UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA and STATE OF ILLINOIS, ex rel. JEFFERY GRAY,	)	
Plaintiff,	)	
v.	)	No. 15-cv-7137
UNITEDHEALTHCARE INSURANCE COMPANY; UNITED HEALTHCARE SERVICES, INC.; UHIC; UNITEDHEALTHCARE, INC.; and UNITEDHEALTH	)	Judge Thomas M. Durkin
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Relator Jeffery Gray brought this action against UnitedHealthcare Insurance Company and related entities (collectively, "United") seeking damages and civil penalties against United for violations of the False Claims Act (Count I) and the Illinois False Claims Act (Count II). Before the Court is United's motion to dismiss the operative Second Amended Complaint (R. 41). For the reasons explained below, United's motion is granted.

LEGAL STANDARD

A Rule 12(b)(6) motion challenges the sufficiency of the complaint. *See Hallinan v. Fraternal Order of Police of Chicago Lodge No. 7*, 570 F.3d 811, 820 (7th Cir. 2009). Under Rule 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under the federal notice pleading standards, a plaintiff's "factual allegations

must be enough to raise a right to relief above the speculative level." *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). "In evaluating the sufficiency of the complaint, [courts] view it in the light most favorable to the plaintiff, taking as true all well-pleaded factual allegations and making all possible inferences from the allegations in the plaintiff's favor." *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). A defendant may raise the statute of limitations in a motion to dismiss if "the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense." *United States v. Lewis*, 411 F.3d 838, 842 (7th Cir. 2005).

Additionally, it is well established that the FCA "is an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b)." *Thulin v. Shopko Stores Operating Co., LLC*, 771 F.3d 994, 998 (7th Cir. 2014). Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "The reference to 'circumstances' in the rule requires the plaintiff to state the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff [.]" *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 705 (7th Cir. 2015); *see also United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009) ("particularity . . . means the who, what, when, where, and how"). Nevertheless, courts should not "take an overly rigid view of the formulation," and the "requisite information . . . may vary on the facts of a given case." *Pirelli v. Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442

(7th Cir. 2011). Thus, although plaintiffs "'are not absolutely required to plead the specific date, place, or time of the fraudulent acts,'" they "still must 'use some alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" *Id.* (quoting 2 James Wm. Moore, Moore's Federal Practice § 9.03[1] [b], at 9-18 (3d ed. 2010)). Rule 9(b) requires a "plaintiff to do more than the usual investigation before filing [a] complaint. Greater precomplaint investigation is warranted in fraud cases because public charges of fraud can do great harm to the reputation of a business firm or other enterprise (or individual)." *Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999) (citations omitted).

BACKGROUND

A. The Medicare Advantage Program

The Medicare Act, 42 U.S.C. § 1395 et seq., establishes a federal health insurance program for disabled and elderly individuals. Parts A and B of the Act create the traditional, commonly-known Medicare program. Under this program, the Center for Medicare and Medicaid Services ("CMS") within the Department of Health and Human Services pays for medical care that eligible individuals receive from participating providers—e.g., doctors, hospitals, and medical groups. The government sets rates for the care and reimburses providers for each service provided. Accordingly, this program is often called Medicare "fee-for-service."

Part C of the Act creates the Medicare Advantage program. This program allows eligible individuals to receive healthcare benefits through private insurance

plans instead of through traditional Medicare. *See id.* § 1395w-21 et seq. Under Part C, a private insurer contracts with CMS to bear the health costs and manage the care of Medicare beneficiaries. The insurer creates a "Medicare Advantage plan" that provides at least the same level of benefits as provided by traditional Medicare. R. 31, Second Am. Compl., ¶ 5. In return, the federal government pays the plan set (or "capitated") per-member-per-month payments calculated to reflect the average amount the government would otherwise expect to spend providing care for those same individuals. The capitated amount is a fixed monthly payment regardless of the volume of services an enrollee uses.

Risk Adjustment Data. The capitated payments are adjusted by CMS based on "risk adjustment data" reported by Medicare Advantage organizations. The data includes information on their members' ages, genders, health and disability statuses, and whether members are receiving treatment or care in an institutional setting, such as a hospital or skilled nursing facility. *See* 42 U.S.C. § 1395w-23(a)(1)(C); *see also* 42 C.F.R. §§ 422.308, 422.310.

Information regarding health status is reported in the form of various codes, including diagnosis codes that describe their members' medical conditions. *See* 42 C.F.R. § 422.310(b). Physicians and other health care providers submit diagnosis codes to the Medicare Advantage organizations, which in turn submit them to CMS. These diagnosis codes contribute to an enrollee's risk score, which is used to adjust a base payment rate. The data submitted must be supported by properly documented medical records. *See* 42 C.F.R. § 422.310(e). This data ensures

Medicare Advantage "organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees)." Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588, 4657 (Jan. 28, 2005). The capitated payments are prospective—CMS uses risk adjustment data from the prior year to establish payments for the following year. 42 C.F.R. § 422.310(g).

Certification. Because the program lends itself to fraud, Medicare Advantage organizations must certify the accuracy, completeness, and truthfulness of the data they provide to CMS, including risk adjustment data, as a condition for receiving payment:

> As a condition for receiving a monthly payment under subpart G of this part, the [Medicare Advantage] organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data includes specified enrollment information, encounter data and other information that CMS may specify.

42 C.F.R. § 422.504(l).

B. Gray's Allegations

United is a Medicare Advantage provider. R. 31 ¶ 7. Gray was a Medicare Advantage beneficiary enrolled in United's plan. *Id.* ¶ 8. Gray's complaint stems from a service that United provided to its plan beneficiaries. Specifically, Gray alleges that in November 2014, United had a program called "HouseCalls" that sent licensed healthcare providers to beneficiaries' homes to conduct in-home physical

examinations. *Id.* ¶ 14. Gray initially declined the offer for a HouseCalls visit, but eventually accepted after he was offered a $25 Walmart gift card. *Id.* ¶ 15. In April 2015, a United nurse practitioner conducted an in-home examination at Gray's house. *Id.* ¶ 16. He received his gift card later that month. *Id.* ¶ 17. Gray alleges that he did not have a certification from his physician asserting that in-home services were medically warranted, and that United never asked him for such a certification. *Id.* ¶ 16. Gray, on "information and belief," believes that United has been offering its Medicare Advantage beneficiaries these services since at least 2012. *Id.* ¶ 19. He also alleges that the "vast majority of [United's] in-home examined beneficiaries were not certified as being medically warranted to receive an in-home examination." *Id.* ¶ 28. Finally, Gray alleges that CMS overpaid United to the extent its payments were based upon the diagnosis codes United obtained through its HouseCalls examinations. *Id.* ¶ 29. Gray does not identify any other United Medicare Advantage beneficiary who underwent this in-home examination. From the complaint, it does not appear Gray has any medical experience or training. *Id.* ¶ 4.

Gray asserts that the HouseCalls program was a fraudulent scheme intended to increase the capitated payments made to United each month. Gray contends that United was not legally permitted to submit diagnostic information identified through these in-home exams as risk adjustment data because the visits were not medically necessary or a covered benefit under United's plan. R. 31 ¶¶ 11, 21. Gray also asserts that the free in-home clinical visits and the gift cards offered to

beneficiaries violate the Anti-Kickback Statute. *Id.* ¶ 30. Because these visits were not covered and the "incentives" violated the Anti-Kickback Statute, Gray alleges United's periodic certifications under 42 C.F.R. § 422.504(l) were false because they were not "accurate, complete, and truthful," in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1).

The United States and Illinois have declined to intervene. R. 10. United has moved to dismiss. R. 41.

DISCUSSION

I. The False Claims Act[1]

The False Claims Act permits "both the Attorney General and private *qui tam* relators to recover from persons who make false or fraudulent claims for payment to the United States." *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 (2010). Liability under the False Claims Act can be predicated on a number of acts, including as relevant here: "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim," § 3729(a)(1)(B); "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to an obligation to pay or

[1] Because "[t]he statutory language and standards for the [federal False Claims Act] and the [Illinois False Claims Act] are substantially the same," the "analysis of the federal statute applies equally to [Gray's] claims under the state statute." *United States ex rel. Bellevue v. Universal Health Servs. of Hartgrove, Inc.*, 2015 WL 1915493, at *4 n.1 (N.D. Ill. Apr. 24, 2015) (citing *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 704 n.5 (7th Cir. 2014)).

transmit money or property to the Government, or knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government," § 3729(a)(1)(G);[2] or "conspir[ing] to commit a violation" of those provisions, § 3729(a)(1)(C).

To establish civil liability under the False Claims Act, Gray must allege that (1) United made a statement in order to receive money from the government; (2) the statement was false; (3) United knew the statement was false; and (4) the false statement was material to the government's decision to pay or approve the false claim. *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 561 (7th Cir. 2015).

"In an archetypal *qui tam* False Claims action, such as where a private company overcharges under a government contract, the claim for payment is itself literally false or fraudulent." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170 (9th Cir. 2006). Here, however, Gray does not allege United made any direct claims for payment to the government. Rather, his complaint alleges a false certification theory of liability. Such theories bring "a claim under the False Claims Act [when] a party merely falsely certifies compliance with a statute or

[2] A violation of subsection (G) is known as a "reverse false claim" because rather than fraudulently receiving money from the government, the defendant fraudulently retains money it is obligated to pay to the government. Gray's allegations are all premised on United fraudulently receiving money, and Gray has not alleged an obligation of United to pay money to the government separate from the money it received via fraudulent statements. A number of courts have dismissed similar reverse false claims as redundant of the subsection (A) and (B) claims. *See United States ex rel. Myers v. Am.'s Disabled Homebound, Inc.,* 2018 WL 1427171, at *3 (N.D. Ill. Mar. 22, 2018) (collecting cases).

regulation as a condition to government payment." *Id.* at 1171. Under a false certification theory, "it is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." *Id.* Courts have recognized both express and implied false certification theories of liability.

Under an express false certification theory, Gray would need to allege that United "falsely and specifically certif[ied] that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *United States ex rel. Cieszyski v. LifeWatch Servs., Inc.*, 2015 WL 6153937, at *6 (N.D. Ill. Oct. 19, 2015). Gray hints at such a theory by alleging that as an express condition of payment under Part C, United certified that to its "best knowledge, information, and belief," the diagnosis codes it submitted as risk adjustment data were "accurate, complete, and truthful, and that such services are covered." R. 31 ¶ 28. But the regulation only requires that the certification attest that the data is "accurate, complete, and truthful." 42 C.F.R. § 422.504(l). There is no requirement that the services be covered. And because Gray does not allege that the data was not accurate, complete, or truthful, he cannot succeed on an express false certification theory. *Cf. United States ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C.*, 2016 WL 5661644 at *6 (N.D. Tex. Sept. 30, 2016) (alleging that the defendant submitted millions of diagnosis codes to CMS that were unsupported and incorrect for the purpose of improperly inflating capitated payments).

Instead, Gray's allegations resemble an implied false certification theory. Under that theory, a knowing failure to disclose a violation of a statutory, regulatory, or contractual requirement may render a claim for payment fraudulent and actionable under the False Claims Act. *See Universal Health Servs., Inc. ex rel. Escobar v. United States*, 136 S. Ct. 1989, 1999 (2016). But as the False Claims Act and cases interpreting it make clear, only those false statements that are *material* to a funding obligation are violations. *See* 31 U.S.C. § 3729(a)(1) (false statements material to a claim or obligation to pay are violations); *Marshall*, 812 F.3d at 561 (to state a False Claims Act violation, the plaintiff must allege a false statement that was *material* to the government's decision to pay or approve the false claim); *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) ("[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulation."). Statutory, regulatory, and contractual requirements, even if labeled conditions of payment, are not automatically material. *Escobar*, 136 S. Ct. at 2001. Instead, the term "material" means having "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Accordingly, a determination of materiality necessarily requires looking at the "effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002.

Despite its seemingly fact-intensive nature, materiality is an issue upon which courts may base a False Claims Act dismissal. *Id.* at 2004 n. 6. False Claims Act plaintiffs must "plead their claims with plausibility and particularity under

Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Id*. To meet the strict materiality standard, Gray must allege that the violations at issue "are so central . . . that the [government] would not have paid these claims had it known of these violations." *Id.* at 2004. One way a False Claims Act plaintiff might adequately plead a requirement's materiality is by alleging that the government consistently refuses to pay claims that violate that particular statutory, regulatory, or contractual requirement, i.e. that violate a "material" funding requirement. *Id*. at 2004.

Gray's claim assumes that the in-home examinations were improper, and that as a result of United's improper submission and certification of the data obtained from those exams, the government mistakenly overpaid. But, as described below, CMS (the governmental entity that pays Medicare Advantage plans) has stated that it will not exclude, for payment purposes, diagnoses obtained through in-home examinations. Gray also fails to identify any violated regulations indicating data from in-home examinations is material to CMS's determination of the capitated payment amount. As a result, Gray fails to allege that United's actions violated a material funding requirement.

A. CMS Decision

In April 2014, CMS released an announcement discussing in-home examinations.[3] It recognized the risk that in-home examinations may be "used

[3] Gray cites the Call Letters in his complaint and his response to United's motion to dismiss, and attaches the 2016 Call Letter to his response. R. 31 ¶ 20; R. 53 at 13, R. 53-1. Courts may take judicial notice of facts that are "not subject to reasonable

primarily for the gathering of diagnoses for payment rather than to provide treatment and/or follow-up care to beneficiaries." Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 27 (April 7, 2014).[4] To mitigate this risk, CMS instituted a new requirement for Medicare Advantage organizations to identify which diagnoses submitted are from home visits. *Id*. CMS planned to study the data to determine whether to exclude such diagnoses from its calculation of capitated payments in the future, but chose not to initially exclude them. *Id*. at 28.

In April 2015, CMS issued another announcement, providing additional guidance to Medicare Advantage plans regarding in-home examinations. Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 144-146 (April 6, 2015) ("2016 Call Letter").[5] In its section titled "Guidance for In-Home Enrollee Risk Assessments," it again chose not to prohibit in-home risk assessments, but rather "encouraged plans to adopt, . . . a core set of components for the in-home assessments they perform, and track subsequent provided care." It again expressed its concern regarding the in-home risk assessments, noting "in-

---

dispute because [they] . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). This includes "agency letters, policy and guidance documents, websites, and other agency data made available to the public . . . by administrative agencies." *In re Frito-Lay N. Am., Inc. All Nat. Litig.,* 2013 WL 4647512, at *4 (E.D.N.Y. Aug. 29, 2013) (listing cases).

[4]Available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2015.pdf.

[5]Available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf.

home assessments [may be] merely a strategy by [Medicare Advantage] plans to find and report more diagnosis codes to CMS, generating higher levels of coding and, therefore, payment." *Id.* at 145. CMS wanted to ensure that the enrollees' providers "actually receive and use the information collected in these assessments and that the care subsequently provided to enrollees is substantially changed or improved as a result of the assessments." *Id.*

But in its discussion, CMS also noted that "in-home assessments can have significant value as care planning and care coordination tools" because in the home setting, "the provider has access to more information than is available in a clinical setting" such as the ability to evaluate the home for potential risks. *Id.* To allow Medicare Advantage plans to take advantage of the opportunity afforded by in-home assessments, CMS did not prohibit plans from conducting those examinations, but rather encouraged them to develop best practices, including by ensuring that in-home assessments be performed by physicians or qualified non-physician practitioners, and by making referrals or connections to ensure appropriate follow-up care and treatment. *Id.* at 146. CMS also vowed to continue to track the data submitted regarding the in-home assessments.[6]

Accordingly, CMS has approved the use of in-home examinations, despite the drawbacks Gray recognizes in his complaint. As the Supreme Court noted, if "the

[6] The most recent Call Letter, dated April 2018, confirmed that CMS is continuing to monitor Medicare Advantage plans' use of in-home assessments to ensure that they are meaningful and effective for beneficiaries' clinical conditions. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 37 (April 2, 2018).

Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Escobar*, 136 S. Ct. at 2003-04. The CMS Call Letters are strong evidence that the in-home examinations are not material to CMS's determination of capitated payments. This is the fundamental flaw in Gray's theory. He cannot allege United's use of in-home examinations "are so central . . . that the [government] would not have paid these claims had it known of these violations," *id.* at 2004, because CMS has determined that it will not refuse to pay claims based on data obtained from in-home examinations. If, at a later date, CMS decides that the use of in-home examinations is material to its decision to pay capitated payments, then a claim may be appropriate. But Gray cannot bring a False Claims Act complaint simply because he finds fault with CMS's decision to consider risk adjustment data received from in-home examinations.

B. Alleged Violations

Gray also fails to show that the regulations United allegedly violated by conducting in-home examinations are material to CMS's determination of the capitated payment amount. Gray alleges that United violated the Medicare Act and the Anti-Kickback Statute because (a) only diagnosis codes resulting from covered services can be submitted to CMS for risk adjustment data; (b) the majority of United's in-home examined beneficiaries were not certified as medically warranted to receive an in-home examination; (c) the in-home examinations were not a CMS-

approved supplemental benefit; and (d) the data was obtained through illegal kickbacks. R. 31 ¶ 28.

Before delving into each violation, the Court must address an overarching assumption made by Gray. He assumes that fraud through traditional fee-for-service and fraud through Medicare Advantage providers is the same. This cannot be the case. Traditional Medicare is potentially harmed every time a service is provided that is not medically necessary or covered, or every time a patient is misdiagnosed leading to additional and unnecessary services. The government is not harmed when this happens with Medicare Advantage providers because those plans necessarily take on the risk that traditional Medicare normally assumes. Unlike traditional Medicare, CMS does not pay for every service provided through Medicare Advantage. Rather, it pays Medicare Advantage plans a set, monthly payment regardless of the number of uncovered, unnecessary, or excessive services provided. Unnecessary services lead to increased capitated payments the following year only if they reveal diagnoses that increase the risk profile of the plan's beneficiaries. But the government is harmed only when the plans make false diagnoses and report that information, causing CMS to pay Medicare Advantage plans a greater capitated amount than it would otherwise pay. If the diagnoses made and information provided were not false, then there is no harm to the government (at least no harm which is enforceable through the False Claims Act). Instead, Medicare Advantage plans are entitled to those increased capitated payments because their risk profile has increased. For example, had the individual

been diagnosed with the same condition through an annual wellness visit (rather than an "unnecessary" in-home examination), the government would likewise have to pay the plan increased capitated payments the following year. And this is how the program works—the government pays Medicare Advantage plans approximately the amount traditional Medicare would have to pay were it to cover those beneficiaries. A less healthy individual costs the government more, regardless of whether that individual is covered through traditional Medicare or Medicare Advantage.

But because the program shifts the risk from traditional Medicare to Medicare Advantage, Medicare Advantage plans have an incentive to reduce unnecessary services, not encourage them—they pay the difference in the costs they actually incur over the monthly payments received from CMS. Rather than waiting for medical services to become too difficult or costly (to United) to treat, United encouraged a type of preventative visit—an in-home assessment—to catch medical issues early and reduce its risk in treating its plan participants. Again, this is how the program is intended to work—by encouraging Medicare Advantage plans to provide the same coverage as traditional Medicare—but more efficiently. Of course, there is the risk that plans will provide services to affect data to increase their capitated payment amount. But without a false submission, this practice is not a violation of the False Claims Act. After all, a false claim is the "sine qua non of a False Claims Act violation." *United States v. Kitsap Physicians Serv.,* 314 F.3d 995, 1002 (9th Cir. 2002).

With this background, the Court's analysis of each alleged violation is not whether the violation is material to the government's decision not to pay claims under traditional Medicare. Rather, the Court views each violation through the lens of whether it is material to CMS's determination of the capitated payment amount.

1. Submitting Diagnosis Codes

42 C.F.R. § 422.310 requires Medicare Advantage plans to "submit . . . the data necessary to characterize the context and purposes of *each* item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner." 42 C.F.R. § 422.310(b) (emphasis added). It goes on to require risk adjustment data to account for the following:

> (i) Items and services covered under the original Medicare program.
> (ii) Medicare covered items and services for which Medicare is not the primary payer.
> (iii) Other additional or supplemental benefits that the MA organization may provide.

Id. § 422.310(c)(1).

Nothing in 42 C.F.R. § 422.310(b) prohibits United from conducting in-home examinations. The examinations then become a "service provided to a Medicare enrollee," and are required to be accounted for in the risk adjustment data. Further, traditional Medicare coverage allows for in-home examinations in some circumstances, such when the care is deemed "medically reasonable and necessary." 2016 Call Letter at 145. In the Call Letter, CMS explicitly stated that "[Medicare Advantage] plans may have less restrictive coverage terms for covering home health and/or in-home visits as a supplemental benefit," *id*., indicating the in-home

examinations may fall into the category of "supplemental benefits." In that case, United would be required to submit that data under 42 C.F.R. § 422.310(b).[7] But again, Gray does not allege that United submitted false data, only that it submitted data from services that were not covered. Nothing in the regulation suggests that CMS would not consider truthful data received from in-home examinations in its calculation.

2. Medically Unnecessary Services

Gray next argues United violated 42 U.S.C. § 1320a-7a(a)(1)(E) by providing medically unnecessary services. R. 53 at 20. This provision imposes civil monetary penalties on any person who submits a claim for medical services that are "not medically necessary." Along with this provision, Gray cites to a number of Medicare manuals that prohibit providers from billing Medicare for medically unnecessary services, and also to 42 C.F.R. § 411.15(k)(1) that excludes from Medicare coverage any services that are "not reasonable and necessary" "for the diagnosis or treatment of illness or injury."

[7] Gray argues that although the phrase "additional" benefits remains in the provision, that portion has been abolished by CMS through the Medicare Advantage program. But even if the in-home examinations only fall into the "additional" benefits category, Gray does not explain why that word is superfluous. CMS only removed "'additional benefits' from the definition of 'basic benefits.'" Medicare Program; Establishment of the Medicare Advantage Program, 70 FR 4588-01, 4594 (Jan. 28, 2005). It did not remove "additional" benefits from § 422.310, which governs risk adjustment data. And even if "United has never been allowed to provide non-covered or non-CMS approved additional or supplemental benefits to its [Medicare Advantage] enrollees," R. 53 at 24, Gray does not point to any regulations that prohibit Medicare Advantage plans from submitting that information as risk adjustment data.

But Gray fails to provide any details as to why the in-home examinations were not medically necessary. *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770 (7th Cir. 2016) is instructive. In *Presser*, a qui tam relator brought a False Claims Act claim alleging that a mental health clinic's four-person evaluation process was not reasonable or necessary for the diagnosis or treatment of the illness or injury at issue. The Seventh Circuit affirmed the dismissal of her allegations for failure to state a claim of fraud with particularity, noting she provided "no medical, technical, or scientific context which would enable a reader of the complaint to understand why Acacia's alleged actions amount to unnecessary care forbidden by the statute." *Id*. at 779. Although the relator identified four specific individuals who received treatment that was allegedly medically unnecessary, the allegations were based entirely on her own personal opinion which was "not supported in any concrete manner." *Id*. at 780.

In *Presser*, the relator was a nurse practitioner with over 20 years of experience and an employee of the defendant who had personal knowledge of the conduct at issue. Despite her qualifications, the Seventh Circuit held that she failed to allege why the policies and practices at issue were false other than with her own opinion that the services were not medically necessary. *Id*. Here, Gray's knowledge of the conduct at issue is based on one examination—his own. He has no knowledge that United conducted these in-home examinations on anyone else, and has no medical experience to know why the services are medically unnecessary. Like in *Presser*, his allegations depend entirely on his own personal beliefs that the

examinations are not medically necessary, but those allegations are not supported in any concrete manner.

Gray does allege that at the time of his examination, he did not have a certification from his treating physician that the in-home examination was medically warranted. R. 31 ¶ 16. But a certification of homebound status is a requirement only for "home health services," which include in-home skilled nursing, speech, or occupational therapy provided by registered nurses and therapists. *See* 42 C.F.R. § 409.42(a)-(c) (to qualify for home health services, the beneficiary must be confined to the home, be under the care of a physician, and need "skilled services" including skilled nursing services, physical therapy services, speech-language pathology, and occupational therapy services); 42 C.F.R. § 440.70(b) ("Home health services include . . . nursing service . . . home health aide service . . . medical supplies, equipment, and appliances . . . physical therapy, occupational therapy, or speech pathology and audiology services"); 42 C.F.R. § 424.22(a)(1)(i). In-home visits by a physician, on the other hand, are covered when "care is medically reasonable and necessary." 2016 Call Letter at 145. But what Medicare considers medically necessary for purposes of covered in-home services may not be the same as what Medicare Advantage plans deem to be medically necessary. *Id.* ("MA plans may have less restrictive coverage terms for covering home health and/or in-home visits as a supplemental benefit."); s*ee also* Medicare Management Care Manual, Ch. 4 § 10.2 ("While an MA plan may offer additional coverage as a

supplemental benefit, it may not limit the original Medicare coverage.").[8] Without particularized allegations as to why United's in-home examinations amount to unnecessary care under 42 U.S.C. § 1320a-7a(a)(1)(E), Gray's allegations fail.

3. Not Covered as Supplemental Benefits

Gray's allegations that the in-home examinations were not covered as a supplemental benefit in United's plan also fail. The regulations Gray cites describe what services Medicare Advantage plans must provide, not what they are prohibited from providing. For example, 42 C.F.R. § 422.100 requires Medicare Advantage plans to provide, at a minimum, all Medicare-covered services. It also allows plans to cover supplemental benefits not usually covered by Medicare, consisting of mandatory supplemental benefits that a Medicare enrollee must purchase, and optional supplemental benefits that the enrollee may choose to purchase. 42 C.F.R. § 422.100(c)(2). The supplemental benefits must be offered to all Medicare beneficiaries residing in the service plan area and must be offered at a uniform premium. 42 C.F.R. § 422.100(d). CMS reviews the plan's benefits to ensure that it meets the fee-for-service guidelines, that the plans do not discriminate against beneficiaries, and that they comply with other Medicare Advantage program requirements. 42 C.F.R. § 422.100. There is no indication that in-home

[8] Throughout his response to the motion to dismiss, Gray string cites to a number of regulations without any additional explanation of the regulation. *See* R. 53 at 13, 17. The Court has addressed what it perceives to be the relevant regulations in the body of this opinion. But the Court is not required to make Gray's arguments for him and will not scour Medicare regulations looking for ways to impose liability on United. If Gray can point to regulations or cases that indicate United violated a material funding requirement, he may address them in any motion to amend the complaint.

examinations are prohibited, or that CMS refuses to consider data from additional services. Likewise, 42 C.F.R. § 422.101(b) specifies that Medicare Advantage plans must comply with national and local coverage guidelines to ensure they provide coverage for all of the same services covered by Medicare Parts A and B. 42 C.F.R. § 422.101(a). 42 C.F.R. § 422.254(a) and the Medicare Management Care Manual, Ch. 4 § 30.1 et. seq, govern submission of bids and specify what types of services may be provided as supplemental benefits. But neither prohibits United from submitting data from those uncovered services as risk adjustment data. And none of the Medicare manuals Gray cites indicate that providing inappropriate *additional* supplemental benefits is a material funding requirement for capitated payments. *See* R. 53 at 20.

Gray argues "the only way that United can increase its 'coverage' to its beneficiaries is by requesting and obtaining approval of a supplemental benefit, such as in-home exams, from CMS as part of United's annual bid submission." R. 53 at 19. Even if this is true, United's failure to obtain that approval does not make it a material funding requirement. The Supreme Court rejected precisely that argument in holding that a plaintiff cannot merely allege a violation of a statute or regulation to bring a False Claims Act. "The False Claims Act does not adopt such an extraordinarily expansive view of liability." *Escobar*, 136 S. Ct. at 2004.

4. The Anti-Kickback Statute

Finally, Gray alleges United violated the Anti-Kickback Statute by providing in-home examinations for free and by providing $25 Walmart gift cards. The Anti-

Kickback Statute criminalizes "offer[ing] or pay[ing] any remuneration" to "induce" a person to "purchase, lease, order, or arrange for . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). A violation of 42 U.S.C. § 1320a-7b(b)(2)(B) constitutes a false or fraudulent claim under the False Claims Act. *Id*. § 1320a-7b(g).

While United receives capitation payments from a Federal health care program generally, the alleged remuneration, even if it does induce enrollees to schedule in-home examinations, does not induce payment to be made for those services. In his response to the motion to dismiss, Gray succinctly describes the scheme he alleges violates the Anti-Kickback Statute—"United's offer of gift cards and free uncovered in-home examinations to its MA beneficiaries to induce them to utilize United's HouseCalls in-home examination services results in United generating ICD-9 (diagnosis) codes from such services, which United submits to CMS, thus increasing such examined MA beneficiaries' risk adjustment scores and resulting in CMS's increased capitated payments to United in connection with such beneficiaries." R. 53 at 16. Thus, to induce payment to United, the alleged kickbacks must go through a number of steps. First, United must schedule an in-home examination. The examination must result in a diagnosis of some condition that was not previously discovered and that would result in a higher risk designation by CMS. United then submits that diagnosis, along with information on a number of other factors, including age, gender, health, and disability status. CMS then uses all

of the collected data to calculate the capitated payments to United for the following year. This theory also assumes that the enrollee would not have otherwise gone to a physician—or the emergency room—so that United would recover that data through "uninduced" means. This theory is too speculative and Gray provides no concrete allegations to support its plausibility.

Gray also fails to point to any case law that supports his theory. Instead, the cases he does cite demonstrate the distinction between this case and those involving actual inducements. For example, in *United States v. Patel*, 778 F.3d 607 (7th Cir. 2015), the owners of a home health services provider approached Patel, a doctor, offering to pay him for "referrals" he made to their company. After the offer, a few, but not the majority, of Patel's patients used the company for their home health care services. *Id*. at 610. The provider was then reimbursed by Medicare for services provided to Patel's patients. *Id*. at 612. The Seventh Circuit held that Patel's receipt of a kickback for his referral was a practice Congress intended to criminalize under the Anti-Kickback Statute. *Id*. at 616. In *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011), Borrasi accepted a salary from a hospital in exchange for continually referring patients to the hospital. The referrals allowed the hospital to maximize its Medicare reimbursement claims. *Id*. at 777. The Seventh Circuit held that the part of his salary that compensated past referrals or induced future referrals violated the Anti-Kickback Statute. *Id*. at 782. *See also United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 757 (S.D.N.Y. 2015) (free housing increased costs to Medicaid because Medicaid reimbursed defendant for the drug services offered in connection

with the free housing and the free housing created a "strong incentive" to overuse defendant's drug treatment programs).

In these cases, it was clear that the injured party was the government because Medicare/Medicaid paid for the services provided. Patel and Borrasi both made referrals that caused other parties to increase their Medicare reimbursement claims. Both Patel and Borrasi also received payment for their services, either in the form of a feigned salary, or in the form of cash. Here, however, United has neither received a kickback for its remunerations nor has Medicare been injured through increased reimbursements. *See United States v. Grp. Health Co-op.,* 2011 WL 814261, at *2 (W.D. Wash. Mar. 3, 2011) (under a capitated payment system, "the government is not spending additional money when an individual [service] is performed."). Rather, United paid for the in-home examinations itself, and then provided services to its plan participants free of charge. This does not violate the purpose of the Anti-Kickback Statute—"to prevent kickbacks from influencing the provision of services that are *charged to Medicare*." *Patel*, 778 F.3d at 616-17. Unlike in *Narco Freedom*, there is also no incentive to over-utilize—there is no guarantee United will recover high-risk data from the in-home examinations. Gray's theory requires too many assumptions and lacks concrete details to allege a violation of the Anti-Kickback Statute.[9]

[9] Because the Court holds neither the free in-home examinations nor the gift cards constitute inducements to cause payment from the government, the Court need not reach United's alternate arguments that the services are protected by the Anti-Kickback Statute's safe harbor provision, 42 C.F.R. § 1001.952(l), or are specifically allowed by the Medicare Rewards and Incentive Program, 42 C.F.R. § 422.134.

* * *

In sum, Gray has not pled with the requisite particularity that any of the alleged violations were so material that the government would refuse payment were it aware of the violation. *Escobar*, 136 S. Ct. at 2004. Gray does not meet the strict materiality showing required to state a claim under the False Claims Act.

II. Leave to Amend

In his response to United's motion to dismiss, Gray asks the Court for leave to amend. Leave to amend a complaint should be "freely given" when justice so requires. Fed. R. Civ. P. 15(a)(2). However, leave need not be given when "there is undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice to the defendants, or where the amendment would be futile." *Right Field Rooftops, LLC v. Chicago Cubs Baseball Club, LLC*, 870 F.3d 682, 693 (7th Cir. 2017). The Court is not convinced that Gray can amend the deficiencies in his complaint based on the alleged scheme. Nevertheless, in the interest of justice, the Court will grant Gray the opportunity to file a motion for leave to amend that

---

However, Gray's allegations that United violated the Rewards and Incentive Program because it only offered gift cards to certain beneficiaries, R. 31 ¶ 24, are not well-supported. Gray has no knowledge of to whom United offered gift cards and whether those alleged offerings discriminated on the basis of race, national origin, gender, disability, chronic disease, or any of the other prohibited categories described in 42 C.F.R. § 422.134(b)(1). Likewise, he fails to allege that United discriminated against enrollees by offering the in-home examinations to some participants but not others. 42 C.F.R. § 1001.952(l)(1)(i) (for the Anti-Kickback Statute safe harbor to apply, United "must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare . . . enrollees covered by the contract unless otherwise approved by CMS."). Further, Gray offers no allegations, other than his opinion, to suggest the free in-home examinations or the gift cards were not an efficient use of health resources. *See* R. 31 ¶ 24.

describes how an amended complaint would cure the deficiencies raised in this opinion.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss the Second Amended Complaint, R. 41, is granted without prejudice. If Relator believes he can cure the deficiencies identified in this opinion, he may file a motion for leave to file an amended complaint on or before July 3, 2018. The motion should attach a redlined comparison between the current complaint and the proposed amended complaint, and it should be supported by a brief of no more than five pages describing how the proposed amended complaint cures the deficiencies in the current complaint. Defendants are not to file a response unless directed to do so by the Court.

ENTERED:

Thomas M Durkin

Dated: June 12, 2018

Honorable Thomas M. Durkin
United States District Judge