UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, the STATES of CALIFORNIA, FLORIDA, GEORGIA, TENNESSEE, AND WASHINGTON, *ex rel.* MICHAEL MULLEN, Relator-Plaintiffs, vs. CARDINAL HEALTH, INC., CARDINAL HEALTH SPECIALTY SOLUTIONS GROUP, CARDINAL HEALTH 108, LLC, CARDINAL HEALTH 118, LLC, TENNESSEE ONCOLOGY, PLLC, CALIFORNIA CANCER ASSOCIATES FOR RESEARCH AND EXCELLENCE, INC., BIRMINGHAM HEMATOLOGY AND ONCOLOGY ASSOCIATES, LLC, ONCOLOGY SPECIALTIES, PC, TENNESSEE CANCER SPECIALISTS, PLLC, SOUTH CAROLINA ONCOLOGY ASSOCIATES, PA, DAYTON PHYSICIANSL, LLC, MICHIGAN HEALTHCARE PROFESSIONALS, PC, NORTHWEST MEDICAL SPECIALTIES, PLLC, AND HEALTH FIRST, MEDICAL, LLC, Defendants.	Civil Action No.: 1:19-cv-12488-IT

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT NORTHWEST MEDICAL SPECIALTIES' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

Northwest Medical Specialties, PLLC ("Northwest"), respectfully submits this memorandum of law in support of its motion to dismiss Relator's First Amended Complaint ("FAC") pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, and for attorneys' fees and expenses pursuant Section 3730(d)(4) of the False Claims Act, 31 U.S.C. §§ 3729, et seq. ("FCA").[1]

PRELIMINARY STATEMENT

Relator's quibbles over whether drug discounts may be credited pre- or post-sale do not a fraud theory make. Such price concessions are expressly permitted not only by the plain language of the Anti-Kickback Statute ("AKS"), but also by regulations promulgated by DHS-OIG ("OIG") thereunder, commonly referred to as "safe harbors." Nothing in law or applicable regulation requires them to be paid post-sale. Because black-letter law forecloses Relator's claim, the Amended Complaint should be dismissed with prejudice. In short, despite every opportunity to change course, Relator has pursued a clearly frivolous, vexatious, and harassing lawsuit, and therefore is responsible to Northwest for attorneys' fees and expenses incurred in defending this action.

ARGUMENT

I. The Amended Complaint Should be Dismissed for Failure to State a Claim

To survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Dismissal is appropriate when the pleadings fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable

[1] Northwest also incorporates herein the arguments set forth in the Joint Memorandum of Law In Support of Practice Defendants' Motion To Dismiss.

legal theory." Berner v. Delahanty, 129 F.3d 20, 25 (1st Cir. 1997); Gagliardi v. Sullivan, 513 F.3d 301, 305 (1st Cir. 2008) (quotation omitted); accord U.S. v. Teva Pharms. USA, Inc., 560 F. Supp. 3d 412, 418 (D. Mass. 2021) ("Threadbare recitals of legal elements which are supported by mere conclusory statements do not suffice to state a cause of action.").

A. Relator Cannot Establish a Violation of the Anti-Kickback Statute

The AKS expressly permits "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A). As Relator concedes, Northwest bills the government for "the administration of a drug covered under Government Health Care Programs" and, for the reasons discussed further below, is not required to report its drug costs. FAC ¶ 70 (emphasis added).

Relator, however, argues that Northwest's discounts went "unreported." FAC ¶ 72. This argument is specious. As OIG made clear more than 31 years ago, dispensing physicians are not required to "report discounts they receive on goods purchased for which a line item charge is not separately made, but rather is included within their professional charge." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35980 (July 29, 1991). OIG further reiterated that, "where a practitioner obtains a discount, defined in this provision, for a good that is included as part of his or her professional service charge, such discounts need not be reported." Id. at 35981.

Relator also argues that the discounts "increase[] the spread between the actual acquisition cost the provider pays and the ASP upon which government reimbursement is based." FAC ¶ 72. To be clear, Relator does not, and cannot, argue that the government's cost is

inflated, only that Northwest is motivated to buy drugs as cheaply as possible to increase its profit margin. That, however, is not only a wholly appropriate and legitimate business rationale, but also is precisely what the government envisioned when it sought to cultivate the growth of physician dispensing practices to increase site-of-care savings and patient satisfaction outside the hospital setting.

Specifically, Northwest's drug costs have no bearing on Medicare Part B reimbursement. See, e.g., Vitreo Retinal Consultants v. U.S. Dep't of Health & Human Servs., 649 Fed. Appx. 684, 692-693 (11th Cir. 2016) ("Under CMS's policy, once it has determined the Average Sales Price and calculated the 106% reimbursement rate for a given drug, CMS does not inquire into individual medical providers' costs when calculating reimbursement. Instead, CMS reimburses at the 106% rate, regardless of the possibility that a given provider may have obtained the drug at a reduced rate."); Medicare Program; Part B Drug Payment Model, 81 Fed. Reg. 13230, 13231 (March 11, 2016) ("The ASP payment amount does not vary based on the price an individual provider or supplier pays to acquire the drug."); id. at 13253 ("Medicare pays this price regardless of the price a provider pays to acquire the drug."). Indeed, the ASP reimbursement methodology ensures that the federal government receives the lowest price at which any drug is sold by any manufacturer to any wholesaler or GPO in the country. See 42 U.S.C. § 1395w-3a(c) (calculating ASP based on the "manufacturer's sale to all purchasers" in the United States

"divided by the total number of such units of such drug or biological sold by the manufacturer in such quarter").[2]

In short, Relator's stunning failure to address, let alone mention, the AKS statutory exception for discounts is telling; it forecloses his claim. See United States v. Shaw, 106 F. Supp. 2d 103 (D. Mass. 2000) (interpreting statutory discount exception); Mason v. Medline Indus., Inc., No. 07 C 5615, 2009 WL 1438096, *4 (N.D. Ill. May 22, 2009) (dismissing FCA complaint alleging AKS violations in the form of "prebates," or "pre-purchase cash payments to providers in exchange for agreed-upon purchase commitments," for failure to "adequately link any of these practices to a particular false cost report").

B. Relator Cannot Establish that the Agreements at Issue are Without an Anti-Kickback Safe Harbor

Because Relator's inability to establish a violation of the AKS is dispositive, the Court need not reach the question whether a regulatory safe harbor promulgated thereunder applies. Indeed, "the regulatory safe harbor both incorporates and enlarges upon the statutory exception." See Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63528 (November 19, 1999). In any event, Relator argues that the "upfront" nature of the discount payments at issue take the arrangements outside the

[2] For example, between 2014 and 2018, Medicare Part B spent over $8 billion on Rituximab 100mg. See Medicare Part B Spending by Drug, available at: https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug (last visited Jan. 4, 2023). In contrast, Relator alleges that the 10 defendants billed Medicare $110 million, collectively, for Rituximab over that same time period, or 1% of total reimbursement. Relator also alleges that Northwest received $2.5 million in discounts from Cardinal. Even assuming, arguendo, those discounts all related to Rituximab, they constitute 0.0003% of total reimbursement. Accordingly, CMS does not require individual practices to report drug costs or discounts because–even assuming wholesalers were selling certain drugs below Wholesale Acquisition Cost—there is no likelihood that such sales would move ASP.

AKS discount safe harbor. See FAC ¶¶ 85-87. Once again, the plain language of the regulation contradicts Relator's claim.

The AKS discount safe harbor requires that "[t]he discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service." 42 C.F.R. § 1001.952(h)(1)(iii). Here, there is no dispute that the terms of the parties' agreement were fixed and disclosed in writing in advance. Specifically, Northwest's agreements with Cardinal specified the discount amount "on future purchases to be made by the Committed Member." Declaration of Anthony J. Mahajan ("Mahaj. Dec."), Ex. A at 2; Ex. B at 1; Ex. C at 1. The agreements further stated that "[t]he rebates paid (or credited) by Specialty Distribution to Committed Member under this LOC constitute a 'discount or other reduction in price,' as such terms are defined under the Medicare/Medicaid Anti-Kickback Statute, on the Products purchased by Committed Member under the Distribution Agreement." Mahaj. Dec. Ex. A at 2; id. Ex. B at 1-2; id. Ex. C at 1-2.

Relator, however, argues that such "rebates" may be paid "post-sale" only. To the contrary, OIG defines a "rebate" as "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." 42 C.F.R. § 1001.952(h)(4) (emphasis added). In other words, the safe harbor does not prohibit pre-sale rebates. Indeed, in October 2000, OIG published a notice of proposed rulemaking clarifying the definition of "rebate" to apply only to discounts "given after the time of sale." Medicare and Federal Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 65 Fed. Reg. 63035, 63041 (Oct. 20, 2000) (emphasis in original). OIG explained that the rule was intended "to make clear that a rebate is a price reduction after the time of sale." 67 Fed. Reg. 11928, 11930 (March 18, 2002) (emphasis added).

Because OIG's proposal was never implemented, Relator's resort to the safe harbor provides no refuge. Accordingly, Relator attempts to rely on misdirection and inapplicable sub-regulatory guidance in a feeble attempt to state a claim. Relator cites a 2003 OIG publication addressed to pharmaceutical manufacturers which obviously involves very different considerations than those applicable to dispensing practices. See FAC ¶ 86. Relator also cites a non-precedential OIG "opinion" letter addressed to a product seller, not a buyer like Northwest. Id. ¶ 87. In fact, Relator's own precedent further undermines his claim: neither publication states that "upfront" discounts are illegal, only that they "potentially implicate" AKS concerns. Here, of course, there are no "traceability" concerns because Northwest's discounts are not reportable. But see id. ¶ 89. Similarly, no "locking-in" concerns exist because Northwest is self-motivated and empowered by statute to buy drugs as cheaply as possible, and Cardinal's agreements were terminable if Northwest received lower pricing "from a competing distributor." See Mahaj. Dec. Ex. A, § 3(e) ("Right of First Refusal"). That ends the inquiry; the Amended Complaint should now be dismissed with prejudice.

II. The Amended Complaint Should be Dismissed for Failure to Plead Fraud with Particularity Pursuant to Rule 9(b)

"FCA allegations and their state counterparts are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b)." U.S. ex rel. Nowak v. Medtronic, Inc., 806 F.Supp.2d 310, 351 (D. Mass 2011). Additionally, "FCA claims premised on violations of the AKS must plead both the FCA violation and the underlying kickback scheme in compliance with Rule 9(b)." United States v. Novartis Pharm. Corp., 13-CV-3700, 2020 WL 1436706, *5 (S.D.N.Y. Mar. 24, 2020); accord U.S. ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-CV-10601-IT, 2018 WL 1996829, at *2 (D. Mass. Apr. 27, 2018); United States ex rel. Bilotta v. Novartis Pharm. Corp., 50 F. Supp. 3d 497, 513-14 (S.D.N.Y. 2014).

For the above-described reasons, Relator has failed to plead his claims with the particularity required of Rule 9(b). For example, pursuant to the AKS statutory exception, Relator makes no attempt to explain, nor could he, how the discounts at issue were not "appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A). Similarly, under the AKS safe harbor, Relator fails to explain how an agreement documenting, in indelible ink, the upfront nature of the payments at issue gives rise to a "strong inference" of fraudulent intent. See Suna v. Bailey Corp., 107 F.3d 64, 68 (1st Cir. 1997) (holding that Rule 9(b) requires facts establishing a "strong inference" of fraudulent intent).

Ultimately, Relator's tortured theories leave the reader unfulfilled as to what incentivized a practice like Northwest to participate in a fraud scheme. For example, Relator argues that Cardinal's payments provided Northwest with cash flow "float" to buy and bill expensive medications it otherwise could not finance. See FAC ¶ 81. This argument is nonsensical for many reasons. First, Northwest "purchased approximately $100 million in specialty pharmaceuticals from SPD annually," FAC ¶ 35, meaning that Cardinal's payments constituted **0.2%** of Northwest's drug spend in 2015-17; **1.2%** in 2017-18; and **0.3%** in 2018-22. See id. Second, because Northwest's patient population is approximately 50% Medicare, see id. ¶ 84, it would be illogical for Northwest to commit fraud based on a cash-flow float on half its drug purchases. Finally, Northwest was provided 45-day payment terms under its contract with Cardinal, whereas Medicare typically reimburses providers within 14 days, though it is permitted 30 days by statute. Compare Mahaj. Dec. Ex. A, § 3(a), with Medicare's Clean Claim Ceiling Payment Terms ("'Clean' claims must be paid or denied within the applicable number of days from their receipt date as follows: 10-01-93 and later – 30.") (Mahaj. Dec. Ex. D); Noridian

Healthcare Solutions' Clean Claim Payment/Interest Policy ("[C]lean claims filed electronically can be paid as early as 14 days after receipt") (Mahaj. Dec. Ex. E). Either way, Northwest receives reimbursement from Medicare before it is obligated to pay Cardinal, thereby eviscerating Relator's false construct.

III. Northwest is Entitled to its Attorneys' Fees and Expenses

Northwest is entitled to its attorneys' fees and costs associated with the defense of this meritless action. Section 3730(d)(4) of the FCA provides, in pertinent part, that "[i]f the Government does not proceed with the action and the person bringing the action conducts the action, the Court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the Court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." 31 U.S.C. § 3730(d)(4).

This is precisely the type of filing in which such an award is appropriate and necessary. Simply put, Relator's claims lack any basis in the law whatsoever. Relator deliberately did not cite, let alone address, the AKS statutory exception for discounts. In addition, Relator's claims under the AKS safe harbor are contradicted by the plain language of the final rule and supporting commentary, which Relator also deliberately omitted to address. Hence, because this action is contrary to black-letter law, it constitutes a frivolous filing. See United States ex rel. Bierman v. Orthofix Int'l, N.V., 113 F. Supp. 3d 414, 429 (D. Mass. 2015) ("A claim is frivolous when, viewed objectively, it may be said to have no reasonable chance of success and present no valid argument to modify present law.").

Just as troubling, Relator had ample notice and opportunity to change course. Specifically, after the government declined to intervene in this action against the practices,

Relator pressed on. After the first-to-file relator, Omni Healthcare, dismissed its action against the practices, Relator pressed on. Again, after the co-relator in this very action dismissed his claim against the practices, Relator pressed on. Each of these discontinuances should have prompted Relator to re-examine the merits of his case and re-assess whether there was a good-faith basis for proceeding with the action.

What did Relator do instead? On July 22, 2022, Relator "doubled-down" with an amended complaint that added a ridiculous and completely absurd "reverse false claim" theory based on prior Cardinal settlements, not anything Northwest knew or recklessly disregarded. By way of further example, Relator alleges that Medicare and patients were harmed by Northwest's scheme because Medicare "pays $2,300 for XGEVA when the $37 generic Pamidronate was and is available." FAC ¶ 82. Yet, Relator makes no attempt whatsoever to establish equivalency or further explain that incendiary allegation. Cf. Wang, Xin et. al., Comparison of the efficacy and safety of denosumab versus bisphosphonates in breast cancer and bone metastases treatment, Oncol Lett. 7, 1997-2002 (2014) (Mahaj. Dec. Ex. F) (published medical study explaining that pamidronate and denosumab (XGEVA) belong to different drug classes and that denosumab "was more effective at preventing pain and skeletal-related events" in patients with breast cancer and bone metastases" than bisphosphonates such as pamidronate).[3] Such a thinly veiled and baseless pleading is shameful, particularly when alleged against a small, "community-based practice specializing in oncology, hematology, and infectious disease." FAC ¶ 35. Unfortunately, Relator's strategy is all-too-common among parasitic late-filers, and he is more familiar than most with the process; Mullen (together with Omni Healthcare, ironically) also was a relator on

[3] Northwest cites this study for the limited purpose of demonstrating the lengths to which Relator has gone to concoct a claim where none exists, not for the truth of the matter.

the government's $625 million dollar settlement with AmerisourceBergen Corporation.[4] In short, Relator's claims against Northwest are frivolous, vexatious, and harassing. See 31 U.S.C. § 3730(d)(4).

CONCLUSION

For all of the foregoing reasons, the Court should dismiss the Amended Complaint with prejudice and award Northwest attorneys' fees and expenses.

Dated: January 6, 2023

By: */s/Anthony J. Mahajan*
Anthony J. Mahajan (admitted pro hac vice)
FRIER & LEVITT, LLC
84 Bloomfield Avenue
Pine Brook, NJ 07058
Tel: (973) 618-1660
Fax: (973) 618-0650
amahajan@frierlevitt.com

Attorney for Defendant, Northwest Medical Specialties, PLLC

By: */s/ Justin Raphaelson*
Justin Raphaelson
RAPHAELSON & RAPHAELSON
11 Foster St. Unit 308
Worcester, MA 01608
(508) 799-0366 telephone
(508) 753-4433 facsimile
jraphaelson@raphlawoffice.com

Local Counsel for Defendant Northwest Medical Specialties, PLLC

[4] See DOJ Press Release, AmerisourceBergen Corporation Agrees to Pay $625 Million to Resolve Allegations That it Illegally Repackaged Cancer–Supportive Injectable Drugs to Profit From Overfill (Oct. 1, 2018), https://www.justice.gov/opa/pr/amerisourcebergen-corporation-agrees-pay-625-million-resolve-allegations-it-illegally (Mahaj. Dec. Ex. G).

CERTIFICATE OF SERVICE

I hereby certify that this document was filed today through the Court's ECF system and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Anthony J. Mahajan
Anthony J. Mahajan, Esq.