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

UNITED STATES, ex rel. DR. SUSAN NEDZA, Relator, v. AMERICAN IMAGING MANAGEMENT, INC., et al., Defendants.	Case No. 15-cv-6937 Judge Alonso Magistrate Judge Cox

MOVANTS' MOTION TO DISMISS
RELATOR'S SECOND AMENDED COMPLAINT

Defendant American Imaging Management, Inc. ("AIM") and its ultimate parent, Defendant Anthem, Inc. (collectively, "AIM Defendants"), as well as Defendants Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Health Plans, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross Blue Shield Healthcare Plan of Georgia, Inc., Community Insurance Company, Compcare Health Service Insurance Corp., Empire HealthChoice HMO, Inc., Empire HealthChoice Assurance, Inc., HMO Colorado, Inc., HMO Missouri, Inc., Blue Cross of Idaho Care Plus, Inc., PacificSource Community Health Plans and Moda Health Plan, Inc. (the "MA Plan Defendants" and together with the AIM Defendants, "Movants")[1] hereby move this Court to dismiss with prejudice all claims asserted against them by Relator Dr. Susan Nedza ("Relator") in the Second Amended Complaint (Dkt. 121) ("SAC").

[1] Movants' Memorandum In Support Of Defendants' Motion to Dismiss Relator's Second Amended Complaint, filed contemporaneously herewith, incorporates the definitions of "AIM Defendants," "MA Plan Defendants," and "Movants" as set forth in this Motion.

In particular, dismissal is proper pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b) because Relator's allegations do not meet the heightened pleading standard for fraud-based claims under Fed. R. Civ. P. 9(b) and otherwise fail to state a claim against the Movants upon which relief can be granted. Specifically, Relator has failed to identify any claims that were submitted to the government, let alone any claims that were purportedly false or fraudulent. Similarly, Relator has failed to identify a single false statement or certification that was made to the government. Relator's SAC also fails because it is based on a legal theory that is untenable and cannot provide the basis for a violation of the FCA and because Relator's claims are impermissibly based upon public disclosures. The SAC should be dismissed as to the Movants, with prejudice.

The Movants also join in other Defendants' Motions to Dismiss, as appropriate, and will confirm by docket number which Motions are joined in the Parties' Joint Status Report, to be filed on April 2, 2018.

This Motion to Dismiss is supported by an accompanying memorandum of law.

Dated: March 13, 2018

Respectfully submitted,

/s/ Lisa M. Noller
Lisa M. Noller
Patrick J. McMahon
Foley & Lardner LLP
321 North Clark Street, Suite 2800
Chicago, Illinois 60654-5313
Telephone: 312.832.4500
Facsimile: 312.832.4700
lnoller@foley.com
pmcmahon@foley.com

Michael J. Tuteur (admitted *pro hac vice*)
Jessica E. Joseph (admitted *pro hac vice*)
Foley & Lardner LLP
111 Huntington Avenue
Boston, MA 02199
Telephone: 617.342.4000

mtuteur@foley.com
jjoseph@foley.com

Attorneys for Movants

/s/ David M. Goldhaber
David M. Goldhaber
Michael J. O'Malley
Wilson Elser Moskowitz Edelman & Dicker LLP
55 West Monroe Street- Suite 3800
Chicago, Illinois 60603-5001
Telephone: 312.704.0550
Facsimile: 312.704.1522
david.goldhaber@wilsonelser.com
michael.o'malley@wilsonelser.com

Attorneys for Moda Health Plan, Inc.

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

UNITED STATES, ex rel. DR. SUSAN NEDZA, Relator, v. AMERICAN IMAGING MANAGEMENT, INC., ANTHEM INC., ANTHEM HEALTH PLANS OF KENTUCKY, INC., ANTHEM HEALTH PLANS OF NEW HAMPSHIRE, INC., ANTHEM HEALTH PLANS, INC., ANTHEM INSURANCE COMPANIES, INC., BLUE CROSS OF CALIFORNIA, BLUE CROSS AND BLUE SHIELD OF GEORGIA, INC., BLUE CROSS AND BLUE SHIELD HEALTHCARE PLAN OF GEORGIA, COMMUNITY INSURANCE CO., COMPCARE HEALTH SERVICE INSURANCE CORP., EMPIRE HEALTHCHOICE HMO, INC., EMPIRE HEALTHCHOICE ASSURANCE, INC., HEALTH FIRST HEALTH PLANS, INC., HMO COLORADO, INC., HMO MISSOURI, INC., BLUE CROSS OF IDAHO CARE PLUS, INC., BLUE CROSS BLUE SHIELD OF MICHIGAN MUTUAL INSURANCE COMPANY, BLUE CROSS AND BLUE SHIELD OF NORTH CAROLINA, MODA HEALTH PLAN, INC., PRIORITY HEALTH, PROVIDENCE HEALTH PLAN, PROVIDENCE HEALTH ASSURANCE, REGENCE BLUECROSS BLUESHIELD OF OREGON, REGENCE BLUECROSS BLUESHIELD OF UTAH, REGENCE BLUESHIELD, REGENCE BLUE SHIELD OF IDAHO, ASURIS NORTHWEST HEALTH, AND PACIFICSOURCE COMMUNITY HEALTH PLANS, Defendants.	Case No. 15-cv-6937 Judge Alonso Magistrate Judge Cox

MEMORANDUM IN SUPPORT OF MOVANTS'[1] MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

[1] Movants incorporate the definitions of "AIM Defendants," "MA Plan Defendants," and "Movants" set forth in Movants' Motion to Dismiss Relator's Second Amended Complaint being filed simultaneously

TABLE OF CONTENTS

herewith. The "MA Plan Defendants" provide Medicare Advantage (MA) benefits to Medicare members; the "AIM Defendants" do not. Where appropriate, the AIM Defendants and the MA Plan Defendants will be referred to collectively herein simply as "Defendants."

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

AIM contracts with its customers, such as the MA Plan Defendants here, to provide utilization management (UM) services to their members. UM is a process – recognized and accepted by the Centers for Medicare and Medicaid Services (CMS) – employed to evaluate certain medical services to determine whether they are medically necessary and appropriate for a particular patient's clinical presentation. Medicare Advantage Plans, like the MA Plan Defendants, receive a capitated amount to provide care for each beneficiary and rely on UM processes to save taxpayers and the government money by ensuring that medically unnecessary services are not authorized and paid for.[2] Relator and former AIM employee Susan Nedza's Second Amended Complaint (SAC) challenges this well-recognized and accepted UM framework by alleging that whenever UM results in a savings or a higher than average claims denial rate than regular fee-for-service Medicare, that result leads ineluctably to a federal false claim. Relator's allegations have no legal support, are pled without sufficient particularity as to any of the defendants, and should all be dismissed with prejudice.[3]

The SAC suffers from pleading deficiencies and cannot satisfy even the pleading standards of Federal Rule of Civil Procedure 8, let alone the more rigorous particularity standard of Rule 9(b). Relator has failed to identify any claims that were submitted to the government, to say nothing of any claims that were purportedly false or fraudulent. Similarly, Relator has failed to identify a single false statement that was made to the government. In fact, the SAC is bereft of any details or information regarding any specific claims or statements that satisfy the

---

[2] For a detailed discussion about the purpose of Medicare Advantage programs and the savings they generate, *see* U.S. Gov't Accountability Off., GAO-11-247R, *Medicare Advantage: Comparison of Bid Plans to Fee-for-Service Spending by Plan and Market Characteristics* (2011).

[3] Relator will not be able to cure the defects in the SAC by re-pleading and should not be allowed to further investigate this matter in an effort to amend. *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740 (7th Cir. 2007).

mandatory pleading requirements. Moreover, Relator's SAC fails because it is based on a legal theory that is untenable and cannot provide the basis for a violation of the FCA and because Relator's claims are impermissibly based upon public disclosures.

First, despite her direct involvement in drafting AIM's clinical guidelines, Relator has not alleged any specifics about which particular guidelines violated which Medicare "rules." This amounts to a failure to state a claim as a matter of law because she has not pled any claims with the necessary particularity required under Fed. R. Civ. P. 9(b). She provides no detail as to any particular patients who did not receive a service covered by their MA Plan, no MA Plan that inappropriately denied coverage, and no description of any false claim that any particular Defendant submitted to the government for payment, or any false statement made to support any claim. Instead, Relator generally alleges facts about AIM's processes amounting to (at most) a breach of contract claim (that she has no standing to pursue), which she then seeks to convert into a claim under the False Claims Act, 31 U.S.C. § 3729, *et seq.* (FCA), by alleging noncompliance with Medicare guidance documents.

Relator also tries to allege an implied certification theory of liability by claiming the MA Plan Defendants falsely certified compliance with "rules" when they agreed to follow UM protocols established by CMS. Though she generally alleges certifications were false, she identified no specific certification, she described no defendant's submission, and she linked no certification to any claim or payment. Boldly claiming the MA Plan Defendants' contracts were false (*see, e.g.*, SAC ¶ 156), without the details required by the FCA and federal law, cannot give rise to an FCA violation. This is particularly so in the Seventh Circuit, which rejected implied certification based on generic statements as a liability theory before the Supreme Court decided

Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016), and reaffirmed its position since.

Second, Relator's SAC fails as a matter of law because she has not shown there was anything improper or unreasonable about AIM's approach to coverage determinations; nor that, even if there were, the government would have considered that approach material to its payment decisions. Indeed, Relator herself alleges the government was aware through its own audits of AIM's UM approach, and made no changes in its payments to the MA Plan Defendants. Relator has not pled facts that satisfy the rigorous materiality requirements the Supreme Court has mandated in *Escobar*.

Finally, and equally fatal, Relator's claims against Defendants are based entirely on publicly available information of which Relator is not an original source. Her claims are barred by the FCA's public disclosure and original source provisions and should be dismissed.

FACTUAL BACKGROUND

Medicare is a federally-funded health insurance program that covers certain medical expenses for persons who are over 65, disabled, or suffer from end stage renal disease. SAC ¶ 27. The Medicare program is administered by CMS and has four parts: A through D. *Id.* at ¶¶ 27-28. Relevant here, Medicare Part C pays private managed care insurance plans (such as the MA Plan Defendants) a capitated rate; that is, a fixed amount per member (*i.e.*, patient or beneficiary) per month, and those plans are then responsible for paying providers for services provided to beneficiaries. *Id.* at ¶ 30. The capitation rate is based on a beneficiary's geographic location, income status, gender, age, and health status. *Id.*

MA plans "assume full financial risk on a prospective basis" for the cost of providing health care for plan beneficiaries, and generally must cover beneficiaries for all the items and services that would be covered by traditional, fee-for-service Medicare. *Id.* at ¶ 35; 42 U.S.C. §

1395w-25(a)(1)(A); (b).[4] Since 2006, MA plans submit to CMS annual "bids" based on estimated costs per enrolled beneficiary for the services covered by traditional fee-for-service Medicare, and CMS only accepts bids meeting the necessary requirements. 42 C.F.R. §§ 422.254, 422.456. The bids are compared to benchmark amounts that are set by formula and vary by geographic area. *Id.* at §§ 422.252, 422.264, 422.304. If a plan's bid is lower than the benchmark, then the MA plan and CMS each receive a portion of the difference between the bid and the benchmark, and the plan must use its share to provide supplemental benefits to its members. *Id.* at § 422.266. If a plan's bid is higher than the benchmark, plan members pay the difference to the MA plan as a monthly premium. *Id.* at § 422.262(a).

CMS' payments to MA plans are adjusted based on prospective risk to account for the cost differences associated with providing care for beneficiaries with various diseases and other demographic factors. *Id.* at § 422.308(c). The MA risk adjustment system assigns a "risk score" to each plan beneficiary based on age, gender, and health status, among other factors. *Id.* This risk score is intended to reflect that beneficiary's predicted health care costs compared to those of an average beneficiary. Risk scores for plan members are then multiplied by the plan's base payment amount, which is either the plan's bid, or the benchmark. *Id.* at §§ 422.304(a), 422.308(c). Because the risk adjustment is prospective, it uses enrollees' diagnoses from one year to calculate the risk adjustment factor for payment the following year. *Id.* at § 422.310(g).

Medicare will only reimburse providers for medical services it deems "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Deciding when any individual clinical service is

---

[4] On a motion to dismiss, courts may consider "information that is properly subject to judicial notice." *Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013). This includes "materials from proceedings in administrative agencies," *Truhlar v. John Grace Branch No. 825 of the Nat'l Ass'n of Letter Carriers*, No. 06C2232, 2007 U.S. Dist. LEXIS 23875, at *26 (N.D. Ill. Mar. 30, 2007), as well as statutes and regulations. *Demos v. City of Indianapolis*, 302 F.3d 698, 706 (7th Cir. 2002) ("[A] district court can always rely on public statutes.").

reasonable and necessary is delegated in the first instance to CMS, which may decide whether to include or exclude certain types of services nationwide by promulgating national coverage determinations (NCDs).[5] 42 U.S.C. §§ 1395y, 1395ff. Additionally, CMS contracts with regional insurance companies — called Medicare Administrative Contractors, or MACs — to serve as CMS's delegated authority in a particular region. 42 U.S.C. § 1395kk-1. Each MAC can create medical coverage determinations of its own, called local coverage determinations (LCDs), which designate coverage criteria applicable only to its own region. 42 U.S.C. §§ 1395y(l)(6)(B); 42 U.S.C. § 1395ff(f)(2)(B). The LCDs promulgated by one MAC may be different from, or even contradictory to, the LCD published by another MAC. *See* DHHS-OIG: *Local Coverage Determinations Create Inconsistency in Medicare Coverage*, 9-11 (2014).

Utilization management is a process used by managed care plans, such as the MA Plan Defendants, with CMS' knowledge, to determine whether a health care service is medically necessary. *G v. Hawaii*, Civ. No. 08-00551 ACK-BMK; Civ No. 09-00044 ACK-BMK, 2011 U.S. Dist. LEXIS 7940, at *49 (D. Haw. Jan 21, 2011); CMS, Medicare Managed Care Manual, Pub. No. 100-16, Ch. 4 § 110.1.1. UM helps ensure patients receive medically necessary care at an appropriate time, thereby improving clinical outcomes and lowering costs. *Steedley v. McBride*, Civ. Action No. 10-215-GMS, 2015 U.S. Dist. LEXIS 94328, at *5 (D. Del. Jul. 20, 2015); *see also United States ex rel. Nudelman v. Int'l Rehab Assocs.*, Civil Action No. 00-1837, 2006 U.S. Dist. LEXIS 17958, at*6 (E.D. Pa. Apr. 4, 2006) ("Utilization management is a set of techniques designed to manage health care costs by influencing clinical decision-making toward the selection of more efficient and efficacious interventions[.]"). One aspect of UM is "pre-

[5] NCDs may be promulgated without a notice and comment period, 42 U.S.C. § 1395hh(2), and many revisions to LCDs (as defined herein) do not require a comment and notice period. CMS, Medicare Program Integrity Manual, Pub. No. 100-08, Ch. 13 § 7.3.

authorization"—the requirement that certain medical services be authorized before they are performed. *G*, 2011 U.S. Dist. LEXIS 7940 at *49. "The purpose of a prior authorization requirement is to manage and coordinate care and ensure consistent coverage determinations. . . . It also includes a cost effectiveness aspect." *Id.* CMS has confirmed that managed care plans may use UM processes, including pre-authorization review.[6] CMS, Medicare Managed Care Manual, Pub. No. 100-16, Ch. 4 § 110.1.1.

MA plans must have effective procedures in place to make individualized determinations of Medicare coverage. These procedures must include individual medical necessity determinations. SAC ¶ 39. AIM assists the MA Plan Defendants in making these individualized coverage determinations by providing UM services; that is, evidence-based coverage decisions that are generally made *before* any service is provided to a patient. This pre-authorization review ensures that patients get necessary services for their conditions, as determined by their physicians; but also that they do not get *unnecessary* services when their clinical circumstances do not warrant it. AIM provides these UM services not only for MA plans, but for dozens of commercial (non-Medicare) plans as well. *Id.* at ¶ 5.

AIM's pre-authorization review process consists of four steps: (1) a medical provider, such as a treating physician, sends AIM a request for pre-authorization for insurance coverage; (2) AIM determines whether the plan should approve or deny that pre-authorization request; (3) AIM communicates its determination to the insurance plan, medical provider, and/or the MA beneficiary; and, (4) the insurance plan applies AIM's decision to approve or deny the request

[6] Indeed, both Congress and CMS have directed that standard UM tools, including the sort of pre-authorization review practiced by AIM, should be made applicable to certain providers of traditional fee-for-service Medicare (Parts A and B) by January 1, 2020. Protecting Access to Medicare Act of 2014, § 218; 42 C.F.R. § 414.94; Department of Human and Health Services, Centers for Medicare & Medicaid Services; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70886, 71104 (Nov. 16, 2015).

accordingly. *Id*. at ¶ 51. In particular, AIM reviews requests for certain advanced imaging services including Computerized Tomography (CT), Echocardiography, Magnetic Resonance Angiograms (MRA), Magnetic Resonance Imaging (MRI), and Positron Emission Tomography (PET) scans, as well as sleep studies, among other procedures. *Id.* at ¶ 52. AIM can only deny a pre-authorization request after it has been reviewed by a licensed physician. *Id.* at ¶ 56.

Although Relator faults the Defendants for their use of UM, the government has directly indicated that it wants advanced imaging services to be a special focus of prior authorization reviews because of their high cost and potential for over-utilization. *See, e.g.*, U.S. Gov't Accountability Off., GAO-12-966, *Higher Use of Advanced Imaging Services by Provider Who Self-Refer Coding Medicare Millions* (2012) (noting 80% increase in self-referred MRI services from 2004 through 2010 and recommending that CMS "[d]etermine and implement an approach to ensure the appropriateness of advanced imaging services referred by self-referring providers").

Relator Nedza served as Chief Medical Officer at AIM from July 2012 until January 2015. SAC at ¶ 16. She alleges that application of AIM's clinical guidelines violated the FCA. Elsewhere in her SAC, however, she alleges the government was aware of AIM and the MA Plans' practices and continued to allow the MA Plans to participate in the MA program and receive payments from Medicare. *Id.* at ¶¶ 16, 73, 107, 119, 120, 136, 137.

ARGUMENT

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). To state a facially plausible claim, a complaint must set forth "direct or inferential allegations concerning all material elements necessary for recovery under the chosen legal theory." *United States ex rel. Bustamante v. United Way/Crusade of Mercy, Inc.*, Case No. 98 C 5551, 2000 U.S. Dist. LEXIS 7326, at *9 (N.D. Ill. May 26, 2000)

(citing *Glatt v. Chicago Park District*, 847 F. Supp. 101, 103 (N.D. Ill. 1994)). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than mere labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Claims brought under the FCA also are subject to heightened pleading requirements that require plaintiffs to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *United States. ex rel. Keen v. Teva Pharms. USA Inc.*, No. 15 C 2309, 2017 U.S. Dist. LEXIS 518, at *6 (N.D. Ill. Jan. 4, 2017) (quoting *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 775 (7th Cir. 2016)). To satisfy Rule 9(b), a Relator must plead "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 . . . or, to put it differently . . . the who, what, where, when and how of the alleged fraudulent conduct." *Keen*, 2017 U.S. Dist. LEXIS 518 at *6 (quotations and citations omitted); *Presser*, 836 F.3d at 776 (internal citations and quotations omitted). In addition, under Rule 9(b), a complaint "should not lump multiple defendants together, but should inform each defendant of the specific fraudulent acts that constitute the basis of the action against the particular defendant." *Suburban Buick, Inc. v. Gargo*, No. 08 C 0370, 2009 U.S. Dist. LEXIS 46124, at *12 (N.D. Ill. May 29, 2009) (internal quotations and citations omitted).

I. Relator's FCA Claims Fail Because She Has Not Pled the Submission of a False Claim.

Relator attempts to plead causes of action under both the False Claim (31 U.S.C. § 3729(a)(1)(A)) and False Statement (§ 3729(a)(1)(B)) prongs of the FCA. Under the "False Claim" provision, the FCA imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

To allege a claim under § 3729(a)(1)(A), Relator must plead as to each Defendant: (1) a false claim; (2) presented by Defendant to the United States for payment or approval; (3) with knowledge the claim was false. *Fowler*, 496 F.3d at 741.

To plead a violation of § 3729(a)(1)(B), the "False Statement" provision, Relator must allege: (1) each Defendant made a statement material to a false claim; (2) the statement was false; and (3) the Defendant knew the statement was false. *Thulin v. Shopko Stores Operating Co.*, 771 F.3d 994, 998 (7th Cir. 2014). Importantly, both subparagraphs (1)(A) and (1)(B) require Relator to plead the submission of a false claim. *Singer v. Progressive Care, SC*, 202 F.Supp.3d 815, 825 (N.D. Ill. 2016) (dismissing §§ 3729(a)(1)(A) and (a)(1)(B) claims where relator failed to plead examples of false claims). Here, Relator has failed to allege even the most basic elements for her causes of action – falsity and the submission of a claim. Without more, this warrants the dismissal of Relator's claims. Even if Relator had alleged these fundamental prerequisites for her causes of action, she has failed to plead them with the particularity required by Rule 9(b). Finally, even if Relator *had* identified a purportedly false claim, failure to comply with guidance documents like the Medicare Managed Care Manual is not an FCA violation. For all of these reasons, her claims fail.

A. Relator Does Not Plead Submission Of Any Allegedly False Claim With Particularity.[7]

[7] Relator only began employment with AIM in July 2012, and does not plead the basis for her knowledge of any alleged improprieties before she began work at AIM. SAC ¶ 16. Allegations about AIM or the other MA Plan Defendants' activities prior to that date are based only on information and belief, which cannot satisfy the need to plead with the particularity required by Rule 9(b). *Cincinnati Life Ins. Co. v. Beyrer*, 722 F.3d 939, 948 (7th Cir. 2013) ("We frown on making allegations 'on information and belief' in the fraud context and generally find that such claims do not meet Rule 9(b)'s particularity requirement.") (citations omitted).

Relator's SAC makes much of the Defendants' alleged noncompliance with Medicare guidelines, but amidst all this, Relator never alleges any *false claim* actually submitted or caused to be submitted by any of the Defendants to the government. An FCA "claim" is defined as a request or demand, whether under a contract or otherwise, for money or property that is presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2)(A). Pleading the actual submission of a false claim for payment to the government is "the *sine qua non* of a False Claims Act violation." *Keen*, 2017 U.S. Dist. LEXIS 518 at *8 (citations omitted). Pleading a scheme by which false claims *might* have been submitted, without pleading the actual submission of a false claim, is insufficient to sustain an FCA action. *United States ex rel. Dolan v. Long Grove Manor, Inc.*, No 10 C 368, 2014 U.S. Dist. LEXIS 98429 at *11 (N.D. Ill. Jul. 18, 2014) ("relator cannot merely describe a private scheme in detail but then . . . allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.") (internal quotations and citation omitted).

Medicare Advantage organizations, like the MA Plan Defendants here, do not submit individual reimbursement claims for each service provided to their beneficiaries. Instead, they receive a capitated advance (per member per month) from the government. SAC ¶ 30. While Relator alleges AIM applied an overly restrictive approach to its medical necessity determinations, *id*. at ¶¶ 57, 150, she fails to allege any claim for payment to the government that was ever submitted for services not provided. She also does not allege that any claim was ever submitted to the government for services that *were* provided, but were not medically necessary. Indeed, the SAC contains no allegation identifying any specific claim whatsoever, let alone any claim submitted through the bid and capitation payment system established by CMS. Instead,

Relator alleges only that not enough services were provided to beneficiaries, which she believes would have resulted in the government being charged *less* each year when the capitation rate for the following year was established.

To comply with Rule 9(b), each count of an FCA complaint must: "(1) identify specific false claims for payment or specific false statements made in order to obtain payment; (2) if a false statement is alleged, connect that statement to a specific claim for payment and state who made the statement to whom and when; and (3) briefly state why those claims or statements were false." *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 378 (7th Cir. 2003); *see also Dolan*, 2014 U.S. Dist. LEXIS 98429 at *11 (allegations must "link specific allegations of deceit to specific claims for payment."); *Keen*, 2017 U.S. Dist. LEXIS 518 at *9-10 (Relator must allege that a false claim for payment was actually submitted to the government and provide "concrete examples"). Relator fails to do so.

Relator also does not identify any specific beneficiary who allegedly did not receive services to which they were supposedly entitled. While Relator makes much of AIM's alleged denial rate, SAC ¶ 110, general industry statistics cannot be used to extrapolate from claims that Relator has not identified in the first place. *United States ex rel. Lisitza v. Par Pharm. Cos.*, No. 06 C 06131, 2017 U.S. Dist. LEXIS 131246, at *64 (N.D. Ill. May 10, 2017) ("statistical likelihood that false claims were submitted" does not suffice to "satisfy the [relator's] burden to prove that at least one specific false claim was submitted.") (citation omitted). She provides five nebulous examples of imaging benefits that allegedly were "denied under AIM Guidelines contrary to Medicare Rules" but does not allege any information as to which AIM guideline counseled the denial of such benefits; or, on the other hand, any specific "Medicare Rule" that required coverage for any of these benefits. SAC ¶ 89. Indeed, Relator does not identify any

specific improper guideline used by AIM. She merely alleges generally that the AIM guidelines were "not based on Medicare Rules [and] were more stringent than Medicare Rules," *id.* at ¶ 89, but does not say *how* any specific AIM guideline was different or deviated from any specific Medicare regulation. And even if AIM or the MA Plan Defendants disobeyed an applicable regulation, "[v]iolating a regulation is not synonymous with filing a false claim." *United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1105 (7th Cir. 2014).

The SAC recites that Relator worked at AIM for more than three years; she therefore had direct access to AIM's guidelines and their use with specific plans. Relator herself states she "was responsible for development of clinical guidelines and regulatory compliance for Medicare programs" at AIM. SAC ¶ 16. Yet despite its prolixity, Relator's SAC fails to identify a single false claim.[8] For this reason alone, the SAC should be dismissed.

B. Relator Does Not Plead A False Claim Submitted By Any Individual Defendant.

Relator also fails to satisfy Rule 9(b) as to all Defendants because she engages in impermissible group pleading throughout the SAC. Relator frequently refers to "Defendant Insurance Plans," a group that includes 27 of the 29 total Defendants, without distinguishing at all among the 27 different entities. *See, e.g.*, *id.* at ¶¶ 4, 6, 8, 155. She also makes repeated references to "Defendants" and "insurance plans" without differentiating among the 29 different Defendants to which her allegations apparently pertain. *See, e.g.*, *id.* at ¶¶ 10, 45-47, 123, 136.

---

[8] While Relator claims that AIM employed tactics such as limiting the number of pages of records it would receive from medical providers by fax, and "prohibiting its nurse and physician reviewers from making more than one follow-up contact to get necessary additional information related to a pre-authorization request[,]" these allegations fall short of pleading a false claim. *Id.* at ¶¶ 72, 77. Relator does not reference any specific patients or physicians who were affected by these alleged practices, nor does she provide any other detailed identifying information that would satisfy Rule 9(b). *See Dolan*, 2014 U.S. Dist. LEXIS 98429 at *11 (allegations must "link specific allegations of deceit to specific claims for payment.").

Indeed, for 15 of the 16 MA Plan Defendants (Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Health Plans, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross Blue Shield Healthcare Plan of Georgia, Community Insurance Company, Compcare Health Service Insurance Corp., Empire HealthChoice HMO, Inc., Empire HealthChoice Assurance, Inc., HMO Colorado, Inc., HMO Missouri, Inc., Blue Cross of Idaho Care Plus, Inc., and Moda Health Plan, Inc.), there is not even a *single* separate allegation – much less the detail required by 9(b) – identifying any conduct by that defendant. The only time Relator even mentions these defendants is in a single paragraph alleging only that "Anthem is also the parent company of [certain] Defendant Insurance Plans that hired AIM to increase profits by utilizing the AIM UM review process" and that "Defendant Insurance Plans also include non-Anthem Insurance Plans[.]" *Id*. at ¶ 23.

Relator also acknowledges Anthem Inc. (Anthem) is not the parent company of Blue Cross of Idaho Care Plus, Inc., PacificSource Community Health Plans (PacificSource), or Moda Health Plan, Inc. *Id.*

Relator only mentions Defendant PacificSource three discrete times in the SAC. *Id*. at ¶¶ 23, 73, 120. She alleges merely that: (1) PacificSource is a "non-Anthem insurance plan[]"; (2) AIM was aware, through CMS audits of the Defendant Regence Idaho and Defendant PacificSource plans in 2014, that AIM's specific practice allegedly violated Medicare Rules; and, (3) PacificSource was cited by CMS for AIM's practices. *Id*. Relator does not plead any other separate conduct by PacificSource, much less any false claim allegedly submitted to or paid by the government in connection with PacificSource. These sparse allegations as to

PacificSource do not set forth even a rudimentary version of the necessary elements for FCA claims under § 3729(a)(1)(A) or (B). *See Fowler*, 496 F. 3d at 741; *Thulin*, 771 F.3d at 998.

Blue Cross of Idaho Care Plus, Inc., PacificSource, and Moda Health Plan, Inc. are not Anthem MA plans, such that any alleged knowledge by Anthem could be imputed to them (even if such imputation could be proper). Nor does Relator allege any of these MA Plans, save for PacificSource, were the subject of any CMS audits. To the extent Relator relies on the CMS audit of PacificSource, such an audit is a prior public disclosure and not a valid basis for her FCA claims. *See infra* § III. Thus, the only "knowledge" Relator apparently pleads as to these three Defendants is that they, and "all" of AIM's insurance plan clients received monthly statements from AIM. SAC ¶ 147. A general allegation that these Defendant MA Plans should have recognized alleged non-compliance by AIM based only on monthly statements of AIM's denial rates or savings cannot sustain Relator's FCA claims. *See Thulin*, 771 F.3d at 1000 (that defendant was a "sophisticated, multiregional business that . . . should have been aware of federal statutes and regulations governing the submission of claims to Medicaid" was insufficient to establish reckless disregard at the pleading stage).

Relator's non-specific pleading as to the MA Plan Defendants and the AIM Defendants fails to satisfy the high bar set by Rule 9(b). *Grenadyor*, 895 F. Supp. 2d at 879 (dismissing complaint for improperly grouping defendants together); *United States ex rel. Walner v. Northshore Univ. Healthsystem*, 660 F. Supp. 2d 891, 897 (N.D. Ill. 2009) (dismissing complaint because relator failed to identify the specific role of each defendant in an alleged fraud); *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 706 (7th Cir. 2015), rev'd on other grounds, *United States ex rel. Nelson v. Sanford-Brown, Ltd.*, 136 S Ct. 2506, 195 L. Ed. 2d 836 (2016) (affirming dismissal of specific defendant where relator "reference[d] 'Defendants' dozens of

times in his amended complaint" without distinguishing that specific defendant's alleged conduct); *United States ex rel. Gross v. Aids Research All.-Chicago*, 415 F.3d 601, 605 (7th Cir. 2005).

C. Relator Also Fails to Allege Any Particular False Statement or Certification.

The SAC asserts a cause of action for the alleged submission of false statements, but Relator fails to specify any false statements that were submitted to the government. Instead, Relator appears intent on having the Court and the Defendants guess as to the potential false statements that might be at issue.

Relator may be attempting to rely upon the certifications the MA Plan Defendants submitted in their contracts with CMS to participate in the MA program to serve as the allegedly false statement at issue in Count II. SAC ¶ 156. Relator claims that in these contracts, the MA Plan Defendants certify "they will comply with all Medicare Rules" and those certifications were false because AIM's determinations "did not comply with Medicare Rules." *Id.* It is well-settled that a simple breach of contract, without more, is not a violation of the FCA. *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011) (a "mere breach of contract does not give rise to liability under the False Claims Act") (citing *Garst*, 328 F.3d at 378); *Escobar*, 136 S. Ct. 1989 ("The False Claims Act is not an all-purpose antifraud statute . . . or a vehicle for punishing garden-variety breaches of contract or regulatory violations.") (internal quotations omitted).

As the Supreme Court indicated in *Escobar*, and as courts in this Circuit have confirmed thereafter, a generic statement certifying compliance with Medicare rules and regulations cannot serve as a predicate for FCA liability. *Lisitza*, 2017 U.S. Dist. LEXIS 131246 at *43-44 ("Before *Escobar*, it was clear in this circuit that it is not enough to . . . prove [a defendant] engaged in a practice that violated a federal regulation because violating a federal regulation is

not synonymous with filing a false claim. . . . There is no reason to think that *Escobar* changed this principle somehow—to the contrary, it expressly declined to address it.") (quotations omitted); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447-48 (7th Cir. 2016). In reality, the MA Plan Defendants accomplished exactly what CMS asked them to do: ensuring through evidence-based guidelines that medically unnecessary services were not submitted for payment. That is not a false claim, nor can certifying compliance generally with CMS rules form the basis of a FCA claim. Rather, liability under an implied certification theory requires that a defendant "makes specific representations about the goods or services provided[.]" *Escobar*, 136 S. Ct. at 2001. Relator fails to make any such allegations.

Relator also does not sufficiently allege any false statement made by any specific defendant, much less that any such false statement directly caused the submission of a false claim for government payment. Relator again impermissibly lumps the Defendants together in one paragraph (SAC ¶ 156). Without more, Relator's allegation does not meet the "rigorous" and "demanding" materiality requirements to form the basis for liability under § 3729(a)(1)(B). *Escobar*, 136 S. Ct. at 2002-3. Relator's § 3729(a)(1)(B) claims should be dismissed.

D. Failure To Comply With Guidance Documents Cannot Be An FCA Violation.

To support her theory that the Defendants violated the FCA, Relator relies entirely on the Medicare Managed Care Manual (the Manual), published by CMS. *See, e.g.*, SAC ¶¶ 37-40. The Manual at Chapter 4, Section 90, among other things, establishes parameters for MA plan coverage for health care items or services, requiring that MA plans cover an item or service so long as: (i) coverage is consistent with general coverage guidelines in original Medicare regulations, manuals, and instructions; (ii) the item or service is covered under a CMS NCD; or, (iii) the item or service is covered under MAC coverage policy (LCDs). CMS, Medicare

Managed Care Manual, Pub. No. 100-16, Ch. 4 § 90.1. Relator seeks to transform these guidelines into binding legal requirements, claiming that AIM and the MA Plans violated the FCA by using AIM Guidelines that "were more stringent than" Medicare coverage requirements found in CMS regulations, policies, NCDs, and LCDs. *See, e.g.*, SAC ¶¶ 87-92. In reality, however, AIM's UM process functioned to ensure medically unnecessary claims were not submitted for reimbursement, thus reducing unnecessary government spending.

Even assuming the truth of Relator's assertion, a violation of regulations pertaining to physician authorization, medical necessity, or economical treatment is a compliance issue, not a false claim for payment. *Lisitza*, 2017 U.S. Dist. LEXIS 131246 at *55. In *Lisitza*, the relator claimed that defendant pharmacies were unlawfully substituting certain drugs for more expensive versions that were dispensed without physician approval, were not medically necessary, and that were not economical within the meaning of the applicable state and federal Medicaid regulations. In analyzing "a violation of a statutory and regulatory scheme that carries its own penalties for violations," the *Lisitza* court stated, "[i]f the government overpaid in these cases, it was not because the claim form misled them about what drugs had been prescribed." *Id*. The court reiterated the limitations of the FCA's reach: "[T]he FCA is not a blunderbuss to assure the enforcement of regulations requiring the provision of only medically necessary treatment in an economical manner." *Id.* at *55–56. The court concluded the pharmacies did not mislead the government about what they provided, or the cost for treatment, because all that was alleged was that the defendants submitted bills, which are not in themselves declarations of legal entitlement to payment. *Id*.

Relator's assertion that any deviation from the Medicare guidance necessarily results in a false claim lacks any legal basis.[9] It is well established – by HHS itself – that the LCDs are inconsistent across the country and provide different guidance rules for coverage depending on the MACs' internal decision-making on medical necessity.[10] *See* U.S. Gov't Accountability Off., GAO-03-175, *Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities* 12-16 (2003); DHHS-OIG, *Local Coverage Determinations Create Inconsistency in Medicare Coverage* (discussing inconsistencies among LCDs). The result of this, of course, is that there are differing determinations as to the services that are reimbursable for a given beneficiary's condition. A claim cannot be objectively false if reasonable persons can read the government's guidance and disagree about whether the service was properly billed to the government. *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (errors based simply on faulty calculations or flawed reasoning are not false under the FCA . . . [a]nd imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA"); *see also United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013) (a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud.").

Further, given the vagueness of many LCDs, MA plans could find themselves being held responsible for exactly the opposite of what is alleged to have been done here; that is, a

---

[9] Significantly, the United States Department of Justice, which is the real party in interest for FCA claims, recently has said that agency guidelines that are not subject to rulemaking are insufficient as a predicate to FCA liability. *See* United States Department of Justice Memorandum for All Components: Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases, Jan. 25, 2018 (attached hereto as Exhibit A, 2).

[10] LCDs are issued by MACs, not CMS or the government itself. 42 U.S.C. §§ 1395y(l)(6)(B); 42 U.S.C. § 1395ff(f)(2)(B).

complainant could allege the MA plan was approving *too many* services (and thus increasing government expenditures). Relator asserts AIM and the MA Plan Defendants apparently should have been approving services for all who sought them, regardless of the existence of evidence-based guidelines demonstrating the services' lack of medical necessity. This is neither a viable nor even a government-approved approach; AIM's Guidelines instead ensured that only medically necessary claims were approved. In addition, because future capitation payments are calculated in part based on the previous amounts spent by MA Plans to care for their beneficiaries, reducing the number of medically unnecessary claims that are approved actually results in *lowering* the future capitation payments made by the government, saving the government and taxpayers money.[11] 42 C.F.R. § 422.254.

E. Relator Has Not Alleged Objective Falsity With Respect To The Defendants' Practices.

The SAC does not allege a single objectively false representation (e.g., a lie) made by either AIM or the Defendants to the government. There was nothing false or fraudulent about the Defendants' practices. *Yannacopoulos*, 652 F.3d at 836 ("False" under the FCA means an "objective falsehood."). Instead, Relator simply rehashes the various ways in which she believes AIM was denying advanced imaging services for MA plans that she believes would have been covered under traditional fee-for-service Medicare. Relator does not allege any expenditures reported to Medicare that were objectively false – *i.e.*, seeking payment for services not provided – but instead says they were false because they were based on incorrect interpretations of medical necessity under the applicable Medicare Advantage contracts and regulations. A complaint that fails to provide a concrete method of determining falsity cannot satisfy Rule

[11] Conversely, the Relator's proposed approach, in which all services simply would be approved, would result in increased future capitation payments for the government and would have greatly increased the government's expenditures during the time period that is at issue in this litigation.

9(b)'s heightened pleading requirements. For example, in *Presser*, 836 F.3d at 780, the Seventh Circuit affirmed the lower court's dismissal because the relator "provide[d] no medical, technical, or scientific context which would enable a reader of the complaint to understand why [defendant's] alleged actions amount to unnecessary care forbidden by the statute." *Id.* at 779. The court concluded the complaint "[failed] to demonstrate how [defendant's] policies compare to other clinics or could otherwise be understood as 'unusual.'" *Id.* at 780 (citation omitted). Further, the court noted that "[defendant's] policies could have entirely innocent explanations." *Id.*

Broad and generic allegations that an entire UM process is flawed and results in false claims—the SAC's blanket allegation here—fall short of pleading with the requisite particularity required by Rule 9(b). For example, in *United States ex rel. Zverev v. United States Vein Clinics of Chi., LLC*, 244 F. Supp. 3d 737, 747 (N.D. Ill. 2017), the court noted the relator provided "no information . . . about bills submitted for procedures performed by any of the doctors who are alleged to have admitted . . . that they performed and billed for medically unnecessary surgeries." *Id.* at 747–48. Consequently, the court held "the complaint's allegations do not provide a basis to rule out a single bill for EVLT procedures from the scope of this alleged scheme; to defend against this claim on the basis of the allegations presented, the defendants would be required to review the details of every procedure performed." *Id.* at 748. In dismissing the claim, the court stated, "this claim is the antithesis of a claim pled with particularity and, accordingly, it fails." *Id.*; *see also Garst*, 328 F.3d at 378 ("A contention that the 'total claims' are false . . . fails the requirement of specificity."). Similarly, here, Relator has failed to provide any details of the specific AIM guidelines, beneficiaries, requested medical treatment or claims at issue and, instead, simply concludes sweepingly that the UM process was improper.

The foregoing decisions in this Circuit establish that Relator's subjective evaluation of medical necessity, standing alone, cannot form the basis for a fraud claim. The FCA is not a "vehicle for policing technical compliance with administrative regulations." *Lamers*, 168 F.3d at 1020; *see also Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732-33 (7th Cir. 1999) ("technical violations of a federal regulation on which a claim is based do not make the claim 'false'"); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) ("The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations . . . unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe.").[12] Having failed to plead any allegedly false claims with the particularity required by Rule 9(b), Relator's SAC should be dismissed.

II. Relator's SAC Fails to Satisfy the FCA's Materiality Requirements.

Relator alleges that "each Defendant Insurance Plan certified to Medicare that it would follow and was following Medicare Rules" and that "those certifications were knowingly false." SAC ¶ 149. Relator fails, however, to plead that any alleged false certification was material such that it can sustain her FCA claims. The Supreme Court has held that, to be actionable under the FCA, a "misrepresentation must be material to the other party's course of action"—which generally means "the Government's payment decision." *Escobar*, 136 S. Ct. at 2001-2. *Escobar*

[12] Even assuming Relator's characterization of motive were accurate and that her understanding of the capitation rate setting process were correct, there is nothing inherently false or fraudulent about seeking to maximize profits by making sure medically unnecessary claims were not approved. *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 528 (6th Cir. 2012) ("Why a business ought to be punished solely for seeking to maximize profits escapes us."); *United States ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 315 (S.D.N.Y. 2011) (finding no falsity where relator "alleged nothing more than that [defendant] took steps to maximize its Medicare reimbursements").

makes clear that the materiality standard in an FCA case is "rigorous" and "demanding." *Sanford-Brown, Ltd.*, 840 F.3d at 447 (citing *Escobar*, 136 S. Ct. at 2002-03 & 2004 n.6).

"To establish materiality, it is not enough to show that 'the Government would have the option to decline to pay if it knew of the defendant's noncompliance.' Instead, 'materiality looks to the effect on the *likely* or *actual* behavior of the recipient of the alleged misrepresentation.'" *Sanford-Brown, Ltd.*, 840 F.3d at 447) (internal citations omitted) (emphasis in original); *see also Coyne v. Amgen, Inc.*, No. CV 17-1522, 2017 U.S. App. LEXIS 25503, at *5 (2d. Cir. Dec. 18, 2017) ("to be material the government must have made the payment as a result of the defendant's alleged misconduct") (quotations and citations omitted); *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (affirming dismissal of FCA complaint lacking detailed factual allegations that CMS would not have reimbursed the claims if the reporting deficiencies had been cured). Moreover, as the Supreme Court explained, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Escobar*, 136 S. Ct. at 2003-04.

Here, Relator has alleged generally that the "United States, unaware of the falsity of the claims and/or statement or records, and in reliance on their accuracy, paid for claims that would otherwise not have been allowed." SAC ¶ 169. As a threshold matter, any payments from the government to MA plans are not for individual claims, nor are they based on any representation concerning any particular claim; rather, they are negotiated capitation payments based on historical and projected data submitted by the plans. 42 U.S.C. §§ 422.256, 422.304, 422.308(c). Moreover, Relator's blanket statement is insufficient to establish materiality under *Escobar*, because she makes no allegation as to how any particular false statement influenced the United

States to make any payment at all. *United States ex rel. Dress v. Qualium Corp.*, No. CV 12-745-BLF, 2016 U.S. Dist. LEXIS 93248, at *20 (N.D. Cal. July 18, 2016) (dismissing FCA complaint that alleged "that the government would not have paid Defendants' claims if they had known of the fraudulent conduct" but which did not "explain why"); *United States ex rel. Maetski v. Raytheon Corp.*, No. 2:06-cv-03614-ODW(KSx), 2017 U.S. Dist. LEXIS 122685, at *20-21 (C.D. Cal. Aug. 3, 2017) (allegation the government would not have paid defendant's requests for payment if it knew that the defendant had not complied with contractual specifications was "insufficient" because "it does not show *how* [the defendant's] misrepresentations were material").

Moreover, as Relator admits, the government actually was aware of AIM's UM procedures, and any potential issues related thereto, because CMS audited Defendants Regence Blue Shield of Idaho, PacificSource Community Health Plans, Anthem, and Blue Cross Blue Shield of North Carolina (BCBSNC) – all customers of AIM. SAC ¶¶ 73, 107, 119, 120, 136, 367. Relator acknowledges that "by at least 2008, AIM also knew its UM process violated Medicare Rules, because by that point, *CMS had cited Anthem in an audit related to cases adjudicated by AIM.*" *Id*. at ¶ 107 (emphasis supplied). Similarly, Relator asserts that a CMS audit finding "prior to 2008 [] *criticized an Anthem plan (through AIM) for ignoring Medicare Rules in the AIM review process.*" *Id*. at ¶ 136 (emphasis supplied).

Yet while Relator alleges the government criticized Anthem and others for aspects of AIM's practices, she does not – and cannot – allege CMS subsequently refused to make, or even reduced, its payments to any of the MA Plan Defendants. To the contrary, as Relator herself admits in the SAC, CMS continued to allow the audited plans to participate in the MA program and continued to pay them to provide coverage to beneficiaries. Relator does not allege there

ever was a time when the MA Plan Defendants were not permitted to participate in the MA program or were instructed to stop using AIM, nor does she allege that even a single payment was withheld because of concerns about AIM's process.

This is not surprising, as the contractual provisions Relator cites in 42 C.F.R. § 422.504(a) and 42 C.F.R. § 422.101, SAC ¶ 32, do not condition payment on an MA plan's compliance with them, but instead provide various corrective measures for noncompliant MA plans that "fail[] substantially to provide medically necessary items and services"—other than revoking payment. 42 U.S.C. § 1395w-27(g); *see also* 42 C.F.R. § 422.510 (offering opportunity to cure). Even if these regulations did require compliance as a condition of payment, "[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Escobar*, 136 S. Ct. at 2003.

Finally, even if the CMS audits were not sufficient to put the government on notice of the alleged falsity of the MA Plan Defendants' certifications based on AIM's UM process, it is "difficult [to] understand[] how the [government] remained unaware that the claims were false after the lawsuit was filed." *City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1079 (N.D. Ill. 2016). Capitation payments continued – a fact that is fatal to the Relator's case under *Escobar*. *See* 136 S. Ct. at 2003-4 ("[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material."); *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017) (where Army had

investigated relators' allegations and continued to pay defendants for their services, any false claims the defendants submitted were immaterial to the government and unrecoverable).

Every year, CMS also reviews MA plans' claims data to determine the risk adjustment values for plan members. *See* 42 C.F.R. § 422.308(c) (describing risk adjustment). "Each MA organization must submit to CMS (in accordance with CMS instructions) 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). Risk adjustment factors for each MA payment year are based on data submitted for items and services furnished during a 12-month period before the payment year that is specified by CMS. *Id.* at § 422.310(g). "After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary." *Id.* at § 422.310(g)(2). There is no allegation that CMS ever identified any problematic discrepancy with the MA Plan Defendants' coverage determinations significant enough to preclude any MA Plan Defendant from continuing to participate in the MA program. From this, there is only one conclusion: the activities complained about by Relator here were not material to the decision by the government to make, and to continue making, capitation payments to the MA Plan Defendants.

Accordingly, given CMS' knowledge of AIM's approach to coverage determinations and the lack of any indication that it disapproved, any alleged misrepresentation would not be material under the FCA, and Relator's claims should be dismissed.

III. Relator's Claims Are Barred Due to Prior Public Disclosure.

The FCA's public disclosure bar forecloses a Relator from bringing a *qui tam* action if "substantially the same allegations or transactions as alleged in the action were publicly disclosed . . . in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation[.]" 31 U.S.C. § 3730(e)(4)(A). "Once a public disclosure is

made, the value of a *qui tam* action is lost as the government is aware of the potential of a false claim and can take responsive action itself." *United States ex rel. McGee v. IBM Corp.*, 81 F.Supp.3d 643, 657 (N.D. Ill. 2015) (citation omitted).[13]

"[A]llegations in a complaint are publicly disclosed 'when the critical elements exposing the transaction as fraudulent are placed in the public domain.'" *United States ex rel. Feingold v. AdminaStar Fed., Inc.*, 324 F.3d 492, 495 (7th Cir. 2003) (citation omitted). Information is "in the public domain" for purposes of the public disclosure bar where the "facts disclosing the fraud itself are in the government's possession." *Cause of Action*, 815 F.3d at 274 (internal citation and quotation omitted). Once allegations in a complaint have been publicly disclosed, the next determination is whether the relator's lawsuit is "'based upon,' *i.e.*, 'substantially similar to,' those publicly disclosed allegations." *Id.* (quoting *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 913, 920 (7th Cir. 2009)).

Relator herself alleges CMS audited Regence Blue Shield of Idaho, PacificSource, Anthem, and BCBSNC, and that those audits revealed that AIM's guidelines allegedly "violated Medicare Rules." SAC ¶¶ 73, 107, 119, 120, 136, 137. These audits are public disclosures, and Relator's allegations are substantially similar to the publicly disclosed conduct. *See United States ex rel. Ziebell v. Fox Valley Workforce Dev. Bd. Inc.*, 806 F.3d 946, 952 (7th Cir. 2015) (where a claim rested on information that was found in an audit, the claim was "plainly based on" the public disclosure of this information) (internal citation and quotation omitted). Moreover, since Relator claims the same improper conduct continued after the audits were completed, all of the allegations in Relator's SAC (including for conduct occurring after the

[13] The only exceptions to the public disclosure bar are an action brought by the Attorney General (here, the United States has declined to intervene) or where "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A); *see also Cause of Action v. Chi Transit Auth.*, 815 F.3d 267, 274 (7th Cir. 2016) (internal citation and quotation omitted).

audits) had been publicly disclosed. *See, e.g.*, SAC ¶ 136; *Bellevue v. Universal Health Services of Hartgrove Inc.*, 867 F.3d 712 (7th Cir. 2017) (allegations concerning conduct occurring after CMS audit, where such conduct was substantially similar to the publicly disclosed information, fell within public disclosure bar and were dismissed); *United States ex rel. Lisitza v. Par Pharm Cos.*, No. 06 C 06131, 2017 U.S. Dist. LEXIS 131248, at *41 (N.D. Ill. Aug. 17, 2017) ("expansion of [the] time period over which [a] fraud scheme operated [is] insufficient to clear [the] substantial similarity hurdle.") (citation omitted); *McGee*, 81 F.Supp.3d at 659-60.

To be an original source, Relator must show she "'has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions' and 'has voluntarily provided the information to the Government before filing [her] action.'" *Cause of Action*, 815 F.3d at 282-3 (quoting 31 U.S.C. § 3730(e)(4)(B)). Because, by Relator's own account, her allegations are substantially similar to the conduct allegedly exposed by the audits, she does not "materially add" to the public disclosure.[14] As such, Relator's claims are barred.

CONCLUSION

For the foregoing reasons, the Movants respectfully request that this Court grant their Motion to Dismiss Relator's Second Amended Complaint with prejudice.

[14] Indeed, Relator's allegations include reference to a CMS audit in 2008, which was years before she began working at AIM in 2012. SAC ¶¶ 16, 136.

Dated: March 13, 2018

Respectfully submitted,

/s/ Lisa M. Noller

Lisa M. Noller
Patrick J. McMahon
Foley & Lardner LLP
321 North Clark Street, Suite 2800
Chicago, Illinois 60654-5313
Telephone: 312.832.4500
Facsimile: 312.832.4700
lnoller@foley.com
pmcmahon@foley.com

Michael J. Tuteur (admitted *pro hac vice*)
Jessica E. Joseph (admitted *pro hac vice*)
Foley & Lardner LLP
111 Huntington Avenue
Boston, MA 02199
Telephone: 617.342.4000
mtuteur@foley.com
jjoseph@foley.com

Attorneys for AIM Defendants, Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Health Plans, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross Blue Shield Healthcare Plan of Georgia, Inc., Community Insurance Company, Compcare Health Service Insurance Corp., Empire HealthChoice HMO, Inc., Empire HealthChoice Assurance, Inc., HMO Colorado, Inc., HMO Missouri, Inc., Blue Cross of Idaho Care Plus, Inc., and PacificSource Community Health Plans

and

/s/ David M. Goldhaber

David M. Goldhaber
Michael J. O'Malley
Wilson Elser Moskowitz Edelman & Dicker LLP
55 West Monroe Street- Suite 3800
Chicago, Illinois 60603-5001
Telephone: 312.704.0550
Facsimile: 312.704.1522
david.goldhaber@wilsonelser.com
michael.o'malley@wilsonelser.com

Attorneys for Moda Health Plan, Inc.