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United States District Court,
D. Massachusetts.

The UNITED STATES of America ex rel.
Kassie WESTMORELAND, Plaintiff,
v.
AMGEN, INC.; International Nephrology Network renamed Integrated Nephrology Network, a d/b/a of Dialysis Purchasing Alliance, Inc.; and ASD Healthcare, Defendants.

Civil Action No. 06–10972–WGY. | Sept. 15, 2011.

Synopsis

Background: Relator brought qui tam action against drug manufacturer and group purchasing organization (GPO) and wholesaler, alleging that they knowingly caused health care providers to make false representations material to the payment of Medicare claims and conspired to get false claims paid by Medicare. After reversal of a previous dismissal of claims brought on behalf of certain states, 2011 WL 2937420, defendants moved for partial judgment on the pleadings, and parties filed cross-motions for partial summary judgment.

Holdings: The District Court, Young, J., held that:
1 requirement of Anti–Kickback Statute compliance contained in provider agreement's certification was a precondition of Medicare payment, such that liability under the False Claims Act could be predicated on a violation of the Anti–Kickback Statute;
2 since drug manufacturer did not include overfill in calculating its drug's average sales price it correctly calculated ASP in seeking Medicare reimbursement for the drug;
3 genuine issue of material fact existed as to whether GPO mailed annual disclosure letters to its members as required for compliance with safe harbor requirements of Anti–Kickback Statute; and
4 genuine issue of material fact existed as to whether wholesaler conspired with drug manufacturer and GPO to defraud the federal government by causing providers to seek Medicare reimbursement for free overfill.

Order in accordance with opinion.

West Headnotes (13)

1 United States
Making or Presentation of False Claims and Other Offenses Relating to Claims

A claim is "materially false or fraudulent" within meaning of False Claims Act (FCA) if it represents compliance with a material condition of payment that was not in fact met. 31 U.S.C.A. § 3729(a)(1).

2 United States
Making or Presentation of False Claims and Other Offenses Relating to Claims

Preconditions of payment need not be expressly designated as such to give rise to false or fraudulent claims within meaning of False Claims Act (FCA). 31 U.S.C.A. § 3729 et seq.

3 United States
Making or Presentation of False Claims and Other Offenses Relating to Claims

False Claims Act (FCA) liability may be imposed only where the defect in the claim is material and where the defendant acts knowingly; a non-submitting entity may be liable for knowingly causing a submitting entity to submit a false or fraudulent claim, regardless whether the submitting entity knew or should have known about the non-submitting entity's unlawful conduct. 31 U.S.C.A. § 3729 et seq.

4 Health
Providers

To receive protection under statutory and regulatory safe harbors of Anti–Kickback Statute, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute. Social Security Act, § 1128B(b), 42 U.S.C.A. § 1320a–7b(b); 42 C.F.R. § 1001.952.

5 **United States**

Making or Presentation of False Claims and Other Offenses Relating to Claims

False statement or misrepresentation that is the premise of a False Claims Act action need not be a certification; so long as the statement is knowingly false when made, False Claims liability can attach no matter whether statement is a certification, assertion, statement, or secret handshake. 31 U.S.C.A. § 3729 et seq.

6 **United States**

Making or Presentation of False Claims and Other Offenses Relating to Claims

Requirement of Anti–Kickback Statute compliance contained in provider agreement's certification was a precondition of Medicare payment, such that liability under the False Claims Act could be predicated on a violation of the Anti–Kickback Statute; compliance with the Anti–Kickback Statute factored into the government's reimbursement decision since government is not only unwilling to pay a claim that is the product of criminal conduct under the Anti–Kickback Statute, but also to submit such a claim for reimbursement is in effect to ask the government to fund criminality retroactively, a result specifically proscribed by the Anti–Kickback Statute. 31 U.S.C.A. § 3729 et seq.; Social Security Act, § 1128B(b), 42 U.S.C.A. § 1320a–7b(b); Social Security Act, § 1815(a), 42 U.S.C.A. § 1395g(a).

7 **Health**

Deference to Agency in General

Provider agreement, which required providers to certify their compliance with the Anti–Kickback Statute as a precondition of Medicare payment, was adopted in accordance with Paperwork Reduction Act (PRA) and represented a valid exercise of Centers for Medicare and Medicaid Services' (CMS) regulatory authority entitled to judicial deference; its certification clause was consistent with the Medicare statutes and regulations as well as the purpose of the Anti–Kickback Statute. Social Security Act, § 1128B(b), 42 U.S.C.A. § 1320a–7b(b).

8 **Health**

Reimbursement

Since drug manufacturer did not include overfill in calculating its drug's average sales price (ASP), it correctly calculated ASP in seeking Medicare reimbursement for the drug.

9 **Evidence**

Mailing, and Delivery of Mail Matter

Under "mailbox rule" recognized at federal common law, the proper and timely mailing of a document raises a rebuttable presumption that the document has been received by the addressee in the usual time; even in the context of regular mail, a presumption of receipt is proper so long as the record establishes that the notice was accurately addressed and mailed in accordance with normal office procedures.

10 **Evidence**

Mailing, and Delivery of Mail Matter

Testimony by someone familiar with company procedures and practices that the letter was sent, together with corroborating evidence that the company procedures and practices were followed in that particular instance, is sufficient to establish proof of mailing.

11 **Evidence**

Rebuttal of Presumptions of Fact

Generally, evidence of non-receipt is insufficient to rebut the presumption of receipt under the mailbox rule, but it does present a triable question of fact whether the letter was properly sent.

12 **Federal Civil Procedure**

False Claims and Qui Tam Actions

Genuine issue of material fact existed as to whether group purchasing organization

(GPO) mailed annual disclosure letters to its members as required for compliance with safe harbor requirements of Anti–Kickback Statute, precluding partial summary judgment in favor of GPO or relator on GPO's safe harbor defense to relator's claim False Claims Act (FCA) claim based on allegations that GPO conspired with drug manufacturer and another defendant to defraud the federal government by causing health care providers to seek reimbursement for free overfill on drug purchased by GPO on each member's behalf. 42 C.F.R. § 1001.952(j)(2); 31 U.S.C.A. § 3729 et seq.

13 Federal Civil Procedure

False Claims and Qui Tam Actions

Genuine issue of material fact existed as to whether wholesaler, which retained discretion to give discounts to providers buying drug and utilized the "pass through" of the administrative fee to provide such discounts, conspired with drug manufacturer and group purchasing organization (GPO) to defraud the federal government by causing providers to seek Medicare reimbursement for free overfill of drug in violation of the False Claims Act (FCA), precluding summary judgment in favor of wholesaler or relator on FCA claim.

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Opinion

MEMORANDUM

YOUNG, District Judge.

I. INTRODUCTION

***1** Relator Kassie Westmoreland ("the Relator") brings this *qui tam* action against Amgen, Inc. ("Amgen"), International Nephrology Network ("INN"), and ASD Healthcare ("ASD") (collectively, "the Defendants") for violations of the federal

False Claims Act, 31 U.S.C. §§ 3729–33. In her Fourth Amended Complaint, the Relator alleges that the Defendants knowingly caused health care providers to make false representations material to the payment of Medicare claims and conspired to get false claims paid by Medicare. Specifically, the Relator alleges that, in violation of the federal Anti–Kickback Statute, the Defendants encouraged providers to submit claims for payment by Medicare for the value of the excess product, or "overfill," contained in the vials of their drug Aranesp but not included in Aranesp's average sales price ("ASP"). This Court has upheld the Relator's allegations as sufficient to state a claim under the False Claims Act.

There are now a number of other motions pending decision by the Court. First, the Defendants move for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c). It is undisputed that health care providers, in signing mandatory Medicare Enrollment Form CMS–855 ("the Provider Agreement"), agree to comply with the Anti–Kickback Statute as a precondition of Medicare payment. The Defendants, however, argue (1) that the clause in the Provider Agreement requiring a certification of compliance with the Anti–Kickback Statute is contrary to the Medicare statutes and regulations, which do not establish Anti–Kickback Statute compliance as a precondition of payment, and (2) that the adoption by the Centers for Medicare and Medicaid Services ["CMS"} of the version of the Provider Agreement that includes the certification clause was procedurally improper and outside the scope of its authority. The Relator, in opposition to the Defendants' motion, argues (1) that the Anti–Kickback Statute itself establishes compliance as a precondition of Medicare payment, and (2) that the certification of compliance in the Provider Agreement is a valid agency interpretation of the regulations. The United States, while not a party to the action, has filed a statement of interest supporting the Relator's position.

Second, the Relator and Amgen bring cross-motions for partial summary judgment as to Count IV of the Fourth Amended Complaint, which alleges that Amgen artificially inflated Aranesp's ASP by failing to include overfill as a "price concession," in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). In her memorandum in support of her motion, the Relator argues that, because Aranesp's ASP was artificially inflated, claims submitted by providers based on this ASP were false and fraudulent as matter of law. Amgen asserts that federal rules and regulations make clear that overfill is not to be included in a drug's ASP and that there is no evidence that Amgen intended to submit an inaccurate ASP for Aranesp.

***2** Third, INN and ASD move for partial summary judgment on the theory that they are shielded from liability by the Anti–Kickback Statute's "safe harbor" provisions for group purchasing organizations ("GPOs"), 42 U.S.C. § 1320a–7b(b)(3)(C), and discounts, *id.* § 1320a–7b(b)(3)(A). The Relator brings a cross-motion for partial summary judgment, arguing that the GPO safe harbor is inapplicable to INN due to its failure to comply with the formalities set forth in the federal regulations and due to its impermissibly close relationships with Amgen and ASD. With respect to ASD and the discount safe harbor, the Relator argues that the "pass through" of an administrative fee paid by Amgen to INN to ASD, who utilized the funds to provide discounts to providers, was unlawful and indicative of the conspiracy to defraud Medicare in which the Defendants allegedly have engaged.

A. Procedural Posture

In June 2006, the Relator filed this *qui tam* action against Amgen, INN, ASD, and two other corporate defendants under the federal False Claims Act and various related state laws on behalf of the United States, fifteen states, and the District of Columbia. Relator's Compl., ECF No. 1. In September 2009, the United States notified the Court that it was not intervening in the action at that time. U.S. Notice Non–Intervention, ECF No. 71. The states and the District of Columbia (collectively, the "States") intervened by filing a separate Multi–State Complaint in October 2009, which they amended in December 2009. Multi–State Compl. Intervention, ECF No. 85; Multi–State First Am. Compl., ECF No. 112. Subsequently, several states voluntarily dismissed, including Delaware, Florida, Louisiana, Nevada, New Hampshire, and Texas. Notices Voluntary Dismissal, ECF Nos. 120, 123, 148, 153, 156, 163.

The Relator filed her Third Amended Complaint in December 2009, bringing claims on behalf of herself, the United States, Georgia, and New Mexico. Relator's Third Am. Compl., ECF No. 113. The Defendants subsequently moved to dismiss Counts I–VI of the Third Amended Complaint and the entirety of the Multi–State First Amended Complaint. Amgen's Mot. Dismiss Relator's Third Am. Compl., ECF No. 139; Amgen's Mot. Dismiss Multi–State First Am. Compl., ECF No. 142; INN & ASD's Mot. Dismiss Relator's Third Am. Compl., ECF No. 138; INN & ASD's Mot. Dismiss Multi–State First Am. Compl., ECF No. 135. The Court dismissed the Multi–State First Amended Complaint and

some of the Relator's federal claims under the federal False Claims Act's first-to-file bar and the remainder of her claims without prejudice under Federal Rule of Civil Procedure 12(b)(6). *United States ex rel. Westmoreland v. Amgen, Inc.*, 707 F.Supp.2d 123 (D.Mass.2010). The First Circuit has since reversed the dismissal of the States' claims under the state False Claims Acts of California, Illinois, Indiana, Massachusetts, New Mexico, and New York, and affirmed the dismissal of the States' claims under Georgia's False Claims Act. *New York v. Amgen, Inc.*, Nos. 10–1629, 10–1630, 10–1633, 10–1634, 10–1635, 10–1636, 10–1954, 10–1955, 2011 WL 2937420 (1st Cir. July 22, 2011).

***3** In May 2010, the Relator filed her Fourth Amended Complaint, and the Defendants again moved to dismiss. Relator's Fourth Am. Compl., ECF No. 238; Amgen's Mots. Dismiss Relator's Fourth Am. Compl., ECF Nos. 251, 253; INN & ASD's Mot. Dismiss Relator's Fourth Am. Compl., ECF. No. 256. On July 21, 2010, the Court denied the Defendants' Motions to Dismiss the Relator's Fourth Amended Complaint. *See United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F.Supp.2d 267 (D.Mass.2010). On August 4, 2010, the Defendants answered the Relator's Fourth Amended Complaint. Amgen's Answer Relator's Fourth Am. Compl., ECF No. 286; INN & ASD's Answer Relator's Fourth Am. Compl., ECF No. 285. INN and ASD asserted their compliance with certain safe harbor provisions of the federal Anti–Kickback Statute as their Ninth Affirmative Defense. INN & ASD's Answer Relator's Fourth Am. Compl., Affirmative Defenses ¶ 15.

On February 18, 2011, INN and ASD filed their Motion for Partial Judgment on the Pleadings. INN & ASD's Mot. Partial J. Pleadings, ECF No. 367; Mem. Supp. INN & ASD's Mot. Partial J. Pleadings, ECF No. 368. Amgen then moved to join INN and ASD's motion on March 1, 2011, and this Court allowed it the following day. Amgen's Mot. Joinder INN & ASD's Mot. Partial J. Pleadings, ECF No. 385; Mem. Supp. Amgen's Mot. Joinder INN & ASD's Mot. Partial J. Pleadings, ECF No. 387. On March 11, 2011, the Relator opposed the Defendants' joint motion. Mem. Opp'n Defs.' Mot. Partial J. Pleadings, ECF No. 408. The Court granted the Defendants leave to file a joint reply brief, which they did on March 17, 2011. Joint Reply Mem. Supp. Defs.' Mot. Partial J. Pleadings, ECF No. 419. On March 18, 2011, the United States filed its statement of interest. U.S. Br. Statement Interest INN & ASD's Mot. Partial J. Pleadings, ECF No. 421. At oral argument on March 24, 2011, the Court denied the motion, and this opinion announces the Court's reasoning for that denial.

On March 1, 2011, the parties brought their various Motions for Partial Summary Judgment. Amgen's Mot. Partial Summ. J., ECF No. 376; Mem. Supp. Amgen's Mot. Partial Summ. J., ECF No. 377; INN & ASD's Mot. Partial Summ. J., ECF No. 379; Mem. Supp. INN & ASD's Mot. Partial Summ. J., ECF No. 380; Relator's Mot. Partial Summ. J. Amgen, ECF No. 383; Mem. Supp. Relator's Mot. Partial Summ. J. Amgen, ECF No. 388; Relator's Mot. Partial Summ. J. INN & ASD, ECF No. 384; Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD, ECF No. 386. On March 22, 2011, the parties filed memoranda in opposition. Mem. Opp'n Relator's Mot. Partial Summ. J. Amgen, ECF No. 429; Mem. Opp'n Relator's Mot. Partial Summ. J. INN & ASD, ECF No. 434; Mem. Opp'n Amgen's Mot. Partial Summ. J., ECF No. 431; Mem. Opp'n INN & ASD's Mot. Partial Summ. J., ECF No. 437. Reply briefs were filed on April 1, 2011. Reply Mem. Supp. Amgen's Mot. Partial Summ. J., ECF No. 450; Reply Mem. Supp. INN & ASD's Mot. Partial Summ. J., ECF No. 453; Reply Mem. Supp. Relator's Mot. Partial Summ. J. Amgen, ECF No. 452; Reply Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD, ECF No. 454. At the hearing on April 11, 2001, the Court orally denied the Defendants' Motions for Partial Summary Judgment on Counts I, II, III, V, VI, and VII of the Relator's Fourth Amended Complaint. Mot. Hearing Tr. ("Tr.Summ. J. Mots.") 21:25 to 22:1–4, 22:13–20, ECF No. 463. It took under advisement the remaining motions concerning Count IV of the Fourth Amended Complaint and INN and ASD's Ninth Affirmative Defense. *Id.*

***4** In an order dated August 25, 2011, the Court denied the Relator's Motion for Partial Summary Judgment that Amgen Artificially Inflated the Average Sales Price of Aranesp in Violation of the False Claims Act, while allowing Amgen's Motion for Partial Summary Judgment as to Count IV of the Fourth Amended Complaint insofar as it alleges that Amgen artificially inflated the Average Sales Price of Aranesp. Order, ECF No. 481. Additionally, the Court denied the Relator's Motion for Partial Summary Judgment as to INN & ASD's Ninth Affirmative Defense as well as INN & ASD's Motion for Partial Summary Judgment with respect to its Ninth Affirmative Defense. *Id.* This opinion explains the Court's rulings.

B. Legal Framework

1. False Claims Act

The False Claims Act prohibits false or fraudulent claims for payment to the federal government and permits civil actions based on such claims to be brought by the Attorney General

or by private individuals, referred to as "relators," acting in the government's name. 31 U.S.C. § 3730(a)-(b). Where the government elects not to intervene, the so-called *qui tam* plaintiff may proceed with the action as the government's assignee. *Id.* § 3730(b)(4)(B).

At the time the Relator filed her complaint, the False Claims Act imposed liability on any person who either "knowingly presents, or causes to be presented to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," *id* . § 3729(a)(2). *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir.2007).

1 **2** A claim is "materially false or fraudulent" if it "represent[s] compliance with a material condition of payment that was not in fact met." *United States ex rel. Hutcheson v. Blackstone Med. Inc.*, 647 F.3d 377, 379 (1st Cir.2011). Determination of whether a claim is materially false or fraudulent "is a fact-intensive and context-specific inquiry." *Amgen*, 2011 WL 2937420, at *6. The first step of the analysis is to identify preconditions of payment under the relevant government program. *See id.* Preconditions of payment, however, need not "be expressly designated as such to give rise to false or fraudulent claims." *Blackstone Med.*, 647 F.3d at 387 (citing *United States v. Science Applications Int'l Corp. ("SAIC")*, 626 F.3d 1257, 1269 (D.C.Cir.2010)). The First Circuit has declined to adopt a categorical rule that preconditions of payment must derive verbatim from a statute or regulation. *Id.* at 388, 391, 393–94. A claim also may be false or fraudulent for non-compliance with a contractual term, even if the contract does not specify compliance as a precondition of payment. *Id.* at 387 (citing *SAIC*, 626 F.3d at 1269); *see United States ex rel. Saltzman v. Textron Sys. Corp.*, No. 09–11985–RGS, 2011 WL 2414207, at *3 (D.Mass. June 9, 2011) (Stearns, J.). *But see Amgen*, 2011 WL 2937420, at *10 (suggesting that a precondition of payment must be established by clear authority). Yet, "non-compliance with a contractual condition is [no] more necessary to establish that a claim is false or fraudulent than non-compliance with an express statute or regulation, or an express misrepresentation on a form submitted with payment." *Blackstone Med.*, 647 F.3d at 394.

***5** **3** The First Circuit's rejection of "a circumscribed view of what it means for a claim to be false or fraudulent," *id.* at 387–88 (quoting *SAIC*, 626 F.3d at 1270), reflects a belief that "other means exist to cabin the breadth of the phrase 'false or fraudulent' as used in the [False Claims Act]," *id.* at 388. *See United States ex rel. Nowak v. Medtronic, Inc.*, Nos. 1:08–cv–10368, 1:09–cv–11625, 2011 WL 3208007, at *27 (D.Mass. July 27, 2011) (Woodlock, J.). Specifically, liability may be imposed only where the defect in the claim is material and where the defendant acts knowingly. *Id.* Longstanding First Circuit precedent establishes "that the [False Claims Act] is subject to a judicially-imposed requirement that the allegedly false claim or statement be material." *United States ex rel. Loughren v. Unum Group*, 613 F.3d 300, 307 (1st Cir.2010). "[A] false statement is material if it has 'a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed.' " *Id.* (quoting *Neder v. United States*, 527 U.S. 1, 16, 119 S.Ct. 1827, 144 L.Ed.2d 35 (1999)). Thus, the second step of the analysis is to determine whether compliance with the identified precondition of payment is "material," i.e., capable of influencing the government's decision to pay the claim. *Amgen*, 2011 WL 2937420, at *6. The First Circuit has observed that "[e]xpress contractual language may 'constitute dispositive evidence of materiality,' but materiality may be established in other ways, 'such as through testimony demonstrating that both parties to the contract understood that payment was conditional on compliance with the requirement at issue.' " *Blackstone Med.*, 647 F.3d at 394.

In addition to materiality, the False Claims Act's knowledge requirement operates as another constraint on liability under the statute. A person acts "knowingly" if he or she "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). "Knowingly" does not require "proof of specific intent to defraud." *Id.* Under Supreme Court and First Circuit case law, a non-submitting entity may be liable for knowingly causing a submitting entity to submit a false or fraudulent claim, regardless whether the submitting entity knew or should have known about the non-submitting entity's unlawful conduct. *Blackstone Med.*, 647 F.3d at 390 (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544–45, 63 S.Ct. 379, 87 L.Ed. 443 (1943)). "[U]nlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party." *Id.* Representations by the submitting entity as to its own compliance with preconditions of payment do not "somehow immunize a non-submitting entity from liability under the 'causes' clause of the [False Claims Act]." *Id.* This is consistent with the congressional intent in passing the False Claims Act "to reach all types of fraud, without qualification,

that might result in financial loss to the Government ." *Id.* at 392 (quoting *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129, 123 S.Ct. 1239, 155 L.Ed.2d 247 (2003)).

2. Anti–Kickback Statute

***6** The federal Anti–Kickback Statute provides that:

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320A–7b(b). The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105, 108 (9th Cir.1989); *United States v. Greber*, 760 F.2d 68, 69 (3d Cir.1985); *see United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir.1989) ("The key to a Medicare Fraud case is the reason for the payment—was the purpose of the payments primarily for inducement.").

A number of statutory and regulatory safe harbors protect certain business arrangements that might otherwise violate the Anti–Kickback Statute. *See* 42 U.S.C. § 1320a–7b(b)(3)(A)–(J). These safe harbors "apply only in very specific instances," *United States v. Shaw*, 106 F.Supp.2d 103, 113 (D.Mass.2000) (Keeton, J.), to "exempt[ ] only a small subset of such transactions," *Bay State Ambulance*, 874 F.2d at 31. Relevant here, such transactions include the common business arrangements of GPOs, 42 U.S.C. § 1320a–7b(b)(3)(C); 42 C.F.R. § 1001.952(j), and discounts, 42 U.S.C. § 1320a–7b(b)(3)(A); 42 C.F.R. § 1001.952(h).

4 To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute. OIG Compliance Program for Pharmaceutical Manufacturers, 68 Fed.Reg. 23731, 23734 (May 5, 2003). "Whether a particular payment practice violates the statute is a question that can only be resolved by an analysis of the elements of the statute as applied to that set of facts." Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the OIG Safe Harbor Anti–Kickback Provisions, 59 Fed.Reg. 37202, 37203 (July 21, 1994). "[T]he gravamen of a violation of the statute is 'inducement' and not necessarily the structure of the arrangement," such that "case by case inquiries must necessarily focus on the intent of the parties." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti–Kickback Provisions, 56 Fed.Reg. 35952, 35955 (July 29, 1991) (citing *Bay State Ambulance*, 874 F.2d at 29); *see Shaw*, 106 F.Supp.2d at 114 ("[T]he fundamental analysis required of a trier of fact is 'to recognize that the substance rather than simply the form of the transaction should be controlling .' " (quoting 56 Fed.Reg. at 35957)). "The reason behind the transaction and the requisite state of mind underlying the criminal act are more significant than form and label." *Shaw*, 106 F.Supp.2d at 116. If the requisite intent to willfully or knowingly solicit or offer a kickback is present, formal compliance with a safe harbor is not sufficient to avoid liability under the Anti–Kickback Statute. *Cf.* Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti–Kickback Statute, 64 Fed.Reg. 63518, 63530 (Nov. 19, 1999).

II. MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

A. Facts

***7** **5** The underlying facts are not relevant to the Court's resolution of the Defendants' Motion for Partial Judgment on the Pleadings. Instead, the issue here is the legal validity of the certification of compliance with the Anti–Kickback Statute that is contained in the Provider Agreement and to which health care providers attest in signing the form. [1] The certification reads:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. 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.

Relator's Fourth Am. Compl., Exs. I–J ("Provider Agreement"), ECF Nos. 238–9, 238–10 (emphasis added). The Provider Agreement further states that this certification is one of the "requirements that the provider must meet and maintain in order to bill the Medicare program." [2] *Id.*

B. Standard of Review

A Rule 12(c) motion implicates the pleadings as a whole. *Aponte–Torres v. University of P.R.*, 445 F.3d 50, 54–55 (1st Cir .2006). Because a motion for judgment on the pleadings, like a motion to dismiss a complaint, "involves some assessment of the merits," the Court must "view the facts contained in the pleadings in the light most favorable to the party opposing the motion—here, the plaintiff—and draw all reasonable inferences in the plaintiff's favor." *Curran v. Cousins*, 509 F.3d 36, 43 (1st Cir.2007). A "court may not grant a defendant's Rule 12(c) motion 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.' " *Rivera–Gomez v. de Castro*, 843 F.2d 631, 635 (1st Cir.1988) (quoting *George C. Frey Ready–Mixed Concrete, Inc. v. Pine Hill Concrete Mix Corp.*, 554 F.2d 551, 553 (2d Cir.1977)).

While this is the standard of review under Rule 12(c), and while both the Relator and the Defendants accept it as such, here there are no factual inferences to draw. Rather, the parties present differing views on purely legal questions of statutory interpretation and administrative law. *See Skinner v. Salem Sch. Dist.*, 718 F.Supp.2d 186, 188 (D.N.H.2010) ("Questions of statutory interpretation are 'ripe for resolution at the pleadings stage.' " (quoting *Simmons v. Galvin*, 575 F.3d 24, 30 (1st Cir.2009))). Unlike factual allegations, "[m]ere legal conclusions 'are not entitled to the assumption of truth.' " *Sanchez v. Esso Standard Oil De P.R., Inc.*, Civ. No. 08–2151–JAF, 2010 WL 3069551, at *2 (D.P.R. Aug.2, 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, ——, 129 S.Ct. 1937, 1950, 173 L.Ed.2d 868 (2009)). "[T]he Court is not required to adopt purely legal conclusions asserted by the moving party." *Crooker v. United States*, Civ. No. 08–10149–PBS, 2010 WL 3860597, at *5 (D.Mass. Sept.29, 2010) (Saris, J.) (citing *Phoung Luc v. Wyndham Mgmt. Corp.*, 496 F.3d 85, 88 (1st Cir.2007)).

C. Analysis

1. Compliance with the Anti–Kickback Statute as a Precondition of Medicare Payment

***8 6** The Defendants ask this Court to hold that, contrary to conventional wisdom, compliance with the Anti–Kickback Statute is not and cannot be a precondition of Medicare payment because it has no legal basis, express or implied, in the Medicare statutes or regulations. In *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 694 F.Supp.2d 48 (D.Mass.2010), this Court acknowledged that "[t]he Medicare statutes and regulations do not expressly contain a precondition of compliance with the Anti–Kickback Statute." *Id.* at 66. In the same case on appeal, the First Circuit declined to address whether, without express statutory or regulatory authorization, compliance with the Anti–Kickback Statute is nonetheless a precondition of payment. *Blackstone Med.*, 647 F.3d at 392. It was unnecessary for the court to decide the issue because the certification clause in the Provider Agreement was "sufficiently clear to establish that the claims submitted by physicians represented that the underlying transactions did not involve kickbacks to physicians prohibited by the [Anti–Kickback Statute]." *Id.* at 393 (emphasis in original omitted). The physicians, in signing the Provider Agreement, agreed that payment is conditioned on Anti–Kickback Statute compliance, and therefore they were bound to abide by the certification clause as matter of contract law. *Id.*

This Court could adopt the same approach here and go no further. But the Defendants' argument is effectively a challenge to the validity of the contractual term making compliance with the Anti–Kickback Statute a precondition of payment. The Defendants argue that, even if health care providers agreed to it, the certification clause in the Provider Agreement is inconsistent with the legal framework governing Medicare payment and reflects improper agency rulemaking. These are novel claims fit for decision by this Court.

The Defendants first contend that the absence of an express condition in the Medicare statutes makes clear that Congress meant to preclude compliance with the Anti–Kickback Statute as a precondition of payment. *See* Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 5–7. The Medicare statutes contain various provisions specifying conditions of Medicare payment, *see, e.g.*, 42 U.S.C. § 1395f ("Conditions of and limitation on payment for services"); *id.* § 1395m ("Special payment rules for particular items and services"), but only one of them relates to the Anti–Kickback Statute, *see id.* § 1395y ("Exclusions from coverage and medicare as secondary payer"). It reads:

> No payment may be made under this title with respect to any item or service ... furnished ... by an individual or entity during the period when such individual or entity is excluded pursuant to section 1320a–7, 1320a–7a, 1320c–5, or 1395u(j)(2) of this title from participation in the program under this subchapter. [3]

Id. § 1395y(e)(1)(A). The Defendants suggest that this provision banning payment to providers who violate the Anti–Kickback Statute is meant to cover only the period that these providers are actually excluded from participating in the Medicare program. In other words, the payment ban would not include the period before providers formally are excluded but during which they are engaged in conduct in violation of the Anti–Kickback Statute. To the extent that the Provider Agreement makes compliance with the Anti–Kickback Statute a precondition of payment, and not just participation, *see Amgen,* 707 F.Supp.2d at 136 n. 4, it therefore goes beyond what the Medicare statutes intended.

***9** The Defendants reach this interpretation of 42 U.S.C. § 1395y(e)(1)(A) by contrasting it to *id.* § 1395nn(g)(1), which prohibits payment for "a designated health service which is provided in violation of [the Stark Act]," and to *id.* § 1395nn (a)(1)(B), which prohibits submission of a claim for a service furnished in violation of the Stark Act. The Defendants argue that these subsections of 42 U.S.C. § 1395nn demonstrate that, had Congress intended to ban payment of a claim made in violation of the Anti–Kickback Statute, it could have done so as it did with respect to the Stark Act. Instead, Congress elected not to condition Medicare payment on Anti–Kickback Statute compliance, unless and until the provider has been excluded from participation for an Anti–Kickback Statute violation. *See* Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 7.

The Defendants' argument amounts to an "absurdity." *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.,* 565 F.Supp.2d 153, 159 (D.D.C.2008) (noting that to hold that compliance with the Anti–Kickback Statute is *not* a precondition of Medicare payment would result in the government funding illegal kickbacks). Preservation of the public fisc would be undermined if a provider could engage in conduct warranting exclusion from the program altogether yet still demand payment until the time of formal exclusion. *See United States ex rel. Willis v. United Health Grp., Inc.,* No. 10–2747, 2011 WL 2573380, at *15 (3d Cir. June 30, 2011); *United States v. Rogan,* 517 F.3d 449, 452 (7th Cir.2008); *cf. Amgen,* 2011 WL 2937420, at *6 (rejecting the Defendants' position that a distinction between conditions of Medicaid payment and conditions of Medicaid participation is relevant where providers, in signing forms akin to the Provider Agreement at issue here, have represented their compliance with the Anti–Kickback Statute). Congress cannot have intended that those brazen enough to violate the Anti–Kickback Statute (thereby risking criminal penalties), yet clever enough not to be caught (thereby avoiding exclusion from participation), would have their claims for Medicare payment paid with government funds. *See United States ex rel. Bidani v. Lewis,* 264 F.Supp.2d 612, 615 (N.D.Ill.2003) (holding that to reimburse a claimant "for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place .... would put the government in the position of funding illegal kickbacks after the fact"). Not only would this run counter to public policy, but also it would belie commonsense. *See* U.S. Br. Statement Interest INN & ASD's Mot. Partial J. Pleadings 10–11. The Defendants have failed to identify how or why Anti–Kickback Statute compliance as an implied precondition of payment is contrary to the Medicare statutes.

Similar to their argument with respect to the Medicare statutes, the Defendants next argue that to deem compliance with the Anti–Kickback Statute a precondition of Medicare payment would be to directly contravene the Medicare regulations. *See* Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 7–9. The Secretary of HHS has promulgated regulations governing Medicare participation and payment for health care providers, including the contents of the Provider Agreement. Under 42 C.F.R. § 424.510(d)(3), when a provider signs the Provider Agreement, he or she "attests that the information submitted is accurate and that [he or she] is aware of, and abides by, all applicable statutes, regulations, and program instructions." The Defendants do not contest the validity of this regulation, but rather note the conspicuous absence of any mention of the Anti–Kickback Statute within it. *See* Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 8. It is difficult to see, however, how this regulation could be read not to include the Anti–Kickback Statute. The regulation states that a provider who signs the Provider Agreement is certifying that he is in compliance with "*all* applicable statutes." 42 C.F.R. § 424.510(d)(3) (emphasis added). Certainly, the Anti–Kickback Statute is "applicable" to Medicare. *See Shaw,* 106 F.Supp.2d at 110 (stating that the purpose of the Anti–Kickback Statute "was to address the 'disturbing degree [of] fraudulent and abusive practices associated with the provision of health services financed by the medicare and medicaid programs' " (quoting H.R.Rep. No. 95–393, pt. 2, at 44 (1977), *reprinted in* 1977

U.S.C.C.A.N. 3039, 3047)). This is true even if "enforcement of the anti-kickback statute cannot be said to be the central purpose of the Medicare program." *Amgen*, 707 F.Supp.2d at 138. Indeed, Medicare regulations specifically name the Anti–Kickback Statute as a statute that is "designed to prevent or ameliorate fraud, waste, and abuse." 42 C .F.R. § 422.504(h); *id.* § 423.505(h). The broad language of 42 C .F.R. § 424.510(d)(3) does not foreclose—and in fact manifestly permits—the Secretary's decision to require providers to certify their compliance with the Anti–Kickback Statute in signing the Provider Agreement.

***10** Additional regulatory support for Anti–Kickback Statute compliance as a precondition of payment can be found in 42 C.F.R. § 424.516(a)(1), which states that "CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, ... [c] ompliance with title XVIII of the [Social Security] Act and applicable Medicare regulations." When the Anti–Kickback Statute was enacted in 1972, it was in fact part of Title XVIII of the Social Security Act. *See* Pub.L. No. 92–603, 86 Stat. 1419 (1972). Although it later was redesignated to a new section, Title XI, *see* Pub.L. No. 100–93, § 4(d), 101 Stat. 680, 688–89 (1989), Congress' intent in doing so was to "broaden" "[t]he scope of these [kickback, bribe, and false statements] provisions ... to encompass offenses against" other federal entitlement programs, in addition to Medicare. S.Rep. No. 100–109 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 698. There is no indication that Congress meant for 42 C.F.R. § 424.516(a)(1) to be read to exclude a reference to the Anti–Kickback Statute.

Turning to the language of the Anti–Kickback Statute itself, the Defendants argue that "Congress's recent amendment to the [statute] has laid to rest any argument that federal law (including Medicare statutes, regulations or other Medicare provisions) conditions Medicare payments upon [Anti–Kickback Statute] compliance." Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 9. On March 23, 2010, Congress amended the Anti–Kickback Statute to state 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 False Claims Act].

Patient Protection and Affordable Care Act ("the PPACA"), Pub.L. No. 111–148, § 6402(f), 124 Stat. 119, 759 (2010), *adding* 42 U.S.C. § 1320a–7b(g). [4] The Defendants contend that, prior to this amendment, Congress had not linked "illegal remuneration" under the Anti–Kickback Statute to making a "false claim" for payment under the False Claims Act. Because it is the first time that the Anti–Kickback Statute expressly has incorporated the False Claims Act, the Defendants view it as a "substantive alteration" of the law. *See* Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 10 (citing *Liquilux Gas Corp. v. Martin Gas Sales*, 979 F.2d 887 (1st Cir.1992)).

In *Liquilux Gas*, the First Circuit looked to various factors in distinguishing an "alteration" from a "clarification": whether it fits within the existing language of the statute; whether it clarifies an ambiguity and, if so, whether it follows fast upon the ambiguity's discovery; whether it affirms an administrative agency's interpretation; and whether it declares the statute's original intent. *Id.* at 890. Here, the Defendants are correct that the PPACA did not purport to clarify an existing section of the Anti–Kickback Statute. Nor was it included alongside other penalties, but rather as its own new subsection.

***11** The amendment's legislative history, however, evinces Congress' intent to clarify, not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act. Senator Ted Kaufman stated that the PPACA's purpose was to "ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves" and to "strengthen [ ] whistleblower actions based on medical care kickbacks" "[b]y making all claims that stem from an illegal kickback subject to the False Claims Act." 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (Sen.Kaufman). The Senator identified the specific impetus for the amendment as (1) "remed[ying]" a then-recent district court decision that had "defeat [ed] legitimate [False Claims Act] enforcement efforts," and (2) adopting the "success[ful]" position that the Department of Justice consistently has advanced in "pursuing False Claims Act matters based on underlying violations of the Anti–Kickback Statute." *Id.* (Sen.Kaufman). Because the intent of Congress is to be culled from the events surrounding the passage of the PPACA, *see Securities & Exch. Comm'n v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 199–200, 84 S.Ct. 275, 11 L.Ed.2d 237 (1963), Senator Kaufman's comments, made in advance of the PPACA being signed into law, reliably suggest that the amendment was intended not to create a new basis for liability but to clarify the reach of the Anti–Kickback Statute, which had been called into question by recent litigation. [5] *See also Willis*, 2011 WL 2573380, at *13

n. 19 (using the word "clarify" to describe the effect of this recent amendment to the Anti–Kickback Statute).

The Relator, along with the United States, correctly suggests that the conclusion that compliance is precondition of payment is "rendered inescapable when the purpose of the [Anti–Kickback Statute] is considered within the context of the Medicare statute." U.S. Br. Statement Interest INN & ASD's Mot. Partial J. Pleadings 5. Medicare, facing literally millions of claims per day, *see id.* at 6 n. 4, relies on providers to seek payment only on items or services "reasonable and necessary for the diagnosis or treatment of illness or injury," 42 U.S.C. § 1395y(a)(1)(A). Kickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole. The Anti–Kickback Statute is intended not only to prohibit but also to prevent such fraudulent conduct. *See United States v. Kruse*, 101 F.Supp.2d 410, 413 (E.D.Va.2000) (stating that the Anti–Kickback Statute's "legislative history also suggests a deterrent, and thus punitive, purpose"); H.R.Rep. No. 95–393, pt. 2, at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3040, 3047, 3050 (stating that the Anti–Kickback Statute was enacted to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the medicare and medicaid programs"). If providers could demand payment for claims resulting from kickback violations, then the Anti–Kickback Statute would be meaningless legislation.

***12** Moreover, courts, without exception, agree that compliance with the Anti–Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the Anti–Kickback Statute. *See, e.g.*, *Willis*, 2011 WL 2573380, at *15 ("Compliance with the [Anti–Kickback Statute] is clearly a condition of payment under Parts C and D of Medicare and appellees do not refer us to any judicial precedent holding otherwise. In fact, the precedents hold the opposite."); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir.2009) ("Falsely certifying compliance with the ... Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the [False Claims Act]."); *Pogue*, 565 F.Supp.2d at 159 ("Legion other cases have held violations of [the Anti–Kickback Statute] ... can be pursued under the [False Claims Act], since they would influence the Government's decision of whether to reimburse Medicare claims."); *Rogan*, 517 F.3d at 452 (rejecting the argument that a kickback was immaterial to the validity of Medicare and Medicaid claims); *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir.2005) ("[C]ompliance with federal health care laws, including the [Anti–Kickback] Statute, is a condition of payment by the Medicare program."); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir.2004) ("A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program."); *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F.Supp.2d 8, 13 n. 5 (D.D.C.2003) (holding that "[c]ompliance with [the Anti–Kickback Statute] is a condition for reimbursement under Medicare"); *United States v. Ruttenberg*, 625 F.2d 173, 177 n. 9 (7th Cir.1980) (stating that Congress need not "have spelled out duties, beyond the duty of avoiding receipt and payment of kickbacks"); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F.Supp.2d 112, 127 (D.Mass.2011) (Stearns, J.) ("The court agrees that in the case of the [Anti–Kickback Statute], compliance is not merely a condition of participation in federal health care programs, but is also material to the government's decision to pay any claim resulting from a kickback."); *United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, No. 1:03–CV–00167, 2008 WL 5282139, at *12 (S.D.Ohio Dec.18, 2008) ("The claims at issue in this case ... involve certification of compliance with the Anti–Kickback Statute, a condition of government payment."); *United States ex rel. Thomas v. Bailey*, No. 4:06CV00465 JLH, 2008 WL 4853630, at *8 (E.D.Ark. Nov.6, 2008) ("[C]ase law supports the proposition that compliance with the Anti–Kickback Statute is a condition of payment under [the federal health care programs, including Medicare]."); *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d 12, 18 (D.Mass.2007) (Saris, J.) ("[T]he Medicare program requires providers to affirmatively certify that they have complied with the Anti–Kickback Statute; failure to comply with the kickback laws, therefore, is, in and of itself, a false statement to the government."); *United States ex rel. Smith v. Yale Univ.*, 415 F.Supp.2d 58, 91 (D.Conn.2006) ("Medicare Regulations and the CMS [Provider Agreement] expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement and as a condition to governmental payment, providers must certify that they are in compliance with the terms on the [Provider Agreement]."); *Bidani*, 264 F.Supp.2d at 615–16 (finding a violation of the Anti–Kickback Statute "material to the government's treatment of claims for reimbursement" and that to find otherwise, "would put the government in the position of funding illegal kickbacks after the fact"); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F.Supp.2d 35, 43 (D.Mass.2000) (O'Toole, J.) (holding

that alleged violations of the Anti–Kickback Statute were sufficient to state a claim under the False Claims Act, despite no express certification of compliance with applicable law); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F.Supp.2d 1017, 1047 (S.D.Tex.1998) ("[E]xplicit certifications of compliance with relevant healthcare laws and regulations ... provided evidence that the government conditioned its approval, payment and Defendants' retention of payment funds on those certifications.").

***13** The Defendants argue that none of these courts reached the "issue of first impression" whether the requirement of Anti–Kickback Statute compliance contained in the Provider Agreement's certification "represents a lawful exercise of CMS' administrative authority." Joint Reply Mem. Supp. Defs.' Mot. Partial J. Pleadings 1. Yet, even if no court explicitly undertook the analysis that the Defendants ask this Court to undertake today, it is difficult to imagine these judges all reaching the same conclusion if that conclusion were somehow contrary to the Medicare statutes and regulations. More importantly, the Defendants have cited no case reaching the opposite conclusion. This Court declines to deviate from well-established precedent that a provider must be in compliance with the Anti–Kickback Statute to seek and receive payment for a Medicare claim.

Courts appear to have reached the conclusion that compliance with the Anti–Kickback Statute is a precondition of payment because, quite simply, kickbacks affect the government's decision to pay. *See, e.g., Rogan*, 517 F.3d at 452 ("[I]nformation that a hospital has purchased patients by paying kickbacks has a good probability of affecting the [government's] decision [to reimburse]."); *Pogue*, 238 F.Supp.2d at 264 ("Certification of compliance with the statute or regulation alleged to be violated must be so important to the contract that the government would not have honored the claim presented to it if it were aware of the violation."); *see also Lisitza*, 765 F.Supp.2d at 127. This reasoning is consistent with the First Circuit's focus on reading a materiality requirement into the False Claims Act as a limitation on the phrase "false or fraudulent," rather than inquiring into the source of a particular precondition of payment. *See Blackstone Med.*, 647 F.3d at 388 (citing *Loughren*, 613 F.3d at 306–07). Liability for the submission of a false claim can arise only where compliance with a precondition of payment is material, that is, capable of influencing the government's decision to pay. *See Amgen*, 2011 WL 2937420, at *6; *see also United States ex rel. Bierman v. Orthofix Int'l, N.V.*, 748 F.Supp.2d 123, 128 (D.Mass.2010) (Harrington, J.).

Here, compliance with the Anti–Kickback Statute clearly factors into the government's reimbursement decision; not only is the government unwilling to pay a claim that is the product of criminal conduct under the Anti–Kickback Statute, but also to submit such a claim for reimbursement is in effect to ask the government to fund criminality retroactively, a result specifically proscribed by the Anti–Kickback Statute. *See* 42 U.S.C. § 1320a–7b(b). "[T]he Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." *Willis*, 2011 WL 2573380, at *15; *see Rogan*, 517 F.3d at 452 ("The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers; the False Claims Act does this by insisting that persons who send bills to the Treasury tell the truth."). The fact that the Provider Agreement identifies compliance with the Anti–Kickback Statute as a "requirement[ ] that the provider must meet and maintain in order to bill the Medicare program," *see* Provider Agreement, is "dispositive evidence" of its materiality. *Blackstone Med.*, 647 F.3d at 394. Yet, even if the Provider Agreement did not identify compliance with the Anti–Kickback Statute as a precondition of payment, this materiality analysis strongly suggests that, because the government will not pay kickback-tainted claims, Anti–Kickback Statute compliance must be a precondition of payment. *See id.* ("If kickbacks affected the transaction underlying a claim, ... the claim failed to meet a condition of payment.")

2. Legal Validity of CMS's Procedure and Authority for Adopting the Provider Agreement

***14** **7** The Defendants next contend that, even if Anti–Kickback Statute compliance as a payment precondition is not at odds with the Medicare statutes and regulations or the language of the Anti–Kickback Statute itself, the adoption of the Provider Agreement was procedurally flawed and undertaken without proper agency authority. Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 10–19. The Defendants acknowledge that, in adopting the Provider Agreement, CMS had to comply only with the Paperwork Reduction Act ("the PRA") and did so, yet they argue that the agency's procedure for including the certification of Anti–Kickback Statute compliance in the Provider Agreement "cast a heavy cloud over its purported administrative interpretation that Medicare conditions payment on [Anti–Kickback Statute] compliance." *Id.* at 14.

In making this argument, the Defendants recite the history of the creation of the Provider Agreement, which the Relator does not dispute. In February 2001, in accordance with the PRA, CMS published notice of revisions to the Provider Agreement, which included the addition of the certification. Agency Information Collection Activities: Proposed Collection; Comment Request, 66 Fed.Reg. 8807 (Feb. 2, 2001); Decl. James M. Becker ("Becker Decl."), Ex. 5 ("Supporting Statement for Paperwork Reduction Act Submissions"), ECF No. 369–5. In July 2001, also in accordance with the PRA, CMS submitted the revised form to the Office of Management and Budget ("OMB") for approval. [6] *See* Becker Decl., Exs. 6a–6b ("Medicare Federal Health Care Provider/Supplier Enrollment Application I"), ECF Nos. 369–6, 369–7. In September 2001, OMB approved the revised Provider Agreement, but "under the firm condition that in the next few months, [it is] republished and opened for public comment along with the proposed rules governing provider enrollment .... [because] it would have been most beneficial to initially release [the Provider Agreement] with [the] proposed rule[s] so that the public could review all of CMS' enrollment policies as a comprehensive package." Becker Decl., Ex. 3 ("Notice of Office of Management and Budget Action I"), ECF No. 369–3. Thus, although CMS had complied with the PRA with respect to developing the Provider Agreement, OMB gave it only conditional approval because CMS had yet to engage in Medicare enrollment rulemaking pursuant to the Administrative Procedure Act ("the APA"), and these rules would "have implications for the burden and practical utility of [the Provider Agreement]." *Id.*

In 2003, in accordance with OMB's mandate, CMS published its proposed rules, along with the Provider Agreement. Medicare Program; Requirements for Establishing and Maintaining Medicare Billing Privileges, 68 Fed.Reg. 22064 (Apr. 25, 2003). CMS explained that its proposed rules "would require that all providers and suppliers ... complete an enrollment form and submit specified information to us, and periodically update and certify to the accuracy of the enrollment information, to receive and maintain billing privileges in the Medicare program." *Id.* at 22064. This time, however, the Provider Agreement did not contain the reference to compliance with the Anti–Kickback Statute within the certification clause. Rather, it stated simply:

> ***15** I agree to abide by the Medicare laws, regulations and program instructions that apply to me. The Medicare laws, regulations and program instructions are available through the Medicare contractor. [7]

Becker Decl., Exs. 7a–7c ("Medicare Federal Health Care Provider/Supplier Enrollment Application II"), ECF Nos. 369–8 to 369–10; *see* 68 Fed.Reg. at 22075. CMS explained that the form had been changed "to provide a better understanding of Medicare policy." 68 Fed.Reg. at 22074.

After receiving comments and republishing the enrollment application in July 2005, *see* Agency Information Collection Activities: Proposed Collection; Comment Request, 70 Fed.Reg. 39513 (July 8, 2005), CMS issued its final enrollment rules in April 2006, *see* Medicare Program; Requirements for Providers and Suppliers To Establish and Maintain Medicare Enrollment, 71 Fed.Reg. 20754 (Apr. 21, 2006). The rules added 42 C.F.R. § 424.510(d)(3), which states that a provider, in signing the certification clause of the Provider Agreement, attests to his compliance with "all applicable statutes, regulations, and program instructions." This time the full certification was again included in the form; in other words, CMS reverted back to the 2001 version, which explicitly refers to the Anti–Kickback Statute. 71 Fed.Reg. at 20764. In so doing, CMS indicated that it had "considered" "comments regarding the provider/supplier enrollment applications that were published in 2001." *Id.* OMB thereafter approved the final rules and the revised Provider Agreement. Becker Decl., Ex. 8 ("Notice of Office of Management and Budget Action II"), ECF No. 369–11.

The Defendants argue that this amounts to a "checkered procedural history" because the only version of the Provider Agreement ever published in the Federal Register was the 2003 version that did not contain the certification of Anti–Kickback Statute compliance. Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 16. This is an inaccurate statement. In July 2005, in accordance with the PRA, CMS published in the Federal Register a "proposed collection[ ]" of information, inviting public comments on the Provider Agreement and including an online link to it. 70 Fed.Reg. at 39513. Not only did this satisfy the PRA, which even the Defendants concede is the applicable statute for publication of the Provider Agreement, but also it provided notice and an opportunity for comments under the more stringent, but ultimately inapplicable, requirements of the APA. [8] Even though CMS, in its final publication of the form, did not specify what led it to revert back to the 2001 version, " 'notice' provisions are neither invariably nor primarily designed to afford exhaustive disclosure, but to alert interested parties that their substantive rights may be

affected" by the rule change. *Visiting Nurse Ass'n of North Shore, Inc. v. Bullen*, 93 F.3d 997, 1010 (1st Cir.1996), *overruled on different grounds by Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50, 57 (1st Cir.2004); *see Natural Res. Def. Council, Inc. v. United States Envtl. Prot. Agency*, 824 F.2d 1258, 1283 (1st Cir.1987) (holding that even substantial changes to a proposed rule are allowed, so long as they keep with the character of the original scheme and extend logically from the notice and comment period); *Athens Cmty. Hosp. v. Heckler*, 565 F.Supp. 695, 699 (E.D.Tenn.1983) ("The Secretary [of HHS] need not respond to all specific issues raised in comments on [a] proposed rule."). Because the Provider Agreement was properly enacted, the Court rejects the Defendants' argument that it is procedurally infirm.

***16** Finally, the Defendants argue that CMS lacked authority under the Medicare statutes and regulations to adopt the Provider Agreement and that, accordingly, the form is not entitled to deference by this Court. Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 12–13. Each time CMS published the Provider Agreement pursuant to the PRA, it included a statement of its "[s]pecific [a]uthority to [c]ollect [e]nrollment [i]nformation." *See, e.g.*, 68 Fed.Reg. 22064. The most relevant statutory provision identified reads:

> The Secretary shall periodically determine the amount which should be paid under this part to each provider of services ... except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such providers under this part for the period with respect to which the amounts are being paid or any prior period.

42 U.S.C. § 1395g(a); *see id.* § 1395l(e) ("No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."). The Defendants argue that this provision "is not a license for CMS to create payment conditions in addition to ones established by Congress." Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 13.

The First Circuit has interpreted 42 U.S.C. § 1395g(a) to "grant[ ] the Secretary broad discretion ... in determining what information is required from providers *as a condition of payment*." *Visiting Nurse Ass'n Gregoria Auffant, Inc. v. Thompson*, 447 F.3d 68, 77 (1st Cir.2006) (emphasis added). This clearly supports the validity of CMS's inclusion of the Anti–Kickback Statute certification in the Provider Agreement "as a condition of payment." The Defendants, however, argue that this First Circuit precedent is inapposite because the court was interpreting a precondition of payment expressly stated in 42 U.S.C. § 1395f(b)(1)(A) regarding reimbursement only for "the reasonable cost" of Medicare services. *See* Joint Reply Mem. Supp. Defs.' Mot. Partial J. Pleadings 4. While the Defendants are correct that the *Visting Nurse Association Gregoria Auffant* court was interpreting an express precondition, here compliance with the Anti–Kickback Statute is an implied but nonetheless definitive precondition of government payment. To hold that the Secretary cannot require information from providers with respect to this firmly established precondition would be to undercut his "broad discretion as to what information to require as a condition of payment to providers under the Medicare program." *Community Hosp. of Monterey Peninsula v. Thompson*, 323 F.3d 782, 790 (9th Cir.2003). "Since 'Congress has explicitly left [this] gap for the agency to fill,' any regulation regarding the issue must be 'given controlling weight unless [it is] arbitrary, capricious, or manifestly contrary to the statute," which it is not. *Id.* (quoting *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–44, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984)). CMS has not exceeded its authority under 42 U.S.C. § 1395g(a) by requiring providers to certify their compliance with the Anti–Kickback Statute as a precondition of Medicare payment. [9]

***17** Furthermore, the Provider Agreement is a valid agency interpretation of its own regulation 42 C.F.R. § 424.510(d)(3), which states that, when a provider signs the Provider Agreement, he or she "attests that the information submitted is accurate and that the provider ... is aware of, and abides by, all applicable statutes, regulations, and program instructions." "Where Congress has entrusted rulemaking and administrative authority to an agency, courts normally accord the agency particular deference in respect to the interpretation of regulations promulgated under that authority." *South Shore Hosp., Inc. v. Thompson*, 308 F.3d 91, 97 (1st Cir.2002). "[S]o long as it is 'reasonable,' that is, so long as the interpretation 'sensibly conforms to the purpose and wording of the regulations,' " courts should give effect to the meaning that an agency has attached to its own regulation. *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 150–51, 111 S.Ct. 1171, 113 L.Ed.2d 117 (1991) (internal citations omitted). Here, CMS reasonably interpreted 42

C.F.R. § 424.510(d)(3), specifically its phrase "abides by ... all applicable statutes," to include compliance with the Anti–Kickback Statute, such that providers may be required to certify their compliance to seek Medicare reimbursement. In the absence of any plain error or inconsistency with the Medicare statutes or regulations, *see South Shore Hosp.*, 308 F.3d at 97, the Court defers to this reasonable interpretation of the agency's own regulation, which itself properly was enacted pursuant to the Secretary's statutorily-granted authority to administer the Medicare program.

Although the Defendants attempt to style their motion as raising novel issues of law, this Court follows the well-established holding of numerous other circuit and district courts that compliance with the Anti–Kickback Statute is a precondition of Medicare payment, even if not expressly stated in the Medicare statutes and regulations or the Anti–Kickback Statute itself. The Provider Agreement, which requires providers to certify their compliance with the Anti–Kickback Statute, was adopted in accordance with the PRA and represents a valid exercise of CMS's regulatory authority entitled to judicial deference. Its certification clause is consistent with the Medicare statutes and regulations as well as the purpose of the Anti–Kickback Statute. The Defendants' Motion for Judgment on the Pleadings is denied.

III. CROSS–MOTIONS FOR PARTIAL SUMMARY JUDGMENT ON COUNT IV OF RELATOR'S FOURTH AMENDED COMPLAINT

A. Facts in the Light Most Favorable to Amgen [10]

Amgen manufactures biologics, including Aranesp and the related drug EPOGEN. Amgen's Resp. Relator's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. ("Amgen's Resp. SOF") ¶ 1, ECF No. 430. In 1985, Amgen entered into a Product License Agreement with Ortho Pharmaceutical Corporation ("Ortho"), a subsidiary of Johnson & Johnson, by which Amgen gained the exclusive right to market EPO (under the name "EPOGEN") in the United States for use with dialysis patients and Ortho gained the exclusive right to market EPO (under the name "Procrit") in the United States for all other uses, including with cancer patients. *Id.* ¶ 5. Amgen, however, could market Aranesp in the United States for non-dialysis uses. *Id.* ¶ 6. In 2001, the Food and Drug Administration ("FDA") approved Aranesp for use in the United States for treatment of anemia associated with chronic renal failure. *Id.* ¶ 7. In 2002, the FDA approved its use for chemotherapy-induced anemia in patients with nonmyeloid malignancies. *Id.* Between 2001 and 2010, Amgen's worldwide revenues from Aranesp totaled more than $23,700,000,000. *Id.* ¶ 4.

***18** Aranesp is sold in single dose vials. *Id.* ¶ 8. A medical provider may use a single dose vial for multiple doses to multiple patients as long as the vial contents are used within the prescribed period. *Id.* "Overfill" is the amount of liquid in excess of the volume indicated on a drug's label necessary to provide a high degree of assurance that even a self-administering patient consistently can withdraw and administer the full labeled dose of a drug despite the numerous variables and factors that affect the fill volume of a vial and the amount that can be withdrawn and administered. *Id.* ¶ 9; Amgen's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. ("Amgen's SOF") ¶ ¶ 14–17, 19, ECF No. 378. The purpose of overfill is not only to allow a medical provider to administer the labeled dosage amount of a drug, but also to allow for even the unskilled self-administering patient consistently to withdraw and administer the labeled dosage and to account for filling variability. *Id.* ¶ 19; Amgen's Resp. SOF ¶ 9. The amount of the drug that cannot be administered because it sticks to the vial or needle, known as "hold up volume," varies depending on the skill of the person administering it. Amgen's SOF ¶¶ 21–22.

The FDA has authority to regulate overfill and set limits on its amount. *Id.* ¶ 1. The amount of overfill should be sufficient to ensure the total amount of drug in a vial meets the standards, tests, assays, and other specifications set forth in the United States Pharmacopeia ("USP") compendia. *Id.* ¶¶ 2, 3. For "informational" purposes only, the USP recommends overfill of 0.10 mL for a vial of 1.0 mL. *Id.* ¶¶ 48–50; Amgen's Resp. SOF ¶ 10. Aside from the volume of the syringe and the size of the needle, however, USP and FDA standards do not impose requirements on manufacturers when determining a drug's appropriate target fill, including overfill, in a vial. Amgen's SOF ¶¶ 8–9. The FDA does require manufacturers to report the amount of overfill as part of the Biologic License Application ("BLA") process for a drug and to provide the rationale for that amount. *Id.* ¶¶ 10–11. The FDA evaluates only whether the manufacturer's proposed amount of overfill is scientifically justified. *Id.* ¶ 24. An amount of overfill is considered scientifically unjustified if it would jeopardize patients' health by risking the delivery of either too little or too much of the drug. *Id.* ¶¶ 25–26. The FDA will not approve a drug's BLA if it has concerns about the drug's overfill amount. *Id.* ¶ 31.

Because overfill falls within the regulatory authority of the FDA, CMS has no policy concerning the proper amount of

overfill. *Id.* ¶ 58. Through 2010, CMS never denied a claim for Medicare reimbursement because the claim included the amount of overfill included in a drug's vial. *Id.* ¶ 60. In November 2010, CMS issued a new final rule prohibiting providers from seeking reimbursement for overfill effective January 1, 2011. *Id.* ¶ 61. CMS continued to pay claims including overfill for the months of November and December 2010. *Id.* ¶ 62. The new rule does not restrict providers' use or administration of overfill. *Id.* ¶ 64.

***19** At the time that Amgen submitted its BLA for Aranesp to the FDA in 1999, the drug's proposed target fill volume was 1.168 mL +/0.040 mL. *Id.* ¶ 34. In 2000 and 2001, Amgen produced a limited number of vials of Aranesp with a target fill volume of 1.190 +/0.040 mL, meaning they had a target overfill of 19.0%. *Id.* ¶¶ 37, 41. Less than a month after approval by the FDA, however, Amgen reduced the target fill volume for Aranesp back to 1.168 mL.[11] *Id.* ¶ 41. The FDA approved both the brief increase in target fill volume and the reduction back to the original amount as "acceptable and adequately reported."[12] *Id.* ¶¶ 12–13, 40, 42; Amgen's Resp. SOF ¶ 12. In 2008, Amgen reduced the overfill in Aranesp vials to 14.3%. Amgen's SOF ¶ 45.

On January 1, 2005, Medicare began reimbursing Aranesp claims on the basis of the ASP that Amgen reported to CMS every quarter. Amgen's Resp. SOF ¶ 33. Amgen did not account for overfill in calculating Aranesp's ASP. *Id.* ¶ 39. Amgen's Rule 30(b)(6) designee for pricing policy declared under oath that he "believed at the time of submission, and believe[s] now, that all ASP reports for Aranesp have been accurate when they did not treat overfill as an adjustment for ASP reporting items. As a result, [he] believe[s] Amgen's quarterly submissions to CMS for Aranesp properly did not take overfill into account when calculating and reporting ASP and in submitting the ASP-related data." Decl. William Dunn Supp. Opp'n Relator's Mot. Partial Summ. J. Amgen, Ex. 37 (Declaration of Fred Manak, Jr.) ("Manak Decl.") ¶¶ 9, 10, ECF No. 433–37.

In 2005, the Office of the Inspector General ("OIG") conducted an audit of Amgen's ASP calculation for Aranesp. Amgen's Resp. SOF ¶ 41. Amgen discussed with OIG its ASP process and the data components that factored into the calculation. *Id.* OIG requested and received documents containing Amgen's written methodology, assumptions, and underlying data. *Id.* OIG concluded that "[o]verall, Amgen's ASP calculation methodology for Aranesp complied with federal requirements."[13] Decl. Kirsten Mayer Supp. Amgen's Mot. Partial Summ. J., Ex. 28 ("2007 OIG Audit"), ECF No. 381–28.

Because it was captured in an email, Amgen does not dispute that its senior finance manager once remarked to other Amgen employees that "overfill rates are a type of hidden discount to customers." Amgen's Resp. SOF ¶ 30. Amgen, however, did not instruct its sales representatives to market overfill or to discuss the amount of overfill in Aranesp vials with customers. *Id.* ¶ 15. Amgen did not instruct its sales representatives to discuss with customers how to draw up and administer overfill. *Id.* ¶ 21. Nor did Amgen direct INN, with which Amgen entered into a GPO Agreement in September 2003, to promote overfill in Aranesp vials to customers.[14] *Id.* ¶¶ 2, 16. Numerous providers who have testified in this case, however, have stated their belief that seeking Medicare reimbursement for overfill was entirely lawful and a common practice in the nephrology industry. Amgen's SOF ¶¶ 72–73.

B. Facts in the Light Most Favorable to the Relator

***20** Amgen is the manufacturer of Aranesp. Relator's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. Amgen ("Relator's SOF Amgen") ¶ 1, ECF No. 389. The FDA has approved the use of Aranesp for treatment of anemia associated with chronic renal failure and of chemotherapy-induced anemia. *Id.* ¶ 6–7. Aranesp is sold in single-dose vials and single-dose pre-filled syringes. *Id.* ¶ 8.

Overfill is drug product contained in vials of injectable drugs in excess of the labeled dosage. *Id.* ¶ 9. The FDA has the authority to regulate overfill and set limits as to the amount, but the FDA has not set a specific level of generally permissible overfill. Relator's Resp. Amgen's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. ("Relator's Resp. SOF Amgen") ¶ 1, ECF No. 432. FDA regulations and USP compendia require that the amount of overfill be in sufficient excess of the labeled volume to permit withdrawal and administration of the labeled amount. *Id.* ¶¶ 2, 6; Relator's SOF Amgen ¶ 9. Since 2001, the USP has recommended a target overfill of 10%. Relator's SOF Amgen ¶ 10. The only legitimate purpose of overfill is to guarantee that a health care provider can administer the labeled dosage amount. *Id.* ¶ 9.

The FDA requires manufacturers to disclose the amount of a drug's target overfill as part of the BLA process. Relator's Resp. SOF Amgen ¶¶ 10, 30. There is no requirement, however, that manufacturers disclose the rationale behind target overfill levels. *Id.* ¶ 11. The FDA will not approve a drug's BLA if it has concerns about the amount of target

overfill in a drug. *Id.* ¶ 31. The FDA has taken further action in cases where it has had concern that a drug included a potentially excessive amount of overfill. *Id.* ¶ 32. Drug manufacturers that fail to comply with USP tests can be found liable under the Food, Drug, and Cosmetic Act ("FDCA") for selling misbranded or adulterated drugs. *Id.* ¶ 4.

Amgen used the drug Kineret, which had different physical properties than Aranesp, to set target fill volume for Aranesp. *Id.* ¶¶ 13, 37. Amgen's reliance on Kineret, instead of Aranesp, for Aranesp fill testing was not disclosed to the FDA. *Id* . ¶ 37. After the failure of the Kineret "conformance lot" between 1999 and 2000, Amgen introduced a new formula for setting target overfill volumes that took additional variables into account. *Id.* These variables included the "hold-up volume of the syringe," the "vial hold-up volume," and the "process variability." *Id.* ¶ 15. There is no scientific rationale, however, that can be applied to determine how to account for the range of sophistication of who will administer the drug (i.e., a medical provider or unskilled, self-administering patient). *Id.* ¶¶ 16, 18. Amgen did not making any provision for the range of sophistication among providers in setting Aranesp's target overfill. *Id.* ¶¶ 16, 21.

***21** Aranesp's overfill was increased from 16.8% to 19.0% in November 2000. *Id.* ¶ 38. At that time, Amgen's BLA for Aranesp was pending, but Agmen did not notify the FDA of the proposed change in relation to the Aranesp BLA. *Id.* Amgen's manufacturing expert testified that he "would have filed it, personally, to the BLA." *Id.* Amgen notified the FDA only after it had already increased the target overfill to 19.0%. *Id.* ¶ 40. Amgen manufactured a limited number of lots at this target overfill volume in 2000 and 2001 before implementing a reduction back to 16.8% target overfill. *Id.* ¶ 41. The FDA approved this 16.8% amount and neither raised an issue with respect to Amgen's validation of an appropriate target overfill volume for Aranesp nor expressed concern that Aranesp's overfill was excessive-although, as noted, Amgen did not inform the FDA that it had tested overfill volume using a different drug, Kineret. *Id.* ¶¶ 12, 42. In 2008, Amgen implemented a two-phase process to further decrease Aranesp's overfill: (1) from 16.8% to 14.3%, and (2) from 14.3% to 13.0%. [15] *Id.* ¶ 45. This two-phase process came at the recommendation of Amgen's marketing department and did not reflect a manufacturing reason. *Id.* ¶¶ 16, 21, 45 n. 38.

Amgen did not account for overfill in its ASP calculation for Aranesp. Relator's SOF Amgen ¶ 39. Amgen never informed CMS that it was not accounting for overfill in calculating Aranesp's ASP. Relator's Resp. SOF Amgen ¶ 171. Amgen similarly did not disclose its exclusion of overfill from Aranesp's ASP calculation when OIG audited it in 2005. *Id.* ¶ 175. The objective of OIG's audit was to "determine whether Amgen's ASP calculation methodology for Aranesp complied with Federal requirements and guidance." *Id.* ¶ 174. OIG's Rule 30(b)(6) witness testified that overfill was "not an issue discussed by either side during the context of that audit." Relator's Resp. SOF Amgen, Ex. 2 (Deposition of Nicole Freda) ("Freda Dep.") 214:16–18, ECF No. 432–3. Amgen never received official approval from a government for its exclusion of overfill from Aranesp's ASP calculation. Relator's SOF Amgen ¶ 42.

Acting in concert with INN, Amgen marketed the "economic benefits" of Aranesp's overfill to providers and instructed them to bill Medicare for the overfill amount, in addition to the labeled dosage. *Id.* ¶¶ 15–16. Amgen produced an "Aranesp Profile" that included information about overfill "to be discussed if directly asked." *Id.* ¶ 17. Amgen's sales team was encouraged to push providers to ask about overfill and, when asked, to distribute to them a "standard overfill letter" detailing the amount of overfill in vials of Aranesp. *Id.* ¶¶ 17–18. Amgen and INN developed spreadsheets comparing (1) the reimbursement cost of Aranesp including overfill versus excluding overfill, and (2) the reimbursement cost advantage of Aranesp versus the competitor drug Procrit when overfill was included. *Id.* ¶¶ 20, 29. These spreadsheets were shown to medical providers. *Id.* Amgen's senior finance manager referred to overfill as "a type of hidden discount to customers." *Id.* ¶ 30. In 2004, however, Amgen had been specifically advised by an outside consulting firm it had retained that medical providers should not have been seeking Medicare reimbursement for overfill because Aranesp's price reflected only the labeled dosage. *Id.* ¶¶ 31, 37.

C. Standard of Review

***22** Summary judgment is proper where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). An issue of fact is "genuine" if there exists a sufficient evidentiary basis on which the trier of fact could find for the non-moving party. *Anderson v. Liberty Lobby,* 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A fact is "material" if it will affect the outcome of the case under the applicable law. *Id.* The moving party bears the burden of showing that no genuine issue of material fact exists. *Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). "The evidence of the non-movant is to be believed, and all

justifiable inferences are to be drawn in his favor." *Anderson,* 477 U.S. at 255. Save as to facts admitted by both parties, the court must disregard all evidence—even if unopposed—which the jury is free to reject, i.e., all evidence upon which a party bears the burden of proof. *Reeves,* 530 U.S. at 151. Thus, summary judgment may be granted when a fair-minded jury could reach only one conclusion: in favor of the moving party.

D. Analysis

The Relator argues that overfill is a "free good" with "independent value" to medical providers, such that it reduces the drug's total acquisition cost. Mem. Supp. Relator's Mot. Partial Summ. J. Amgen 5. Because Amgen did not account for overfill as a "price concession" in determining Aranesp's ASP, the Relator claims that Aranesp's ASP is artificially inflated. *Id.* Amgen acknowledges that it did not include overfill in Aranesp's ASP calculation, but asserts that whether overfill is to be included as a factor in determining a drug's ASP is a purely legal question. Mem. Opp'n Relator's Mot. Partial Summ. J. Amgen 1. If, as matter of law, overfill is part of the ASP calculation, then the ASP that Amgen calculated for Aranesp cannot be deemed false or fraudulent.

In simplified terms, a drug's ASP represents the manufacturer's total sales divided by the total number of units of the drug sold in a quarter. 42 U.S.C. § 1395w–3a(c)(1)(A)–(B). Manufacturers are required to "deduct price concessions" from the numerator of this mathematical equation, which include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates. *Id.* § 1395w–3a(c)(3); 42 C.F.R. § 414.804(a)(2)(i). Overfill is not explicitly mentioned in the statute as a type of price concession. Acting in conjunction with OIG, the Secretary of HHS, which houses CMS, has the authority to identify "other price concessions" beyond those already enumerated in the statute, but it has not done so with respect to overfill. 42 U.S.C. § 1395w–3a(c)(3).

The exclusion of overfill as a price concession is, in fact, a conscious choice by CMS. In November 2010, the agency, consistent with its rulemaking authority under 42 U.S.C. § 1395w–3a(c)(5)(C), promulgated its final rule with respect to "[d]etermining the [p]ayment [a]mount for [d]rugs and [b]iologicals [w]hich [i]nclude [i]ntentional [o]verfill." Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed.Reg. 73170, 73466 (Nov. 29, 2010). The final rule definitively concludes that overfill is not included in the ASP calculation and that medical providers may not seek reimbursement for it. It reads, in substantial part:

> ***23** Since [April 1, 2008], [CMS has] become aware of situations where manufacturers, by design, include a small amount of 'intentional overfill' in containers of drugs. We understand this 'intentional overfill' is intended to compensate for loss of product when a dose is prepared and administered properly. For instance, a hypothetical drug is intended to be delivered at a 0.5 mg dose that must be drawn into a syringe from a vial labeled for single use only. The vial is labeled to contain 0.5 mg of product but actually contains 1.5 mg of product. The additional 1.0 mg of product is included, by design, and is intended to be available to the provider so as to ensure a full 0.5 mg dose is administered to the patient.
>
> Our ASP payment calculations are based on data reported to us by manufacturers.... In order to accurately calculate Medicare ASP payment limits under section 1847A of the Act, we interpret "the amount in one item" to be the amount of product in the vial or other container as indicated on the FDA approved label.
>
> It has been longstanding Medicare policy that in order to meet the general requirements for coverage under the "incident to" provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies. Such physicians' services and supplies include drugs and biologicals under section 1861(s)(2)(A) of the Act. In accordance with this policy, providers may only bill for the amount of drug product actually purchased and that the cost of the product must represent an expense to the physician.
>
> We further understand that when a provider purchases a vial or container of product, the provider is purchasing an amount of drug defined by the product packaging or label. Any excess product (that is, overfill) is provided without charge to the provider. In accordance with our current policy as explained above, providers may not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursable, and providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.

> Because such overfill is currently not included in the calculation of payment limits under the methodology in section 1847A of the Act and does not represent an incurred cost to the provider, we proposed to update our regulations at 42 CFR part 414 Subpart K to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We also proposed to update our regulations at Subpart J to clearly state that payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label, will not be made under Medicare....
>
> ***24** Our policy is not intended to limit the use of intentional overfill during the care of beneficiaries or in medical practice; such measures are beyond CMS' authority. Rather, we are clarifying our ASP pricing and payment policies, describing how we utilize manufacturer reported data, and updating our regulations at 42 CFR part 414.

Id. at 73466–67 (internal citations omitted). The regulations themselves now state that "[t]he manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA approved label," 42 C.F.R. § 414.804(a) 6); that "CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label," *id.* § 414.904(a)(3)(i); that "[a]dditional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit," *id.* § 414.904(a)(3)(ii); and that "[n]o payment is made for amounts of product in excess of that reflected on the FDA-approved label," *id.* § 414.904(a)(3)(iii).

In responding to comments to the proposed rule, CMS stated that these additions to the Medicare regulations are clarifications, not policy changes.[16] CMS remarked that "[t]he intent of this proposal is merely to clarify that the Medicare ASP payment limit is based on the amount of drug conspicuously indicated on the FDA label, and that no payment will be made for any intentional overfill included as free drug for the proper preparation of a single therapeutic dose." 75 Fed.Reg. at 73467; *see id.* at 73468 ("[T]he intent of this proposal is to clarify that the ASP payment limit is *currently* based on the amount of drug indicated on the FDA label, and that no payment will be made for any intentional overfill." (emphasis added)); *id.* at 73468–69 ("The intent of this proposal is to clarify that the ASP payment limit is based on the amount of drug clearly identified as the amount on the FDA label and packaging. *We do not intend to change the ASP calculation methodology to include intentional overfill* because of the operational difficulty in accurately identifying the amount of overfill." (emphasis added)); *id.* at 73469 ("Our policy clarifies that we will not pay for intentional overfill.").[17] When asked at deposition whether the new rule represents "a change in payment policy," CMS's Rule 30(b)(6) witness testified that the new rule is "a further application of the policy requiring the provider to have incurred a cost .... [and] to the way in which we calculate prices for Part B drugs."[18] Decl. of William Dunn Supp. Opp'n Relator's Mot. Partial Summ. J. Amgen, Ex. 1 (Deposition of John F. Warren) ("Warren Dep.") 214:24–25, 215:9–12, ECF No. 433–1. This witness also testified that CMS had never suggested that overfill should be included in the ASP calculation and that it was his "understanding up until this point that manufacturers have, in fact, reported their ASP data based on the FDA approved label amounts," i.e., not including overfill. *Id.* at 228:10–25, 229:1–2.

***25** CMS's rules and regulations confirm Amgen's position that overfill is not, and never was to have been, accounted for in Aranesp's ASP calculation.[19] There is, however, a plausible inconsistency in the rules and regulations that the Relator tries to exploit. CMS, in its November 2010 rulemaking, characterized overfill as "excess product" that "is provided without charge to the provider" and "free product for which the provider did not incur a cost." 75 Fed.Reg. at 73466, 73468. In defining overfill as such, CMS failed to explain the difference, if any, between "free product" and "free goods that are contingent on any purchase requirement" and must be accounted for as "price concessions" when calculating a drug's ASP. 42 U.S.C. § 1395w–3a(c)(3); 42 C.F.R. § 414.804(a)(2)(i)(D). The Relator argues that, because CMS has termed overfill "free product," it is therefore a price concession that must be deducted from the ASP determination. Mem. Supp. Relator's Mot. Partial Summ. J. Amgen 5–6. But, this argument contradicts the entirety of the November 2010 rule, which states that overfill is not included in the ASP calculation. Furthermore, while CMS did not explicitly reject the notion that overfill is a free good contingent on a purchase requirement,[20] it recognized its authority to identify additional price concessions that must be accounted for in the ASP calculation and "declin[ed] to consider overfill to be [an in-kind] discount for purposes of the ASP calculation."[21] 75 Fed.Reg. at 73468.

In addition, even though CMS has characterized overfill as "free product," the agency has not suggested that overfill

has independent value. The Anti–Kickback Statute "makes it illegal to offer, pay, solicit or receive anything *of value* as an inducement to generate business payable by Medicare or Medicaid." Publication of OIG Special Fraud Alerts, 59 Fed.Reg. 65372, 65375 (Dec. 19, 1994) (emphasis added); *see* 42 U.S.C. § 1320a–7a(i)(6) (broadly defining "remuneration" as "transfers of items or services for free or other than fair market value"); *Klaczak v. Consolidated Med. Transp.*, 458 F.Supp.2d 622, 678 (N.D.Ill.2006) ("Remuneration, for purposes of the [Anti–Kickback Statute], is defined broadly, meaning 'anything of value.' "); 56 Fed.Reg. at 35958 ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever."). Because CMS has deemed overfill "not reimbursable," 75 Fed.Reg. at 73466, it can have no independent value attached to it apart from the rest of the dosage in the vial. The only legitimate purpose of overfill is to ensure that providers and self-administering patients are able to draw up the full dosage amount, and the FDA recommends that manufacturers include it for this purpose. *Cf.* 56 Fed.Reg. at 35978 ("[Where a free computer] can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests .... it appears that the computer has no independent value apart from the service that is being provided and that the purpose of the free computer is not to induce an act prohibited by the statute. Rather, the computer is part of a package of services provided at a price that can be accurately reported to the programs.").

***26** If the Relator were correct that overfill is free product with independent value, such an arrangement would be inherently suspect and could violate the Anti–Kickback Statute.[22] *See* OIG Advisory Op. No. 04–16 at 4, 2004 WL 5701861 (Nov. 18, 2004), *also available at* http://oig.hhs.gov/fraud/docs/advisoryopinions/ 2004/ao0416.pdf. But the potential for fraud does not develop into actual fraud under the False Claims Act without the requisite knowledge that providing the free product would cause, and does in fact cause, a false claim to be presented to the government for Medicare payment. The illegality arises where drug manufacturers, like Amgen, and their affiliates, like INN and ASD, encourage health care providers to seek reimbursement for any independent value the overfill may have had but for which they did not pay. The fraud is in asking the government to pay a debt that it does not owe because the debt was never incurred by the provider.

In her reply memorandum, the Relator admits that, in its November 2010 rulemaking, CMS declined "to require manufacturers to uniformly deduct all overfill amounts as a 'price concession' in its ASP calculations." Reply Mem. Supp. Relator's Mot. Partial Summ. J. Amgen 7. Taking a slightly different tack in light of this, she then argues that, since CMS did not explicitly foreclose the possibility of individual exceptions to its general rule that overfill is not a factor in a drug's ASP determination, Amgen still had an obligation to deduct overfill from Aranesp's ASP calculation because the manufacturer was actively encouraging providers to bill for that overfill. *Id.* at 8. In essence, the Relator claims that Amgen should have altered Aranesp's ASP calculation to account for its allegedly illegal marketing scheme.

What the Relator fails to consider in making this argument is that CMS's November 2010 rule has two parts: first, overfill is not a cost to the provider and thus is not a factor in a drug's ASP, and, second and accordingly, providers must not bill Medicare for overfill.[23] The first part of the rule necessitates the second part if the government is to be protected from false claims. Only together do these two parts create a workable approach to Medicare reimbursement. The fact that the second part of the rule may have been violated in this case by Amgen allegedly encouraging providers to bill for overfill does not mean the Court must carve out an exception to the applicability of the first part of the rule for Amgen's calculation of Aranesp's ASP. Rather, Amgen was required to comply with both parts of the rule, and the fact that it complied with the first part does not preclude liability at trial for causing providers to submit false or fraudulent claims in violation of the second part. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d at 19 (suggesting that, although "mere publication of a false [average wholesale price ("AWP")], without more, does not constitute an offer of remuneration where reimbursement is based on a median of AWPs, ... the publication of a false AWP with the specific intent to induce purchase of [the manufacturer's] branded drug in conjunction with a strategy of 'marketing the spread' to the providers" may constitute a kickback); 68 Fed.Reg. at 23736 ("The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute."); *see also United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30–32 (1st Cir.2009) (reversing the district court's dismissal of a False Claims Act complaint alleging that a drug manufacturer gave health care providers free product *so that* they could submit it for Medicare reimbursement).

***27** The Court hastens to add that, even if the Relator proves at trial that Amgen, along with INN & ASD, marketed Aranesp by encouraging providers to bill Medicare for the drug's overfill, the Defendants cannot be held liable unless they acted knowingly in causing providers to submit false claims for payment. The Defendants must have either known that it was unlawful to seek Medicare reimbursement for overfill, even where administered to the patient, or acted in deliberate ignorance or reckless disregard of the truth or falsity of this information. *See* 31 U.S.C. § 3729(b); *United States v. President & Fellows of Harvard Coll.*, 323 F.Supp.2d 151, 189 (D.Mass.2004) (Woodlock, J.) (holding that innocent mistakes and negligence are not actionable under the False Claims Act). CMS, in its November 2010 rulemaking, repeatedly stated that its decision not to reimburse providers for overfill was but an application of its longstanding policy to cover only those expenses that providers actually incur. *See, e.g.*, 75 Fed.Reg. at 73469. At the same time, CMS issued the rule to "clarify" its approach to overfill, suggesting there was some ambiguity before the rule was announced. In addition, until the rule took effect on January 1, 2011, CMS continued to pay claims for Medicare reimbursement irrespective of the inclusion of overfill.

Thus, liability in this case may turn on whether CMS's policy prohibiting reimbursement for overfill was sufficiently clear prior to the issuance of its November 2010 rule, such that the Defendants' marketing scheme, if proved, must have been undertaken at least in reckless disregard of the policy. As a mixed question of law and fact, it is for the jury to decide whether it was unreasonable to expect that, given the state of the law at the time, the Defendants could have known or recklessly disregarded that overfill was not reimbursable and that therefore marketing it as such was unlawful. *See Presidents & Fellows of Harvard Coll.*, 323 F.Supp.2d at 192; *United States ex rel. Suter v. National Rehab Partners, Inc.*, Nos. CV–03–015–SBLW, CV–03–128–S–BLW, 2009 WL 3151099, at *9 (D.Idaho Sept.29, 2009) (holding that the reasonableness of a defendant's interpretation of a regulation is a relevant inquiry with respect to the knowledge requirement of the False Claims Act, while noting "[t]he scant case law on this issue"); *United States v. Newport News Shipbuilding, Inc.*, 276 F.Supp.2d 539, 564 (E.D.Va.2003) (holding that "both the clarity of the regulation and the reasonableness of a [defendant's] interpretation" are "indicative of a reckless disregard"); *see also Loughren*, 613 F.3d at 308 n. 10 ("[M]ixed questions of law and fact have typically been resolved by juries." (citing *United States v. Gaudin*, 515 U.S. 506, 512, 115 S.Ct. 2310, 132 L.Ed.2d 444 (1995))). In making this determination, the jury properly may consider that the Defendants were obliged to take reasonable steps to ensure their compliance with applicable statutes and regulations and may not now "hide[ ] behind a shield of self-imposed ignorance." *United States v. Cabrera–Diaz*, 106 F.Supp.2d 234, 238 (D.P.R.2000). If the Relator can show that the Defendants knew that CMS interpreted its regulations to exclude reimbursement for overfill prior to November 2010 and that the Defendants' marketing of Aranesp's overfill was inconsistent with the regulations as interpreted by CMS, then "any possible ambiguity of the regulations is water under the bridge." *Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053 (8th Cir.2002).

***28** **8** On these cross-motions for partial summary judgment, however, the issue before the Court is simply whether Amgen correctly calculated Aranesp's ASP, and it did. Because the ASP calculation does not include overfill and because Amgen followed this methodology in calculating Aranesp's ASP, the Court need not address the Relator's additional arguments that Amgen had a legal duty to report its assumption that overfill was not included in the ASP calculation and that Amgen failed to meet this duty. [24] Even if Amgen failed to comply with a reporting obligation, such failure could not have resulted in an artificially inflated ASP because CMS has confirmed the validity of the "assumption" that overfill is not a factor in the ASP calculation. Furthermore, Amgen's intent or knowledge in making its ASP calculation is irrelevant because the ASP it submitted to CMS each quarter was not erroneous as matter of law. The Relator again mistakenly conflates the fraud Amgen allegedly committed in urging providers to seek reimbursement for free overfill with an alleged, but unproven, impropriety in its ASP calculation. Having moved for summary judgment only with respect to Amgen's ASP calculation for Aranesp, the Relator's motion is denied, and Amgen's motion on this same matter is granted. [25]

IV. CROSS–MOTIONS FOR PARTIAL SUMMARY JUDGMENT AS TO INN & ASD'S NINTH AFFIRMATIVE DEFENSE

A. Facts in the Light Most Favorable to the Relator [26]

INN purports to be a legitimate GPO. Relator's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. INN & ASD ("Relator's SOF INN & ASD") ¶ 1, ECF No. 390. INN was established by Raj Mantena, an entrepreneur, who started other specialty GPOs at that same time, including ION and IPN. *Id.* ¶ 4–5. AmerisourceBergen Corporation ("ABC")

acquired a 100% interest in Mantena's GPOs between 2000 and 2003. *Id.* ¶ 6. In terms of ABC's corporate structure, Mantena's GPOs were grouped with ASD under ABC's subsidiary, AmerisourceBergen Specialty Group ("ABSG"). *Id.* ¶ 7. INN was sometimes referred to as "doing business as" these other entities, particularly IPN, and sometimes described as having its own corporate structure. *Id.* ¶¶ 5, 14. Certain INN executive-level employees used email addresses with the domain names "iononline.com" or "ipnonline.com." *Id.* ¶ 9. The salaries paid to INN employees were deducted from the revenue of all of Mantena's GPOs. *Id.* ¶ 10.

ASD is a distributor of specialty pharmaceutical products. Relator's Resp. INN & ASD's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. ("Relator's Resp. SOF INN & ASD") ¶ 2, ECF No. 439. ASD and INN formerly had an exclusive partnership as distributor-GPO. *Id.* ¶ 2. INN's Rule 30(b)(6) witness is actually employed by ASD to oversee both the distribution and group purchasing aspects of INN's business. Relator's SOF INN & ASD ¶¶ 12, 14. INN and ASD share an accounting department, and their financial reports are consolidated and reported to ABSG as "ASD operations." *Id.* ¶¶ 15–16.

***29** Amgen is a therapeutics company in the biotechnology industry that develops products to treat kidney disease. Relator's Resp. SOF INN & ASD ¶ 3. In September 2003, INN and Amgen signed a GPO agreement. Relator's SOF INN & ASD ¶ 18. At that time, Amgen was the only manufacturer with which INN dealt. Relator's Resp. SOF INN & ASD ¶ 2. Almost all of INN's revenue came from selling Aranesp. *Id.* Pursuant to the GPO agreement, INN also received an administrative fee from Amgen, fixed at 3% of all sales of Aranesp, except between April 1, 2004 and August 14, 2004, when it was set at 1% of all sales plus 2% earned through growth of INN members' purchases of Aranesp, as measured by Aranesp's increased capture of the market share, as compared to the competitor drug Procrit. Relator's SOF INN & ASD ¶ 21.

INN was aware of its disclosure requirement under the Anti–Kickback Statute to inform each of its members at least annually of the amount of administrative fees it received from each vendor with respect to purchases made on the provider's behalf. *Id.* ¶ 91. The reporting requirement was included in INN's agreements with its members as well as its GPO agreement with Amgen. *Id.* ¶ 92. INN has not produced photocopies of these annual letters as they were sent. *Id.* ¶ 95. It has produced a set of twenty-six draft letters with edits marked from 2003 as well as one additional form letter from 2008. *Id.* ¶¶ 95–96. INN's Rule 30(b)(6) witness testified at deposition to his "understanding" that the raw data regarding purchases was sent to an outside firm that completed a mail merge and mailed the actual disclosure letters. Relator's Resp. INN & ASD's Supplemental Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J.("Relator's Resp. Supp'l SOF INN & ASD"), Ex. N (Deposition of William J. Venus) ("Venus Dep.") 77:18–24, ECF No. 455–14. The witness, however, had seen only a sample letter prior to his deposition and could not recall or was not aware of the details. Relator's Resp. Supp'l SOF INN & ASD ¶ 38. INN has not produced evidence of this outside firm's work on its behalf. *Id.* ¶ 41. INN also contends that in more recent years the letters were sent by facsimile to its members, but INN has not produced evidence of these letters. *Id.* ¶ 44.

Upon receiving the 3% administrative fee from Amgen, INN then passed through one-third of the fee (equal to 1% of all sales of Aranesp) to ASD. Relator's SOF INN & ASD ¶ 23. This "pass through" of the administrative fee from Amgen to INN to ASD was part of the INN/ASD business model. *Id.* ¶¶ 23–24. INN did not disclose to its members orally or in writing that it passed through a portion of the administrative fee from Amgen to ASD. *Id.* ¶ 25. The "pass through" of the administrative fee paid by Amgen represented all of the revenue that ASD received from INN. *Id.* ¶ 26. ASD also received money from Amgen in the form of chargebacks, fee-for-service agreement fees, and service fees. *Id.* ¶ 27. Chargebacks represented the difference between ASD's wholesale acquisition cost of Aranesp and the price paid by INN's members under the GPO agreement. *Id.* ¶ 28. Fee-for-service agreement fees were to compensate ASD for distribution-related services it provided, such as transmitting data, managing inventory, processing chargebacks, and maintaining a certain number of filled orders. *Id.* ¶ 29. Services fees were paid by Amgen to ASD where a provider was given 120 days to pay for the Aranesp purchased. *Id.* ¶ 30.

***30** INN and ASD worked together to market and sell Aranesp to providers. *Id.* ¶¶ 52–53. ASD informed INN of medical practices that were not members of INN but were purchasing Aranesp or its competitor Procrit, and INN utilized this information to recruit the practices to join its membership. *Id.* ¶ 54. In addition, Amgen provided INN with target lists of health care providers whose business it sought to capture. *Id.* ¶ 56. INN then referred providers to ASD for the purchase of Aranesp and offered discounts on Aranesp contingent on a commitment to purchase exclusively through ASD. *Id.* ¶¶ 71–72. INN members who purchased Aranesp

from ASD received additional discounts above the price documented in the GPO agreement between INN and Amgen. *Id.* ¶ 31. ASD was not required by its contract with Amgen, however, to give discounts beyond the price negotiated by Amgen and its customers. Relator's Resp. Supp'l SOF INN & ASD ¶ 4.

Some of these discounts were funded by the "pass through" of the administrative fee from Amgen to INN to ASD. Relator's SOF INN & ASD ¶ 32. The discounts derived from the "pass through" varied in amount and were not offered uniformly to all INN members. *Id.* ¶ 33. ASD did not keep records documenting how these discounts were calculated or applied. *Id.* ¶ 34. ASD did not inform INN regularly of the discounts INN's members received, and INN did not request information regarding ASD's use of the "pass through." *Id.* ¶¶ 35–36. ASD's standard invoice to providers failed to specify the nature and amount of all discounts. Relator's Resp. Supp'l SOF INN & ASD ¶ 3. The former chief operating officer of ABSG expressed concerns about the legality of the "pass through" because it was a GPO administrative fee not earned by ASD. Relator's SOF INN & ASD ¶¶ 42–43. His employment was summarily terminated two weeks after he brought these concerns to ABC's chief executive officer. *Id.* ¶ 49.

When Amgen reduced the administrative fee from 3% to 1% in 2004, ASD stated that it could not afford to offer additional discounts to INN members if the "pass through" was reduced, and it was INN's sales director who shared ASD's position with Amgen. *Id.* ¶¶ 79–81. Amgen then reinstated the 3% administrative fee. *Id.* ¶ 83. In 2006, Amgen required an amendment to its GPO agreement with INN that no portion of the administrative fee would be passed through to ASD. *Id.* ¶ 84. ASD remained able to offer additional discounts to INN members, however, because INN and ASD were commonly owned by ABSG. *Id.* ¶ 85.

The Defendants all shared the same purported policy against marketing the value of overfill. *Id.* ¶ 59. Amgen established the policy because it believed discussing the potential profitability of overfill with providers was illegal. *Id.* ¶ 60. After learning of Amgen's policy, INN and ASD were instructed to follow the same unwritten policy. *Id.* ¶ 61. Despite the policy, the Defendants utilized financial models comparing the acquisition cost versus the reimbursement for Aranesp for providers. *Id.* ¶ 58. They gave information to health care providers about overfill in Aranesp vials, including in comparison to Procrit vials. *Id.* ¶ 62. It was assumed that INN, as a purported GPO, could "go where pharma cannot go." *Id.* ¶¶ 65–66. Accordingly, as matter of routine sales practice, INN directed its strategic account managers ("SAMs") to market Aranesp based on the amount of overfill contained in the vials and to explain to providers that Medicare reimbursement for overfill made Aranesp a more profitable drug than Procrit. *Id.* ¶ 63. Sales calls and presentations were sometimes coordinated such that Amgen representatives would leave at the time that INN discussed overfill with providers; at other times Amgen participated in the presentations. *Id.* ¶¶ 67–68, 70.

B. Facts in the Light Most Favorable to INN & ASD

***31** INN is a GPO specializing in the support of community-based nephrology practices. INN & ASD's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. ("INN & ASD's SOF") ¶ 1, ECF No. 382. GPOs allow for the efficient distribution of medical devices, supplies, and drugs. INN & ASD's Supplemental Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. ("INN & ASD's Supp'l SOF") ¶ 33, ECF No. 436. Consistent with the safe harbor provisions of the Anti–Kickback Statute, a GPO may receive administrative fees from vendors, including pharmaceutical manufacturers. *Id.* ¶ 24. This compensation structure incentivizes a GPO to sell to its members more of the vendors' products in its portfolio. *Id.* ¶ 27. It is also not uncommon for a GPO to "pass through" a portion of the administrative fees that it receives from vendors to its members. *Id.* ¶ 28. In this way, a GPO can provide more favorable pricing to its members. *Id.* As a purchasing agent for its members, a GPO will discuss with its members the economic consequences of their purchases by laying out the relative costs and expenses of various products. *Id.* ¶¶ 29–30. From the members' perspective, the primary reason to join a GPO is to take advantage of economic benefits like better pricing on devices, supplies, and drugs as well as services like educational opportunities. INN & ASD's SOF ¶ 21.

Mantena created INN as part of a network of specialty GPOs. *Id.* ¶¶ 39, 44, 49. ABC later acquired the entire network, including INN. *Id.* ¶ 52. In 2002, a year after INN was formed and before it was acquired by ABC, Mantena approached Amgen, the manufacturer of the drug Aranesp, about entering into a GPO agreement with INN. *Id.* ¶ 60. After an initial rejection and renewed pursuit by Mantena, the parties entered into a nonexclusive GPO agreement for the sale of Aranesp in September 2003. *Id.* ¶¶ 61–65, 67. The agreement provided that INN would receive an administrative fee from Amgen in the amount of 3% of all Aranesp sales to INN's members. *Id.* ¶ 68.

At the time it formed the GPO agreement with Amgen, INN already had 180 members. *Id.* ¶ 66. INN disclosed to its members in writing the 3% administrative fee it would be receiving from Amgen, although Amgen was not referred to by name. *Id.* ¶ 69. INN also informed its members that it would disclose to them in writing on an annual basis the amount it received in fees from each vendor for purchases made on their behalf. *Id.* For the years 2003 to 2006, INN utilized an outside firm, Bulk Mailing and Addressing, Inc. ("BMA"), to send its members the annual disclosure letters. INN & ASD's Supp'l SOF ¶ 35. INN would prepare the template for the letter and then send the "raw data around the purchases" to BMA for completion of the mail merge and mailing of the letters. *Id.* ¶¶ 37–38. The record includes an email titled "IUN/IDN/INN Mailer" from IPN's contract manager, Brett Howery, to a BMA employee, Vincent Buscemi, purporting to send "letters pre-merged for the mailing" and including an attachment, among others, called "Merged INN 2003 Admin Fee Letter.doc." INN & ASD's Supp'l SOF, Ex. 12 (Dec. 21, 2004 Email from Brett Howery to Vincent Buscemi) ("Howery Email"), ECF No. 436–12; *see* INN & ASD's Supp'l SOF, Ex. 13 (Dec. 28, 2004 Email from Vincent Buscemi to Brett Howery) ("Buscemi Email"), ECF No. 436–13. In his declaration, BMA's president, Paul Ort, identified a draft annual disclosure letter as an example of the type of mail it would mail on INN's behalf on a regular basis. INN & ASD's Supp'l SOF, Ex. 15 (Declaration of Paul W. Ort) ("Ort Decl.") ¶ 7, ECF No. 436–15. A subpoena to produce BMA's records related to its business with INN could not be served on BMA's custodian of records, however, as BMA appeared to no longer operate at its location. INN & ASD's Supp'l SOF ¶¶ 45–49. For the years 2007 and 2008, unidentified INN employees supervised by INN's manager of member services, Jennifer Russell, sent the letters by facsimile. INN & ASD's Supp'l SOF, Ex. 23 (Declaration of Jennifer Russell) ("Russell Decl.") ¶¶ 3, 5–6, ECF No. 436–23. In 2009, unidentified INN employees supervised by Russell sent the letters by regular mail. *Id.* ¶ 7.

***32** ASD is INN's preferred, but not its only, wholesaler. INN & ASD's Supp'l SOF ¶ 12. As a wholesaler, ASD purchases products from pharmaceutical manufacturers at wholesaler acquisition cost ("WAC"). *Id.* ¶ 1. ASD then sells and distributes the products to health care providers, including pursuant to the terms set forth in the providers' contracts with GPOs and manufacturers. *Id.* ¶ 2. ASD retains discretion to offer discounts in addition to the terms of these contracts. *Id.* In fact, pursuant to most agreements between manufacturers and wholesalers, wholesalers are required to provide additional discounts to providers. *Id.* ¶ 4. ASD's standard invoice informs providers of that stated prices may include discounts, which providers are obligated to report. *Id.* ¶ 3. It reads:

> Sales reflected on this invoice may include price discounts or be subject to subsequent reductions or adjustments in price, which may be reflected on other documentation. Buyer will comply with all applicable federal and state laws requiring it to report or reflect such discounts, reductions, or adjustments on cost reports or claims submitted to federal or state healthcare programs or other third party payers, retain this invoice and related pricing documentation, and make the invoice and such documentation available on request to federal or state healthcare program or other third party payer representatives.

Id. ASD reports to manufacturers the contract price and the number of units of the product sold and distributed by ASD. *Id.* ¶ 5. The manufacturers then provide ASD with a "chargeback," or the difference between the contract price and ASD's acquisition cost. *Id.*

ASD entered into a wholesaler distribution agreement with Amgen in accordance with these customary practices. *Id.* ¶ 6. ASD purchases Aranesp, among other products, from Amgen and sells it to nephrology practices based on the providers' contracts with Amgen, while retaining discretion to offer additional discounts. *Id.* ¶ 7. Maintaining a record of discounts given to providers, ASD then reports its sales and prices to Amgen, which in turn pays ASD chargebacks. *Id.* ¶¶ 8–10. ASD has its own sales team. *Id* . ¶ 14.

From 2007 to 2010, INN and ASD shared an accounting department and consolidated their financial reports. *Id.* ¶ 21. INN's SAMs directed providers to ASD's internal sales team to establish new accounts and manage the logistics of ordering portfolio products like Aranesp. *Id.* ¶ 16. INN then passed through one-third of the administrative fee it received from Amgen to ASD as a way to reimburse ASD for certain pricing discounts ASD provided to INN's members and for performing certain distribution services related to INN's GPO agreement with Amgen. INN & ASD's SOF ¶ 73. INN passed through portions of the administrative fees it received from vendors other than Amgen to ASD as well. *Id.* ¶ 75. Furthermore, ASD offered INN members additional discounts based on their purchase volume and payment terms that were not funded by the "pass through" of the administrative fee from Amgen to INN to ASD. INN &

ASD's Resp. Relator's Rule 56.1 Statement Facts Supp. Mot. Partial Summ. J. ("INN & ASD's Resp. SOF") ¶ 39, ECF No. 435. In 2006, however, INN and Amgen amended their GPO agreement to prohibit the "pass through" of a portion the administrative fee to ASD. INN & ASD's SOF ¶ 76. At that time, INN ceased paying the "pass through" to ASD. *Id.* ¶ 77.

***33** INN discussed with providers the "economics" of their purchasing decisions, including how to maximize profit. *Id.* ¶¶ 83–84. INN utilized financial spreadsheets that illustrated the acquisition costs of certain drugs versus their reimbursement costs. *Id.* ¶ 84. The recruitment of nephrology practices to INN by INN's SAMs included a discussion of this economic calculus. *Id.* ¶ 85. The SAMs believed that they were operating under the GPO safe harbor of the Anti–Kickback Statute when they had these discussions with providers. *Id.* ¶¶ 86–89, 91.

INN's members raised questions with INN's SAMs about the amount of overfill in Aranesp vials. *Id.* ¶ 100. Amgen provided information to INN's SAMs about this overfill. *Id.* ¶ 101. INN developed a policy that SAMs were not to initiate communication with providers about overfill but could answer questions and clarify the amount of overfill in the vials. *Id.* ¶ 102. INN believes that the use of overfill is ultimately a clinical decision. *Id.* ¶ 103. Similar but distinct from INN's policy, ASD's approach to overfill was not to raise the issue with providers and to refer providers directly to Amgen if questions arose. INN & ASD's Supp'l SOF ¶ 23.

C. Standard of Review

Summary judgment is proper where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). An issue of fact is "genuine" if there exists a sufficient evidentiary basis on which the trier of fact could find for the non-moving party. *Anderson*, 477 U.S. at 248. A fact is "material" if it will affect the outcome of the case under the applicable law. *Id.* The moving party bears the burden of showing that no genuine issue of material fact exists. *Celotex Corp.*, 477 U.S. at 323. "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson*, 477 U.S. at 255. Save as to facts admitted by both parties, the court must disregard all evidence—even if unopposed—which the jury is free to reject, i.e., all evidence upon which a party bears the burden of proof. *Reeves*, 530 U.S. at 151. Thus, summary judgment may be granted when a fair-minded jury could reach only one conclusion: in favor of the moving party.

D. Analysis

1. INN and the GPO Safe Harbor of the Anti–Kickback Statute

INN does not dispute that it discussed with providers the "economics" of their purchasing decisions, including how to maximize profit, by comparing the acquisition costs of certain drugs with their reimbursement costs. INN argues, however, that it was operating under the GPO safe harbor of the Anti–Kickback Statute, such that it is exempt from liability for any false claims for overfill submitted by providers in this case. *See* Mem. Supp. INN & ASD's Mot. Partial Summ. J. 8–9. The Relator disputes that INN meets the strict requirements for safe harbor protection set forth in the federal statute and regulations. First, she argues that INN has failed to prove that it mailed annually letters disclosing the administrative fees it received from vendors, *see* Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD 6–7, and, second, she contends that, even if INN did follow this disclosure requirement, the close relationships that it maintained with Amgen and ASD are so inconsistent with the congressional intent in creating the GPO safe harbor as to make it inapplicable to INN, *see id.* at 8–9.

***34** The GPO exception to the Anti–Kickback Statute is "designed to apply to payments from vendors to entities authorized to act as a GPO for individuals or entities who are furnishing Medicare or Medicaid services." 56 Fed.Reg. at 35953. The term "group purchasing organization" is defined by federal regulations as an "entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs." 42 C.F.R. § 1001.952(j)(2). For the safe harbor protection to apply, the entities on whose behalf the GPO acts must be neither wholly owned by the GPO nor subsidiaries of a parent company that owns the GPO, whether directly or through another wholly-owned entity. *Id.* There also must be a written agreement between the GPO and each entity specifying the fee that vendors, like pharmaceutical companies, will pay the GPO. *Id.* § 1001.952(j)(1). The standard fee that GPOs may receive is 3% or less of the purchase price of the goods or services, but the parties may set the fee at a higher amount, provided they so specify in their agreement. *Id.* § 1001.952(j)(1)(i)-(ii). Where the entity who is receiving the goods or services from the vendor is a health care provider, the GPO must disclose in writing to the provider annually the amount it received in fees from

each vendor with respect to purchases made on the provider's behalf. *Id.* § 1001.952(j)(2).

Here, INN properly entered into a written agreement with each of its members. In these agreements, INN stated that it would disclose in writing to each member annually the amount it received in fees from each vendor for purchases made on the member's behalf. Thus, the sole dispute with respect to INN's compliance with the safe harbor requirements concerns whether the annual disclosure letters were in fact mailed.

9 Under the well-settled "mailbox rule" recognized at "federal common law," "the proper and timely mailing of a document raises a rebuttable presumption that the document has been received by the addressee in the usual time." *Hoefs v. CACV of Colorado, LLC,* 365 F.Supp.2d 69, 72–73 (D.Mass.2005) (adopting the Report and Recommendation of Neiman, M.J.) (quoting *Schikore v. BankAmerica Supplemental Ret. Plan,* 269 F.3d 956, 961 (9th Cir.2001)). "[E]ven in the context of regular mail, a presumption of receipt is proper so long as the record establishes that the notice was accurately addressed and mailed in accordance with normal office procedures." *Lopes v. Gonzales,* 468 F.3d 81, 85 (2d Cir.2006). On these cross-motions for summary judgment, however, the issue is not whether the annual disclosure letters actually were received by INN members, but rather whether INN mailed them as required by the GPO safe harbor provisions. "Since the focus here is on only whether notice was mailed, the mailbox rule does not operate in this context." *Custer v. Murphy Oil USA, Inc.,* 503 F.3d 415, 419 (5th Cir.2007).

***35** **10** **11** The mailbox rule remains "germane," however, because "[a] threshold question for the application of the mailbox rule is whether there is sufficient evidence that the letter was actually mailed." *Id.* "[T]estimony by someone familiar with company procedures and practices that the letter was sent," together with corroborating evidence that the company procedures and practices were followed in that particular instance, is sufficient to establish proof of mailing. *Davis v. U.S. Bancorp,* 383 F.3d 761, 766 (8th Cir.2004); *see United States v. Ekong,* 518 F.3d 285, 287 (5th Cir.2007) ("A sworn statement is credible evidence of mailing for the purposes of the mailbox rule." (quoting *Custer,* 503 F.3d at 420)). Generally, evidence of non-receipt is insufficient to rebut the presumption of *receipt* under the mailbox rule, but it does present a triable question of fact whether the letter was properly *sent. See In re Schepps Food Stores, Inc.,* 152 B.R. 136, 139–40 (Bankr.S.D.Tex.1993); *see also In re Yoder Co.,* 758 F.2d 1114, 1117 (6th Cir.1985) ("Testimony of non-receipt is evidence that the notice was not mailed.").

12 The summary judgment record contains no direct proof that the annual disclosure letters were mailed, such as copies of the letters as sent, postmarked envelopes, certified mail receipts, or facsimile records. *See Custer,* 503 F.3d at 419–20. Instead, the circumstantial evidence produced by INN consists of a set of twenty-six draft disclosure letters from 2003; templates for other years; testimony by INN's Rule 30(b)(6) witness that it was INN's custom to send "the raw data around the purchases" to BMA for completion of a mail merge and actual mailing of the letters; an email from Brett Lowery, IPN's contract manager, to BMA employee Vincent Buscemi transmitting the 2003 letter "premerged for the mailing;" a declaration by Paul Ort, BMA's president, that INN was BMA's client from 2003 to 2006 and that BMA regularly completed mail merges and mailed pieces of mail like the disclosure letter on INN's behalf; and a declaration by Jennifer Russell, INN's manager of member services, that employees whom she supervised sent the letters by facsimile for the years 2007 and 2008 and by regular mail for the year 2009. This evidence establishes that INN had a routine procedure in place for mailing the annual disclosure letters, although it changed over time. The email from Lowery to Buscemi sending the 2003 disclosure letter to be mail-merged and printed and Russell's declaration stating that she supervised the mailings for years 2007 to 2009 provide some corroboration that the procedure in place at the time was followed.

The Relator argues that, where INN has been in continual operation since 2001 and started out with 180 members, a set of twenty-six draft letters from 2003 and sample letters from other years fall short of the evidentiary showing required to prove INN is a legitimate GPO entitled to claim the safe harbor protection. *See* Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD 6; Reply Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD 2–5. Furthermore, she contends that Ort's declaration is unsubstantiated, particularly where a subpoena could not be served on BMA's custodian of records because BMA appeared to have ceased business operations at its location. Reply Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD 5–6. Also, in response to Lowery's email attaching the 2003 letter, Buscemi sent an email stating that the letters were missing signatures and that the addresses to which the letters were to be mailed were incomplete. *See* Buscemi Email; Reply Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD 4. There is no evidence in the record that Lowery or any other INN employee corrected these

problems identified by Buscemi so that the letters could be mailed. Finally, the Relator contends that, if INN employees supervised by Russell in fact had sent the letters by facsimile or regular mail in more recent years, one would assume that copies or records would have been kept in INN's files, and yet Jennifer Russell's rather cursory and non-specific declaration is the only evidence of their mailing that INN has adduced. *See* Tr. Summ. J. Mots. 12:24–25, 13:1; Reply Mem. Supp. Relator's Mot. Partial Summ. J. INN & ASD 9–11.

***36** Because INN bears the burden of proof on its affirmative defense that it is protected by the GPO safe harbor of the Anti–Kickback Statute, the Court must disregard all of its evidence in its favor, even if uncontradicted, that the jury would be free to disbelieve. The Relator has made no admission material to whether INN has met the safe harbor disclosure requirements. This leaves only the undisputed facts, which are that INN acknowledged its duty to disclose in its agreements with members and that the some draft and template fee disclosure letters do exist. The inference to be drawn from these facts, if any, as to whether INN complied with its obligation to send annual disclosure letters to its members must be reserved for the jury. For this reason, the Court denies the partial summary judgment motions of both parties. Furthermore, while the Relator's memorandum effectively pokes holes in the sufficiency of INN's evidence, she has not produced evidence that providers did not receive the disclosure letters, and even if her evidentiary presentation could be viewed as demonstrative of non-receipt, this would simply raise a question of fact, not warrant summary judgment.

Assuming that at trial INN could prove by a fair preponderance of the evidence that it strictly complied with the annual disclosure letter requirement, the Relator argues that INN still cannot assert the GPO safe harbor as an affirmative defense because, by allegedly conspiring with Amgen and ASD to sell as much Aranesp as possible through marketing the Medicare reimbursement value of overfill, INN violated the fiduciary duty that it owed its members as their purchasing agent. As matter of law, the Court agrees with the Relator's position that statutory and regulatory compliance alone cannot absolve INN of liability under the False Claims Act if the relationship between the Defendants is shown to have revolved around a marketing scheme intended to induce providers to bill Medicare for the value of Aranesp's overfill, where the Defendants either knew, deliberately ignored, or acted in reckless disregard of CMS's policy that overfill is not reimbursable. But, this conclusion is rooted not in principles of agency law, as the Relator suggests, although they too may lend support for it.

Regardless whether INN is protected by the Anti–Kickback Statute safe harbor, this Court is aware of no legal precedent, binding or persuasive, holding that a legitimate GPO cannot be held liable for causing providers to submit false claims for government payment. The GPO safe harbor exists to exclude the "payment practice[ ]" of vendors paying GPOs administrative fees as part of an agreement to furnish goods or services to health care providers and other entities from being treated as an "illegal remuneration" under the Anti–Kickback Statute. 42 C.F.R. § 1001.952(j); *see* 42 U.S.C. § 1320a–7b(b)(3) (providing that the definition of "illegal remuneration" "shall not apply to ... any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program"). Nowhere in the statute or regulations is it suggested that a GPO, solely by virtue of being a GPO, may engage in activities that would otherwise subject it to criminal or civil liability.

***37** Thus, even if the Relator could show that INN breached its fiduciary duty to its members, or that Amgen paid INN the administrative fee for an improper purpose, *see Bay State Ambulance*, 874 F.2d at 29; *Shaw*, 106 F.Supp.2d at 121, or that this administrative fee was not a "bona fide service fee" because it improperly was passed through to ASD and providers in the form of discounts, *see* 42 C.F.R. § 414.802, it would be of no consequence in adjudicating the False Claims Act issues. INN's potential liability under the False Claims Act is independent of any claim of exemption from liability that it may have under the Anti–Kickback Statute for its receipt of the administrative fee from Amgen. Furthermore, even if the Court assumes the truth of INN's contention that, as a purchasing agent, it lawfully could discuss the "economics" of different drugs with providers, this was not a license for it knowingly to urge providers to bill Medicare for expenses they did not incur.

2. ASD and the Discount Safe Harbor of the Anti–Kickback Statute

The parties agree that at least up until 2006 one-third of the 3% administrative fee that Amgen paid to INN was passed through to ASD. ASD concedes that, pursuant to its agreement with Amgen, it retained discretion to give discounts to providers buying Aranesp and that it utilized the "pass through" of the administrative fee to provide such discounts. ASD argues that in so doing it was protected by

the discount safe harbor of the Anti–Kickback Statute. Mem. Opp'n Relator's Mot. Partial Summ. J. 13–15. The Relator, in a footnote only, argues that ASD may not rely on this safe harbor because "the undisputed evidence shows that ASD did not keep records sufficient to show any manner by which Aranesp discounts were allocated and funded." Mem. Supp. Mot. Partial Summ. J. INN & ASD 9 n. 6. She primarily focuses, however, on the "pass through" of the administrative fee from Amgen to INN to ASD to providers in the form of discounts as improper under federal regulations. *Id.* 8–9.

The discount safe harbor is "intended to encourage price competition that benefits the Medicare and Medicaid programs." 56 Fed.Reg. at 35953. "[L]imited in application to reductions in the amount a seller charges for a good or service to the buyer," a discount may "take the form of a specified price break, or the inclusion of an extra quantity of the item purchased 'at no extra charge.' " *Id.* ("The remuneration in a discount is merely a lowered price that a purchaser would obtain from a seller, which is made as an inducement to purchase larger quantities."). It does not "protect many kinds of marketing incentive programs such as cash rebates, free goods or services, redeemable coupons, or credits." *Id.* To qualify as a discount, the reduction in the amount a buyer is charged by the seller must be "based on an arms-length transaction," 42 C.F.R. § 1001.952(h)(5), and "not [made] through a joint-venture or collusive contract," *Shaw,* 106 F.Supp.2d at 116 (citing 56 Fed.Reg. at 35977). Furthermore, the seller must comply with disclosure requirements by "fully and accurately report[ing] such discount on the invoice, coupon or statement submitted to the buyer," 42 C.F.R. § 1001.952(h)(2)(ii)(A); *id.* § 1001.952(h)(2)(iii)(B), and "the value of the discount must be accurately reflected in the actual purchase price," 64 Fed.Reg. at 63527.

***38** The Court need not address in depth ASD's argument that its provision of discounts to providers, funded in part by the "pass through" of the administrative fee, was covered by the discount safe harbor of the Anti–Kickback Statute. For the same reason that it is ultimately immaterial whether INN is a legitimate GPO because this alone does not immunize it from False Claims Act liability, ASD's claim of safe harbor protection for the "pass through"-funded discounts given to providers has no bearing on whether ASD independently or as part of a conspiracy with the other Defendants encouraged the submission of claims for reimbursement for overfill in violation of the False Claims Act.

Turning to the Relator's argument with respect to the "pass through" of the administrative fee, an administrative fee paid by a vendor, like Amgen, to a GPO, like INN, is bona fide service fee, so long as it is "not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug." 42 C.F.R. § 414.802. Federal regulations establish that "bona fide service fees are not considered price concessions" for purposes of calculating a drug's ASP. *Id.* § 414.804.

13 The Relator originally had alleged that, because the administrative fee paid by Amgen to INN was then passed through to ASD and providers in the form of discounts, this fee should have been, but was not, deducted from Aranesp's ASP calculation. The Court dismissed this claim under the False Claims Act's first-to-file bar, 31 U.S.C § 3730(b)(5). *See Amgen,* 707 F.Supp.2d at 131. Without retreating from that ruling, the Court does not preclude the possibility that, at trial, evidence of the administrative fee being passed through yet not deducted accordingly from Aranesp's ASP may be admissible for the limited purpose of showing the nature of the relationship between the Defendants. There remains a genuine dispute of fact as to whether ASD conspired with Amgen and INN to defraud the federal government by causing providers to seek reimbursement for free overfill. Relatedly, on this summary judgment record, whether ASD actively marketed overfill to providers is a question for the jury.

V. CONCLUSION

For the reasons stated above, the Court announced its rulings orally at the motion hearings [ECF Nos. 440, 463] and by subsequent written Order [ECF No. 481]:

• DENYING the Defendants' Motion for Partial Judgment on the Pleadings [ECF No. 367];

• DENYING the Relator's Motion for Partial Summary Judgment that Amgen Artificially Inflated the Average Sales Price of Aranesp [ECF No. 383];

• ALLOWING Amgen's Motion for Partial Summary Judgment [ECF No. 376] as to Count IV of the Relator's Fourth Amended Complaint insofar as it alleges that Amgen artificially inflated the Average Sales Price of Aranesp;

• DENYING Amgen's Motion for Partial Summary Judgment [ECF No. 376] as to the allegations within Count IV of the Relator's Fourth Amended Complaint that Amgen caused health care providers to submit false or fraudulent claims for government payment in violation of the False Claims Act,

and as to all other counts of the Relator's Fourth Amended Complaint;

***39** • DENYING the Relator's Motion for Partial Summary Judgment as to INN & ASD's Ninth Affirmative Defense [ECF No. 384];

• DENYING INN & ASD's Motion for Partial Summary Judgment [ECF No. 379].

Footnotes

1 There are two Provider Agreements—Form CMS–855A for institutional providers and Form CMS–855I for physicians and non-physician practitioners—which contain nearly identical language. *See Amgen,* 707 F.Supp.2d at 134 n. 3. For simplicity's sake, they are both referred to as the Provider Agreement. CMS is an agency within the United States Department of Health and Human Services ("HHS").

2 "[T]he false statement or misrepresentation that is the premise of [a False Claims Act] action need not be a certification." *Nowak,* 2011 WL 3208007, at *28. "So long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach." *Blackstone Med.,* 647 F.3d at 390 (quoting *United States ex rel. Hendow v. University of Phoenix,* 461 F.3d 1166, 1172 (9th Cir.2006)). Here, however, the clause in the Provider Agreement is perhaps best characterized as a "certification," and thus that is the term the Court uses.

3 Sections 1320a–7 (a)(1) and 1320a–7 (b)(7) of title 42 authorize the exclusion of providers who violate the Anti–Kickback Statute.

4 The United States Supreme Court has stated that the PPACA "makes no mention of retroactivity," such that this new provision, 42 U.S.C. § 1320a–7b(g), almost certainly is inapplicable to the present action. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson,* —— U.S. ——, —— n. 1, 130 S.Ct. 1396, 1400 n. 1, 176 L.Ed.2d 225 (2010).

5 Citing *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.,* 447 U.S. 102, 100 S.Ct. 2051, 64 L.Ed.2d 766 (1980), the Defendants argue that Senator Kaufman's statements are entitled to little or no weight. Reply Mem. Supp. Defs.' Mot. Partial J. Pleadings 4. The United State Supreme Court case on which the Defendants rely, however, was discussing "[a] mere statement in a conference report ... as to what the Committee *believes an earlier statute meant.*" *Id.* at 118 n. 13 (emphasis added). The Supreme Court remarked that "[s]uch history does not bear strong indicia of reliability ... because as time passes memories fade and a person's perception of his earlier intention may change. Thus, even when it would otherwise be useful, subsequent legislative history will rarely override a reasonable interpretation of a statute that can be gleaned from its language and legislative history prior to its enactment." *Id.* This undercuts the Defendants' argument because Senator Kaufman's statements constitute "legislative history prior to its enactment," even if they are less formal than other types of legislative history.

6 The Defendants state that CMS, in its submission to OMB, did not give a reason for or legal citation in support of its inclusion of the certification clause in the Provider Agreement, *see* Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 12, although CMS's "Supporting Statement for Paperwork Reduction Act Submissions" contained various citations to the Medicare statutes or regulations, *see* Supporting Statement for Paperwork Reduction Act Submissions 2. The Defendants do not go so far as to suggest, however, that the Provider Agreement failed to comply with the PRA.

7 This version removed the reference to compliance with not only the Anti–Kickback Statute but also the Stark Act, which even the Defendants concede clearly is a precondition of Medicare payment. *See* Mem. Supp. INN & ASD's Mot. Partial J. Pleadings 6–7. This suggests that CMS did not remove the second part of the certification clause because it had decided that Medicare payment is not conditioned on compliance with the Anti–Kickback Statute after all.

8 The Provider Agreement was subject only to the PRA, whereas it was the agency's Medicare enrollment rules (which are not at issue here) that were subject to the APA. While OMB admonished CMS for failing to engage in rulemaking under the APA prior to issuing the 2001 version of the Provider Agreement, OMB made clear that this shortcoming had no bearing on the validity of the form itself, so long as CMS followed up with proper rulemaking, which it did. *See* Notice of Office of Management and Budget Action I. Therefore, this Court need not dwell on whether the Provider Agreement was adopted pursuant to the APA.

9 The Defendants also argue that 42 U.S.C. § 1395g(a) only authorizes the Secretary to collect information necessary "to determine the amounts due," not to determine compliance with another statute. Joint Reply Mem. Supp. Defs.' Mot. Partial J. Pleadings 5 (quoting 42 U.S.C. § 1395g(a)). But in order for CMS to determine the amounts due to a provider, it necessarily must know whether the provider is (or at least attests to be) in compliance with the Anti–Kickback Statute because, as discussed, it would be contrary to public policy, as well as commonsense and logic, if the agency were required to pay claims tainted by kickbacks. *See infra.* Thus, information necessary to determine the amounts due may include, by extension, information as to the provider's compliance with the Anti–Kickback Statute.

10 As required on motions for summary judgment, the factual summary presented here consists of undisputed facts as to which the Relator bears the burden of proof and disputed facts in the light most favorable to Amgen, the non-moving party. The Court is

to review the record as a whole, but "it must disregard all evidence favorable to the moving party that the jury is not required to believe." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 151, 120 S.Ct. 2097, 147 L.Ed.2d 105 (2000). Accordingly, the Court must disregard evidence in favor of the Relator—even if uncontradicted—that the jury would be free to disbelieve. *See id.*

11 As a point of comparison, in 2003, Amgen reduced the amount of overfill in EPOGEN vials from 16.8% to 14.4%, and then again reduced EPOGEN's overfill amount to 11.1% in 2004. Amgen's Resp. SOF ¶ 13.

12 Between 2003 and 2010, the FDA approved BLAs for at least six other injectable liquid biologics with target overfills in excess of 20%. Amgen's SOF ¶ 54.

13 Its non-compliance concerned "price concessions" and "minor calculation errors;" Amgen's exclusion of overfill in its ASP calculation was not at issue. 2007 OIG Audit 3–4.

14 Amgen does not appear to dispute that INN's sales representatives in fact engaged in a practice of marketing overfill, although Amgen suggests that such discussions with customers were reactive, not proactive. Amgen's Resp. SOF ¶ 16.

15 Only phase one of the two-phase process has been carried out, such that the current overfill target for Aranesp is 14.3%. Relator's Resp. SOF Amgen ¶ 45. The Relator argues this means providers are receiving 1.3% more overfill than even Amgen has determined to be necessary. *Id.*

16 CMS indicated its "appreciat[ion for] the comments in support of our proposal," including some commenters' mention of "ongoing litigation which alleges that some manufacturers provided kickbacks to providers by marketing and furnishing intentional overfill and encouraging providers to bill federal health care programs to increase the providers' profits and sales volumes for the drugs." 75 Fed.Reg. at 73467.

17 CMS also rejected the arguments of those commenters who "disagree[d] that Medicare has a longstanding policy that an expense must be incurred by the provider in order for payment to be made by Medicare," who noted that there is no law or regulation prohibiting a provider from billing for intentional overfill, and who stated that CMS had not expressed concern about overfill in the face of past OIG reports detailing providers' use of it in a way that altered their costs. 75 Fed.Reg. at 73469. CMS reiterated that its policy of reimbursing only for expenses actually incurred by medical providers under the "incident-to" provision is "longstanding." *Id.*

18 The witness acknowledged that the new rule "is an application [of CMS's policy requiring the provider to have incurred a cost] that the agency has never before articulated," but did not adopt counsel's characterization of it as "novel." Warren Dep. 215:13–19.

19 The Rule 30(b)(6) witness for CMS answered affirmatively when asked whether the agency "has determined that overfill amounts should—have not been and should not be reported for ASP purposes." Warren Dep. 214:6–10.

20 OIG's Rule 30(b)(6) witness stated that, although the agency had been informed that providers were utilizing and billing for overfill, he never instructed manufacturers like Amgen to include overfill in the average acquisition cost, and he did not consider overfill to be a free good contingent on any purchase requirement. Decl. William Dunn Supp. Opp'n Relator's Mot. Partial Summ. J. Amgen, Ex. 2 (Deposition of David Tawes) ("Tawes Dep.") 75:8–18, ECF No. 433–2.

21 CMS identified "operational feasibility" as the "practical reason" for which it did not consider overfill to be a discount for purposes of the ASP calculation. 75 Fed.Reg. at 73468. "The amount of overfill in vials varies from drug to drug and often is not easily or consistently quantifiable because actual fill amounts may also vary slightly due to the manufacturing process. In contrast, manufacturer sales data, ASP calculations, and ASP payment limits use exact quantities of drug that are represented by exact monetary values." *Id.*

22 Previously, this Court held that the Relator adequately had alleged that Amgen included "excess" overfill in its Aranesp vials, or more overfill than was necessary to withdraw the labeled dosage, and that such "excess overfill is in effect free doses of Aranesp, which create the potential for providers to profit from Medicare reimbursement." *Amgen*, 738 F.Supp.2d at 273–74. The Court's intention, however, was not to limit its holding to "excess" overfill, as opposed to overfill generally. The Court recognized that the Medicare Reimbursement Policy Manual indicated that Medicare would reimburse a claim only up to the labeled amount and not including any overfill. *Id.* at 274 n. 11. Now that CMS has further clarified that *all* overfill, regardless of FDA approval, medical necessity, or administration to the patient, "is free product for which the provider cannot incur a cost" and thus is not reimbursable, 75 Fed.Reg. at 73468, this Court's prior use of the phrase "excess overfill" appears to have been a redundancy in terms, at least with respect to the propriety of billing for and marketing the value of overfill under the False Claims Act.

> The concept of "excess overfill" continues, however, to constitute the very foundation of the Relator's claim that the Defendants caused providers to submit *kickback-tainted* false claims. Excess overfill is that which is in excess of the target fill volume approved by the FDA after reviewing whether the manufacturer has complied with mandatory testing procedures set forth in FDA regulations and USP compendia. Because the FDA mandates that manufacturers include some amount of overfill to ensure that patients receive neither too much nor too little of a drug, the inclusion of overfill in the drug's vial implicates the Anti–Kickback Statute only where the amount exceeds the FDA-approved level. Where overfill is excessive, suspicions properly arise that it has been given to providers for an illegitimate purpose, i.e., to induce them to purchase more Aranesp. *Amgen*, 738 F.Supp.2d

at 273–74; *see United States ex rel. Woodard v. DaVita, Inc.*, Memorandum & Order 22–23, No. 1:05–CV–227 (E.D.Tex. May 9, 2011), ECF No. 137.

Here, it is undisputed that the FDA approved the target overfill level proposed in Aranesp's BLA, which was 1.168 mL +/0.04 mL. The propriety of the FDA's review and approval of this level is not a proper jury issue, but there remains a triable issue of fact whether the overfill contained in Aranesp vials actually comported with the FDA-approved level at all times. *See Amgen*, 738 F.Supp.2d at 274 n. 9. Whether the brief increase to 19% overfill was properly disclosed to and approved by the FDA is also an issue for the factfinder. *See id.* These factual disputes bear primarily on the Relator's kickback claim, but they also may be relevant to the allegations that the Defendants marketed Aranesp in part by emphasizing that its vials contained more overfill than those of its competitor drug.

23 The Relator acknowledges that CMS could have reached the same result by mandating that overfill is to be included in a drug's ASP calculation, in which case a manufacturer like Amgen could have passed the cost of overfill onto the providers who, in turn, could have sought reimbursement for it. *See* Mem. Supp. Relator's Mot. Partial Summ. J. Amgen 18. Because CMS elected to exclude overfill from the ASP calculation, Amgen's ASP for Aranesp was properly calculated, but this does not exempt Amgen from liability if in fact it improperly represented overfill as reimbursable and promoted the reimbursement value of Aranesp's overfill to providers.

24 For the proposition that drug manufacturers must identify any and all assumptions made in calculating a drug's ASP, the Relator cites a "question and answer" posted on CMS's website. Mem. Supp. Relator's Mot. Partial Summ. J. Amgen 9 n. 11 (citing CMS Answers (published Sept. 16, 2004, updated Nov. 2, 2010)). It reads in full:

> Can manufacturers make assumptions with respect to a particular aspect of the Average Sales Price (ASP) calculation in the absence of specific guidance in the Social Security Act or Federal regulations?
>
> In the absence of specific guidance in the Social Security Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of Average Sales Price (ASP), consistent with the general requirements and the intent of the Social Security Act, Federal Regulations, and its customary business practices. These assumptions should be submitted along with the ASP data and the signed certification form.

CMS Answers. The Relator is correct that, before November 2010, overfill was not addressed in either the Medicare laws or regulations, such that, arguably, it was a matter with respect to which drug manufacturers could have made reasonable assumptions and should have reported those assumptions to CMS.

As Amgen points out, however, whether it failed to meet a reporting requirement with respect to assumptions made in the ASP calculation is distinct from whether it actually miscalculated Aranesp's ASP. Mem. Opp'n Relator's Mot. Partial Summ. J. Amgen 15. Thus, the Court need not decide whether this subregulatory, online "question and answer" stating that providers "should" submit their assumptions is sufficient to impose a legal reporting duty on drug manufacturers.

25 The Relator asks the Court to hold Amgen liable for the full amount paid by Medicare for every claim for Aranesp submitted since January 1, 2005, when ASP replaced AWP as the basis for Medicare reimbursement. Mem. Supp. Relator's Mot. Partial Summ. J. Amgen 19 & n. 19. Because these claims were not based on an artificially inflated ASP for Aranesp, and because Amgen's liability otherwise has not been established in the context of these cross-motions, there can be no damages calculation at this time. Likewise, the proper theory for assessing damages in a pricing case is irrelevant.

26 As required on motions for summary judgment, the factual summary presented here consists of undisputed facts as to which INN & ASD bear the burden of proof and disputed facts in the light most favorable to Relator, the non-moving party. The Court is to review the record as a whole, but "it must disregard all evidence favorable to the moving party that the jury is not required to believe." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 151, 120 S.Ct. 2097, 147 L.Ed.2d 105 (2000). Accordingly, the Court must disregard evidence in favor of INN & ASD—even if uncontradicted—that the jury would be free to disbelieve. *See id.*

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