material"); *U.S. ex rel. Duffy v. Lawrence Mem. Hosp.*, No. 14-2256, 2018 WL 4748345, at *8 n.8 (D. Kan. Oct. 2, 2018) (rejecting defendant's materiality argument based on lack of impact on the Treasury, noting that "whether the U.S. Treasury is ultimately impacted is not relevant to the question of whether an alleged misrepresentation affected or would likely affect a reimbursement decision"); *Morris*, 2000 WL 432781, at *4–5 (rejecting defendant's argument that, "because it was reimbursed at a flat fee based upon each patient's DRG, the specific services provided to individual patients are irrelevant to Medicare's payment," lest a defendant have the ability to "pick and choose what can be false on a bill submitted to Medicare so long as the DRG code is correct").[15]

[15] The Court disagrees with several pre-*Escobar* district court decisions finding that FCA liability did not attach in the context of fixed reimbursements. *See, e.g.*, *U.S. v. Grp. Health Co-op.*, No. 09-603, 2011 WL 814261, at *2 (W.D. Wash. Mar. 3, 2011); *Wagemann v. Doctor's Hosp. of Slidell, LLC*, No. 09-3506, 2010 WL 3168087, at *7 (E.D. La. Aug. 6, 2010); *U.S. ex rel. Stephens v. Tissue Sci. Labs.*,

Bayer's reliance on *In re Plavix Mktg., Sales Practice & Prods. Liab. Litig. (No. II)*, 332 F. Supp. 3d 927 (D.N.J. 2017) as this District's endorsement of Bayer's fixed-fee defense is misplaced. In *Plavix*, the relator alleged that the defendants falsely marketed their blood thinner as a superior drug to aspirin, when in fact the drug was no more effective than aspirin but cost one hundred times as much. 332 F. Supp. 3d at 933. The relator claimed that subsequently submitted claims violated a condition of payment under Medicaid that limits coverage to cost-effective treatments. *Id.* However, because states included Plavix on their preferred drug lists, Plavix was exempt from prior reimbursement authorization requirements that apply to other drugs, and state Medicaid payors were "obligat[ed] . . . to reimburse claims for Plavix automatically." *Id.* at 945. The court held that, because claims for Plavix were automatically reimbursed without consideration of physicians' certifications, those certifications "could not have been material to Medicaid's decision to pay for Plavix" under *Escobar*. *Id.* In dismissing the complaint, the court emphasized that the relator's "automatic reimbursement allegations essentially concede[d] that government Medicaid payors would consistently reimburse claims for Plavix *with full knowledge of the purported false certification* of physicians that Plavix was cost-effective." *Id.* at 949 (emphasis added). Here, by contrast, Relator argues that "the Government would not reimburse claims involving Trasylol if it had actual knowledge that the claims were tainted by Bayer's alleged fraud and resulting false certifications." (ECF No. 330 at 28). And unlike claims for Plavix, claims for Trasylol (or claims for surgeries using Trasylol) have not been deliberately identified or singled out by the Government payor as automatically reimbursable. Furthermore, Relator here alleges violations of the AKS—a well-settled trigger of FCA liability—whereas the relator in *Plavix* relied

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Inc., 664 F. Supp. 2d 1310, 1317–19 (N.D. Ga. 2009); *U.S. ex rel. Kennedy v. Aventis Pharm., Inc.*, No. 03-2750, 2008 WL 5211021, at *3 (N.D. Ill. Dec. 10, 2008); *U.S. ex rel. Digiovanni v. St. Joseph's/Candler Health Sys., Inc.*, No. 04-190, 2008 WL 395012, at *6 (S.D. Ga. Feb. 8, 2008); *Magid*, 2004 WL 945153, at *8–9.

upon state cost-effectiveness requirements and "failed to cite to a single successful claim under [those provisions]," as required by *Escobar*. 332 F. Supp. 3d at 948. The failure of Bayer's DRG defense under the present facts is therefore not inconsistent with the decision in *Plavix*.[16]

Finally, the Court rejects Bayer's argument that "it was impossible for Trasylol to influence the Government's payment decision because . . . Trasylol was 'not identified on the inpatient claim.'" (ECF No. 329 at 15). Relator does not dispute that the Government paid claims for surgeries involving Trasylol without knowing that an allegedly noncompliant item had been used. (*See, e.g.*, 10AC ¶ 379 ("Unaware of Bayer's misconduct, the United States made Medicare reimbursements for inpatient treatments involving Trasylol.")). Rather, Relator's logic is that Bayer was able to perpetrate the alleged fraud precisely because the DRG system disguised the use of kickback-tainted items from Government payors, who would not have otherwise paid those claims. (10AC ¶ 379). Therefore, that "the Government would not know the drug was used" in a particular surgery by virtue of the DRG system's non-itemized UB form, (Bayer Br. at 24), has no bearing on the materiality inquiry. *See, e.g.*, *Medtronic*, 2017 WL 4023092, at *9–10 (rejecting defendant's argument that materiality is defeated as a matter of law where "those responsible for making reimbursement decisions as to Medicare and Medicaid coverage[] would not know whether one or more of the [noncompliant devices] had been used in a particular surgical

[16] The Third Circuit's decision in *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017) is similarly distinguishable. In *Petratos*, the Circuit considered an FCA claim alleging noncompliance with Medicare's "reasonable and necessary" requirement arising from the defendant's failure to report data to the FDA that showed safety risks from on-label uses of a drug. 855 F.3d at 485. But, like the relator in *Plavix*, the relator in *Petratos* conceded that the relevant Government actors "have deemed [the alleged] violations insubstantial (or at least would do so if made aware)," and did "not dispute that CMS would reimburse [the claims at issue] even with full knowledge of the alleged reporting deficiencies." *Id.* at 490. Such concessions were clearly fatal to an FCA claim under the *Escobar* standard, which requires plausible allegations that the Government "would not have paid [the] claims had it known of [the alleged] violations." *Escobar*, 136 S. Ct. at 2004. Relator here makes no such concessions, alleging instead the opposite: "[i]f the United States had known that Trasylol was not reasonable or necessary for some uses, it would not have made reimbursements for treatment involving those uses." (10AC ¶ 403).

procedure" as a result of the DRG system). Simply put, the goal of this Court's materiality analysis is to determine what the Government would have done *had it known* about the alleged noncompliance involving Trasylol. *See Escobar*, 136 S. Ct. at 2004; *Plavix*, 332 F. Supp. 3d at 939 ("[A] plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare . . . laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims.") (quoting *Wilkins*, 659 F.3d at 307); *U.S. ex rel. Greenfield v. Medco Health Sys., Inc.*, 223 F. Supp. 3d 222, 229 (D.N.J. 2016) (a plaintiff must show that claims "would not have been paid by the government had it known about defendants' false representation that they complied with the AKS"), *aff'd*, 880 F.3d 89 (3d Cir. 2018).

Having rejected Bayer's assertion of a bright-line rule immunizing claims made pursuant to the DRG system from FCA liability, the Court examines the undisputed facts in light of what the materiality standard *does* require in this case. First, Bayer is correct that whether the Government labels an underlying statutory requirement as "a condition of payment is relevant to but not dispositive of the materiality inquiry." *Escobar*, 136 S. Ct. 2001. Put differently, "[w]hile [*Escobar*] admonishes that mere designation as a condition of payment is not necessarily sufficient to prove materiality, it is nonetheless an important factor to consider in favor of materiality." *Visiting Nurse Serv. of N.Y.*, 2017 WL 5515860, at *9 n.5. The Court notes at the outset, therefore, that both the AKS and the "reasonable and necessary" requirement in 42 U.S.C. § 1395y(a)(1)(A) are designated as conditions of payment under Medicare. *See Wilkins*, 659 F.3d at 313; *Petratos*, 855 F.3d at 490. Such a designation weighs in favor of a finding of materiality.

Beyond this important factor, Relator must provide "evidence that [Bayer] knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with" the AKS or the reasonable and necessary requirement as it relates to off-label drug uses.

Escobar, 136 S. Ct. at 2003. The Court disagrees with Bayer's suggestion that such evidence must be limited to the Government's refusal to pay noncompliant claims specifically in the DRG context. (*See* ECF No. 329 at 18). Rather, *Escobar* instructs courts to examine the Government's practice of payment or nonpayment of claims based on the same underlying violation—claims that are noncompliant "with the particular statutory, regulatory, or contractual requirement" at issue. *Escobar*, 136 S. Ct. at 2004. Indeed, the Supreme Court's finding that materiality was met in the case before it focused on the alleged underlying violations, concluding that the licensing requirements violated by the defendant were "so central to the provision of [health services] that the Medicaid program would not have paid these claims had it known of these violations," which the Court distinguished from noncompliance with "insignificant regulatory or contractual" provisions. *Id.* The focus of the inquiry is therefore not on the payment mechanism used in a given context, but rather on "whether the defendant knowingly violated *a requirement* that the defendant knows is material to the government's decision to pay a claim." *Petratos*, 855 F.3d at 492 (emphasis added) (quoting *U.S. ex rel. Garzione v. PAE Gov't Servs., Inc.*, 670 F. App'x 126, 127 (4th Cir. 2016)); *see also U.S. ex rel. Doe v. Heart Sol., PC*, 918 F.3d 300, 310 (3d Cir. 2019) (underlying reasonable and necessary violation was material to Government's payment decision where Government showed that Medicare would not pay claims in the absence of physician certification that testing was supervised by licensed neurologist, as required by regulation); *Petratos*, 855 F.3d at 490 (materiality not met for defendant's failure to report data to FDA concerning safety risks of on-label drug uses, as relator failed to cite "a single successful claim under [the reasonable and necessary requirement] involving drugs prescribed for their on-label uses," and noting that the reporting failure did not "violate[] any statute or regulation"); *Jersey Strong*, 2017 WL 4122598, at *4 ("[Relator] must also plead that the [Medicare Secondary Payer]

laws are material to the government's decision to pay the submitted claims.").

Here, therefore, the Court's focus is on the Government's actual or likely conduct with respect to payment of claims that are noncompliant with the AKS or with Medicare's reasonable and necessary requirement as it relates to off-label drug uses—the two alleged underlying violations in this case. Relator argues that materiality is met because these provisions "relate to central requirements of the Medicare program, which a reasonable person would understand are fundamentally important to the Government's payment decision." (Rel. Br. at 29). Relator also intends to marshal evidence at trial that the Government routinely refuses to pay false claims based on kickbacks (in violation of the AKS) and promotion of drugs for off-label uses (in violation of the reasonable and necessary requirement). (*See* ECF No. 330 at 24–25 & n. 22). Bayer may try to rebut Relator's evidence with proof that "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," or evidence that "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 its position." *Escobar*, 163 S. Ct. at 2003–04. Such evidence would tend to show that such noncompliance was merely "minor or insubstantial." *Id.* at 2003. Ultimately, because evidence showing the effect of the alleged fraud on the Government's decision to pay claims for Trasylol is not before the Court and discovery is still ongoing, the Court is unable to grant summary judgment in favor of Bayer on the question of materiality. [17]

[17] The Court acknowledges receipt of a letter from Bayer dated April 3, 2019, (ECF No. 347), a response from Relator dated April 16, 2019, (ECF No. 348), and a response from the Government dated April 17, 2019, (ECF No. 349)—well after the briefing on these cross-motions had concluded, after oral argument had been heard, and while this Opinion was nearing publication. Despite reiterating that "there is no genuine factual dispute precluding this Court's decision," Bayer requests an opportunity to obtain additional discovery from the Government "before any decision is made that materiality is a factual question for the jury." (ECF No. 347 at 2). Bayer makes this request in light of objections to discovery made by the Government that, in Bayer's view, contradict the Government's position at oral argument, where the Government argued that material factual disputes precluded a decision as a matter of law on Bayer's motion. (ECF No. 347 at 1–2). The Government responds that "no discovery is needed for the

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All fraud is disguised—until it is not. That the alleged fraud involving Trasylol was hidden from the Government by virtue of the DRG system does not insulate Bayer from liability for that fraud as a matter of law. Indeed, among "Congress's primary goals" in enacting the *qui tam* provisions of the FCA were "encouraging disclosure and aiding prosecution of fraud" of which the Government would otherwise remain unaware. *U.S. ex rel. Mistick PBT v. Housing Auth. of City of Pittsburgh*, 186 F.3d 376, 391 (3d Cir. 1999). Whether the fraud alleged by Relator was material to the Government's decision to pay claims for surgeries involving Trasylol is a question, among others, that must be answered by a jury in this case.

B. Relator's Motion

Relator's motion seeks only a determination as a matter of law that the FCA does not foreclose liability for claims paid pursuant to Medicare's bundled, fixed-fee DRG payment system. (Rel. Br. at 11). Relator asks the Court to enter an order stating the following:

> Bayer may be held liable under the [FCA] for claims for Medicare and Medicaid reimbursement for surgical procedures in which Trasylol was administered, regardless of whether the relevant requests for reimbursement were bundled rather than itemized[, and] regardless of whether the administration of Trasylol in these procedures affected the total amount of corresponding reimbursement.

Court to reach and resolve the DRG issue." (ECF No. 249 at 2). Relator responds that, in seeking summary judgment, "Bayer has conceded the absence of any material facts for resolution of its own motion," and that Bayer's letter represents a "request for conditional adjudication" of its motion. (ECF No. 348 at 3). As an initial matter, the Court reminds the parties that a Special Master has been appointed to facilitate the resolution of ongoing discovery disputes. (*See* ECF No. 328). Secondly, notwithstanding the issues raised in Bayer's letter, the Court finds (in concordance with the parties' original joint representation) that the "narrow issue" on which the Court ordered these motions, (*see* ECF No. 321), is ripe for summary judgment, and the Court has rendered a decision accordingly. However, if, at a later stage, good cause is shown for summary judgment motions to be renewed or other relief to be sought, an appropriate request may be made to the Court at that time.

(ECF No. 324-3 at 1–2). In denying Bayer's motion for partial summary judgment on this issue, the Court holds precisely that. Relator does not suggest that she has met her burden of proving liability on any element of her FCA claim—falsity, causation, knowledge, and materiality, *see Petratos*, 855 F.3d at 487—at this stage. (*See* Hearing Tr. 6:19–7:6, 9:6–10). Both parties acknowledge ongoing disputes of fact that are material to a determination of liability on any element. (*See* Hearing Tr. 8:9–9:1, 40:3–12). As a result, the Court cannot grant partial judgment as a matter of law in favor of Relator. *See Anderson*, 477 U.S. at 247 (summary judgment requires a showing "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law") (quoting Fed. R. Civ. P. 56(c)).

The Court need not grant Relator's motion in order to endorse her view of the law on this issue, which the Court necessarily does in denying Bayer's motion. However, partial summary judgment in Relator's favor would be premature at this stage. In order to prevail at trial, Relator must prove all four FCA elements—including materiality—according to the tests set forth in *Escobar* and other applicable precedent as described above.

IV. CONCLUSION

For these reasons, the parties' cross-motions for partial summary judgment are denied. An appropriate Order accompanies this Opinion.

DATED: April 22nd, 2019

JOSE L. LINARES
Chief Judge, United States District Court