[Docket No. 19]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

UNITED STATES *ex rel.* ALLSTATE INSURANCE COMPANY, Plaintiff-Relator, v. PHOENIX TOXICOLOGY AND LAB SERVICES, LLC, Defendant.	Civil Action No. 22-6303 (RMB/AMD) **MEMORANDUM OPINION & ORDER**

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RENÉE MARIE BUMB, Chief United States District Judge:

"Men must turn square corners when they deal with the Government." *Rock Island A. & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920) (Holmes, J.). "This observation has its greatest force when a private party seeks to spend the Government's money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; [defendants] could expect no less than to be held to the most demanding standards in [their] quest for public funds." *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 64 (1984).

In this *qui tam* action under the False Claims Act, 31 U.S.C. § 3729, *et seq*, Plaintiff-Relator Allstate Insurance Company ("**Allstate**") accuses Defendant Phoenix Toxicology and Lab Services, LLC ("**Phoenix Toxicology**"), a clinical laboratory based in Arizona, of presenting reimbursement claims to Medicare, Medicaid, and the Federal Employee Health Benefits Program for duplicative, excessive, and medically unnecessary urine drug testing ("**UDT**"). Nearly all its referrals came from three New Jersey medical providers. Allstate submits that, in recent years, the opioid abuse crisis has fueled UDT for pain management and prescription compliance, ripening opportunities for fraud, waste, and abuse. It links Phoenix Toxicology to a growing, and disturbing, trend of unnecessary UDT.

Moving to dismiss Allstate's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6), Phoenix Toxicology argues that Allstate's allegations are not pleaded with particularity, in violation of the heightened requirements of Rule 9(b). It

contends that the allegedly fraudulent schemes outlined in the Complaint impermissibly extrapolate from its private (and now settled) dispute with Allstate, failing to raise a plausible inference that false claims were submitted *to the United States*.

Having considered the parties' submissions, and resolving Phoenix Toxicology's Motion without oral argument, *see* FED. R. CIV. P. 78(b); L. CIV. R. 78.1(b), the Court cautiously disagrees. At this stage, Allstate has asserted just enough facts to raise a plausible inference that false claims were submitted to the federal government, based in part on the claims that Phoenix Toxicology submitted to Allstate and other private insurers. For this reason, as more fully expressed below, the Motion to Dismiss will be **DENIED**, and this action will proceed to discovery.

I. FACTUAL BACKGROUND

In this False Claims Act case, Allstate accuses Phoenix Toxicology of engaging in a scheme to defraud the United States by performing, and obtaining reimbursement for, medically unnecessary UDT. [Compl. ¶¶ 1, 5–6, ECF No. 1.] Allstate alleges that, between 2016 and 2022, Phoenix Toxicology submitted claims to Medicare, Medicaid, and the Federal Employee Health Benefits Program for tests that were either duplicative, medically unnecessary, or performed prior to certain initial screening tests only because they were more expensive. [*Id.* ¶¶ 6, 9–10.] During this period, data publicly available from the Centers for Medicare and Medicaid Services ("**CMS**") indicate that Phoenix Toxicology submitted claims totaling approximately $18 million and received approximately $3.7 million in payment. [*Id.* ¶ 10.] Before

describing the allegedly fraudulent scheme in greater detail, the Court first identifies the parties and their prior relationship.

Phoenix Toxicology is an outpatient clinical laboratory based in Phoenix, Arizona. [*Id.* ¶¶ 14–15.] It is exclusively in the business of performing UDT services to referring medical providers. [*Id.* ¶¶ 45, 119.] As alleged, providers refer patients for UDT to ensure that they are complying with their medication regimens and refraining from illicit drug use. [*Id.* ¶ 4.] Approximately ninety percent (90%) of Phoenix Toxicology's referrals came from three New Jersey providers: (i) Advanced Spine and Pain, LLC *d/b/a* Relievus; (ii) Raritan Anesthesia Associates; and (iii) Union Anesthesia and Pain Management. [*Id.* ¶¶ 79–80.]

Allstate describes itself as a "leading nationwide property and casualty insurer." [*Id.* ¶ 24.] As a private insurer, it routinely reviews and pays for claims of its insureds who seek treatment for pain management as a result of injuries sustained in automobile accidents. [*Id.*] Allstate is based in Northbrook, Illinois. [*Id.* ¶ 12.]

The parties are not new to one another. In 2013, Allstate sued Summit Pharmacy, Inc. ("**Summit**"), and other related parties, in New Jersey state court, asserting various violations of healthcare regulations and statutes. [*Id.* ¶ 23.] Joel and Jonathan Morton owned and controlled Summit, eventually renaming the entity, "Phoenix Toxicology." [*Id.*] Based on Allstate's allegations, the Court understands Summit to be Phoenix Toxicology's predecessor-in-interest. [*See id.*]

During its lawsuit against Summit, Allstate allegedly discovered nonpublic information that Phoenix Toxicology submitted claims for payment to Allstate for medically unnecessary services rendered to its insureds. [*Id.* ¶¶ 21–22, 24–26; *see also id.* ¶ 43 ("Relator discovered fraud with respect to the claims Phoenix Toxicology submitted to Relator.").] Allstate's discovery is alleged to stem from its review and analysis of nonpublic documents, including bills, reports, and notes produced by Phoenix Toxicology. [*Id.* ¶¶ 25, 130.] Allstate further states that it "discovered that Phoenix Toxicology submitted a significant number of claims to Medicare and Medicaid," [*Id.* ¶ 27], which it alleges on information and belief to contain "the same false and fraudulent misrepresentations regarding the performance of medically unnecessary and excessive urine drug testing and billing for services not rendered as the claims submitted to Allstate," [*id.* ¶ 28]. On August 6, 2021, the parties stipulated to dismissing all claims and counterclaims with prejudice. See *Allstate v. Summit Pharm., Inc.*, Case No. GLO-L-1138-13, at Trans ID LCV20211838681 (N.J. Super. Ct. Law Div. filed Aug. 6, 2021).

Having previewed that this *qui tam* action is predicated on the discovery produced in connection with Allstate's prior dispute with Phoenix Toxicology, the Court next describes the allegedly fraudulent scheme in greater detail. In the Complaint, Allstate identifies three distinct schemes, what it terms the (i) "Duplicative Presumptive UDT Scheme," [see Compl. ¶¶ 82–90, 116–23, 139–81]; (ii) "Definitive UDT Standing Order Scheme, [*id.* ¶¶ 82, 114–17, 124–29, 178–88]; and (iii) "Drug Classes Standing Order Scheme," [*id.* ¶¶ 131–38, 151–88]. Though Allstate alleges

that these schemes were apparent in its private dispute with Phoenix Toxicology, Allstate also clearly alleges that Phoenix Toxicology similarly defrauded the United States. [*E.g.*, *id.* ¶¶ 27, 81–82, 191.]

The **Duplicative Presumptive UDT Scheme** operated as follows. First, referring providers performed "presumptive" UDT at their offices—in other words, a screening test to determine whether a patient's urine contains the presence of a drug. [Compl. ¶¶ 55, 83.] This test, also called a point-of-care or "dipstick" test, provides a "qualitative" result: the patient's urine is either "positive" or "negative" for the presence of the drug. [*Id.* ¶¶ 55, 58, 65, 83.] According to Allstate, Phoenix Toxicology's requisition form solicits from the provider the result of the screening test when the provider refers a patient for UDT, and whatever the result of the screening test—positive or negative—Phoenix Toxicology allegedly performed a second test on the same urine sample. [*Id.* ¶¶ 85, 88.] This second test is alleged to be unnecessarily duplicative and contrary to CMS regulations where the referring provider's screening test rendered a negative result. [*Id.* ¶¶ 86, 89; *see also id.* ¶ 118 ("There is no medical necessity for claims submitted where Phoenix Toxicology repeated screening-type testing on the same urine sample that had already undergone a screening test.").] Allstate also alleges that Phoenix Toxicology encouraged providers to conduct point-of-care screening tests *and* to refer patients for duplicative testing by soliciting the result of the screening on its requisition form. [*Id.* ¶ 90.]

Next, the **Definitive UDT Standing Order Scheme** operated as follows. According to Allstate, Phoenix Toxicology performed "definitive" UDT on patients' urine samples without regard for the patient's (1) needs, (2) medication regimen, (3) risk of abuse or noncompliance, and (4) medical history. [*E.g.*, Compl. ¶¶ 178–88, 193–97.] In contrast to "presumptive" testing, "definitive" testing is more sensitive, employing a different methodology (such as liquid chromatography mass spectrometry (LC/MS)) to confirm the presumptive results of an initial screening test. [*Id.* ¶¶ 56–61.] "Definitive" testing is capable of reporting a "quantitative" result, meaning that it can determine the precise amount or concentration of a drug present in an analytic sample. [*Id.* ¶ 62.] It is more complicated and expensive than presumptive or qualitative testing. [*Id.* ¶ 66.] But definitive testing must be clinically indicated. [*Id.* ¶ 55.] As a result, clinical laboratories are typically required to perform a presumptive test prior to performing a definitive test to ensure that the additional (and more expensive) test is medically necessary. [*Id.* ¶ 68.] As alleged, Phoenix Toxicology employed "excessive and unjustifiable confirmatory testing to confirm the absence of a drug that was clearly reported as 'negative,' or not present, in the screening tests performed by both the referring provider and Phoenix Toxicology." [*Id.* ¶ 127; *see also id.* ¶¶ 107, 128.] Phoenix Toxicology also performed definitive testing prior to even receiving presumptive testing results. [*Id.* ¶ 147; *see also id.* ¶ 192 (same for claims submitted to CMS).] These tests are thus alleged to have resulted in unnecessary claims for reimbursement.

Finally, much like the Definitive UDT Standing Order Scheme, the **Drug Classes Standing Order Scheme** operated as follows. According to Allstate, Phoenix Toxicology allegedly performed tests of multiple drug classes as a matter of course, even if a patient's individualized circumstances made testing for the concentration of the drug unnecessary. [Compl. ¶¶ 136–37.] For instance, Phoenix Toxicology performed definitive testing for the concentration of the drug "PCP" in the urine of nearly every Medicare patient referred, notwithstanding the fact that use of PCP is especially unlikely among the elderly. [*Id.* ¶¶ 136–38; *see also id.* ¶¶ 189–90.] Allstate alleges that Phoenix Toxicology failed to validate that that its claims for reimbursement were for tests that were medically necessary. [*Id.* ¶¶ 134–36.]

The Complaint identifies specific, representative examples of the Duplicative Presumptive UDT Scheme, Definitive UDT Standing Order Scheme, and Drug Classes Standing Order Scheme stemming from Phoenix Toxicology's submission of claims for payment to Allstate. [*E.g.*, Compl. ¶¶ 148–88.] In one notable example, Allstate refers to Phoenix Toxicology's testing of an octogenarian woman who was referred for UDT by Relievus after a 2015 automobile accident. [*Id.* ¶¶ 184–85.] Even though the woman had no history of drug abuse, Phoenix Toxicology performed UDT on ten occasions, testing for the concentration of between 6 and 22 different drug classes, including PCP. [*Id.* ¶¶ 186–87.] Referring to an expert opinion, Allstate alleges that this amount of definitive testing was not clinically indicated, especially

given PCP's virtual nonexistence in the general population. [*Id.* ¶ 189.] Allstate alleges that it was especially unnecessary to test an elderly person for PCP. [*Id.* ¶ 190.]

As noted, Allstate alleges that the fraudulent schemes identified above were not limited to Phoenix Toxicology's submission of claims to Allstate but extended to the federal government. [*See, e.g.*, *id.* ¶¶ 8, 77, 121, 197.] It alleges that the fraudulent schemes were part and parcel of Phoenix Toxicology's business model, [*see id.* ¶¶ 6–9, 88], which it pursued to inflate its profits, [*see, e.g.*, *id.* ¶ 122.] Allstate claims that its allegations are well founded. Its investigation of Phoenix Toxicology's internal documents revealed the submission of similar claims to other private insurers, such as Amica and GEICO. [*Id.* ¶¶ 165–68.] Allstate recognized the similarity by examining the current procedural terminology ("**CPT**") and healthcare common procedure coding system ("**HCPCS**") codes for the tests performed. [*Id.*; *see also id.* ¶¶ 52–53 (explaining purpose of coding systems).] Examining CMS data as well, Allstate identifies that Phoenix Toxicology sought reimbursement from the federal government for the same CPT and HCPCS codes identified in claims it submitted to Allstate, to the tune of approximately $3.7 million—or eight times the amount of money Allstate reimbursed during the same period (i.e., 2016–2022). [*Id.* ¶¶ 46–51.] It thus alleges that Phoenix Toxicology submitted claims to the federal government reflecting the same three fraudulent schemes identified above.

One final background note. Clinical laboratories, such as Phoenix Toxicology, submit claims for reimbursement to CMS and private insurers using the health

insurance claim form known as "CMS-1500." [*Id.* ¶ 69.] The CMS-1500 form includes the following certification: "NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties." [*Id.* ¶ 70.] A laboratory's submission of the reimbursement form reflects its underlying belief that the testing it performed was medically necessary. [*See id.* ¶ 91.]

II. PROCEDURAL HISTORY

On October 27, 2022, Allstate filed *in camera* this *qui tam* action under the False Claims Act, 31 U.S.C. § 3729, *et seq*. [*See generally* Docket.] As the private "relator," Allstate was entitled to bring this action in the name of the United States. *See* 31 U.S.C. § 3730(b)(1). In its Complaint, Allstate asserts three claims against Phoenix Toxicology. [Compl. ¶¶ 199–211, ECF No. 1.] In Counts I and II, Allstate asserts that Phoenix Toxicology violated § 3729(a)(1)(A) and (a)(1)(B), respectively. [*Id.* ¶¶ 199–208.] In Count III, Allstate asserted a so-called "reverse" False Claims Act violation under § 3729(a)(1)(G), [*id.* ¶¶ 209–211], which it has withdrawn.

As required, Allstate served a copy of the Complaint on the United States, *see* 31 U.S.C. § 3730(b)(2), and this action was maintained under seal. On June 1, 2023, the United States declined to intervene pursuant to § 3730(b)(4)(B). [Notice of Election to Decline Intervention, ECF No. 4.] The next day, the matter was unsealed, and the Court ordered Allstate to serve Phoenix Toxicology. [Order, ECF No. 5.]

On October 4, 2023, having entered an appearance, Phoenix Toxicology filed a pre-motion letter pursuant to Rule I.A. of the Court's Individual Rules and Procedures, indicating its intention to move to dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(6). [Phoenix Toxicology's Ltr., ECF No. 14.] Allstate timely filed a responsive letter opposing Phoenix Toxicology's arguments but indicating its intention to voluntarily dismiss Count III.[1] [Allstate's Ltr. at 1–3 & n.4, ECF No. 15.] Having reviewed the parties' pre-motion letter exchange, the Court determined that a conference would not be productive, and it indicated that Phoenix Toxicology could proceed with its contemplated motion. [Text Order, ECF No. 18.]

On October 23, 2023, Phoenix Toxicology filed its Motion to Dismiss pursuant to Rule 12(b)(6). [Mot., ECF No. 19; Def.'s Mem. Supp. Mot., ECF No. 19-1 ("**Def.'s Br.**").] Allstate opposed, [Pl.'s Mem. Opp'n Mot., ECF No. 23 ("**Pl.'s Opp'n**")], and Phoenix Toxicology filed a reply brief, [Def.'s Reply Supp. Mot., ECF No. 24 ("**Def.'s Reply Br.**")]. As the Motion is fully briefed, it is ripe for adjudication.

III. LEGAL STANDARDS

A. Motion to Dismiss—Rule 12(b)(6).

A complaint may be dismissed for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6); *Connelly v. Lane Constr. Corp.*, 809 F.3d 780,

[1] Allstate filed its dismissal papers on November 17, 2023, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i). [Notice of Voluntary Dismissal, ECF No. 22.] Therefore, Count III has been dismissed without prejudice. *See* FED. R. CIV. P. 41(a)(1)(B).

786 (3d Cir. 2016). To withstand a Rule 12(b)(6) motion to dismiss, a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The plausibility standard is met when there is enough factual content in the complaint to allow a court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

When reviewing the sufficiency of a complaint, a court must accept as true all well-pleaded allegations in the complaint, including all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008); *Evancho v. Fisher*, 423 F.3d 347, 350–51 (3d Cir. 2005). A court need not accept "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or "a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986). A court may "generally consider only the allegations contained in the complaint, exhibits attached to the complaint[,] and matters of public record." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (citing *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)).

A district court's role in reviewing the sufficiency of a complaint is thus limited: the issue is not "whether the plaintiffs will ultimately prevail" but "whether they are entitled to offer evidence to support their claims." *Langford v. City of Atlantic City*, 235 F.3d 845, 847 (3d Cir. 2000). "When presenting a Rule 12(b)(6) motion, the defendant

bears the burden to show that the plaintiff has not stated a claim." *Davis v. Wells Fargo*, 824 F.3d 333, 349 (3d Cir. 2016) (citation omitted).

B. Heightened Pleading—Rule 9(b).

When a plaintiff alleges a violation of the False Claims Act, as here, the complaint must meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 195 n.6 (2016); *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 168 (3d Cir. 2019). Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Courts typically cast this requirement in terms of alleging " 'all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.' " *United States ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)); *see also, e.g.*, *United States ex rel. Judd v. Quest Diagnostics Inc.*, 638 F. App'x 162, 168 (3d Cir. 2015). This level of particularity is critical to "place the defendant on notice of the 'precise misconduct with which it is charged.' " *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (quoting *Lum v. Bank of America*, 361 F.3d 217, 223–24 (3d Cir. 2004)) (cleaned up).

Though the circumstances of the fraud must be alleged with particularity, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b).

IV. DISCUSSION

In this case, Allstate asserts that Phoenix Toxicology violated two provisions of the False Claims Act: 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B). [Compl. ¶¶ 199–208, ECF No. 1 (Counts I and II).] As set out above, Allstate alleges that Phoenix Toxicology violated these provisions by submitting claims to the United States for reimbursement of duplicative, excessive, and medically unnecessary urine drug testing. [*E.g.*, *id.* ¶ 82.] Allstate has supported its claims by alleging the circumstances of three fraudulent schemes that Phoenix Toxicology allegedly perpetrated against Allstate and other private insurers between 2016 and 2022: the (i) Duplicative Presumptive UDT Scheme; (ii) Definitive UDT Standing Order Scheme; and (iii) Drug Classes Standing Order Scheme. Allstate submits that it is reasonable to believe that Phoenix Toxicology similarly defrauded the United States.

Moving to dismiss Allstate's Complaint under Rule 12(b)(6), Phoenix Toxicology contends that Allstate has failed to comply with the heightened pleading requirements of Rule 9(b) because the alleged circumstances of fraud *on the United States* are exclusively and impermissibly founded *on a private scheme*. [Def.'s Br. at 1.] Allstate's claims on behalf of the United States in this action stem from its discovery and review of nonpublic documents produced by Phoenix Toxicology in a prior dispute with Allstate in New Jersey state court.

Before the Court is the question whether Allstate has sufficiently stated a violation under the False Claims Act where its allegations concerning Phoenix Toxicology's submission of false claims to the federal government focus on Phoenix

Toxicology's relationship with private insurance companies. To answer this question and determine whether Allstate's pleading complies with the requirements of Rule 9(b), the Court first provides an overview of the False Claims Act, then turns to the essential elements of a False Claims Act claim, and then considers the allegations contained in the Complaint.

A. The False Claims Act.

"Enacted in 1863, the False Claims Act 'was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)). Repeatedly amended since then, today the scope of the False Claims Act is broad: "[it] is meant 'to reach all types of fraud . . . that might result in financial loss to the Government.'" *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 486 (3d Cir. 2017) (quoting *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003)). To accomplish this aim, the False Claims Act imposes liability on those who present or directly induce the submission of false or fraudulent claims for payment to the federal government. *Escobar*, 579 U.S. at 182 (citing 31 U.S.C. § 3729(a)).

A violation of the False Claims Act occurs when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The statute also prohibits a person from causing a false claim to be paid or approved by knowingly making, using, or causing to be made or used, a false record or statement. 31 U.S.C. § 3729(a)(1)(B). The only difference between

subsections (A) and (B) is that subsection (B) contains an additional element—use of a false record or statement. *See United States ex rel. Zwirn v. ADT Sec. Servs., Inc.*, Case No. 10-cv-2639, 2014 WL 2932846, at *5 (D.N.J. June 30, 2014) (Hayden, J.).

The United States Department of Justice may sue under the False Claims Act to recover money paid by the United States Treasury as a result of a fraudulent claim. 31 U.S.C. § 3730(a); *United States ex rel. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004). Alternatively, as here, a private individual, known as a "relator," may bring a *qui tam* action on behalf of the United States to enforce the liability provisions of the statute and may share in any recovery resulting from the lawsuit. 31 U.S.C. § 3730(b), (d); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). Defendants are subjected to civil monetary penalties between $11,181 and $22,363 per false claim, plus treble damages. 31 U.S.C. § 3729(a)(1); 28 C.F.R. 85.5 (adjusting penalties for inflation).

B. Pleading an FCA Claim.

"A False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (first citing *Escobar*, 579 U.S. at 182; then citing *Wilkins*, 659 F.3d at 304–05). The Third Circuit sometimes recounts these elements differently. To state a prima facie FCA violation, a relator must plead that: " '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.' " *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175

(3d Cir. 2019) (quoting *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004)).

In the FCA context, as noted above, Rule 9(b) requires that a relator's allegations be supported with " 'all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.' " *United States ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). "This is a greater level of detail than that associated with mere notice pleading." *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 272 (3d Cir. 2016) (Fuentes, J., concurring in part, dissenting in part, and dissenting from the judgment). However, the Third Circuit has adopted a "nuanced" pleading standard and clarified that "it is sufficient for a plaintiff to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.' " *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). To state a prima facie case at the pleading stage, a relator need not identify a specific claim that was actually presented to the federal government. *Wilkins*, 659 F.3d at 308; *see also Foglia*, 754 F.3d at 156–57.

Allegations concerning the "date, place, or time" of an alleged fraud satisfy Rule 9(b), "but nothing in the rule requires them." *Seville Indus. Mach. Corp. v. Southmost*

Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). "Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Id.*; *see also, e.g.*, *United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 223 (D.N.J. 2021) (citing *Seville* standard in the FCA context).

C. Sufficiency of Allstate's FCA Allegations.

Here, Phoenix Toxicology contends that Allstate's allegations fail to meet the heightened pleading requirements of Rule 9(b). Specifically, Phoenix Toxicology argues that Allstate (1) does not adequately plead a false or fraudulent claim was submitted to the federal government, (2) does not adequately plead scienter, and (3) fails to plead that any misrepresentation was material to the federal government's decision to pay for the UDT claims. [Def.'s Br. at 9–10.] The Court addresses these arguments in turn.

1. Falsity.

Under the FCA, a claim may be either factually or legally false. *Petratos*, 855 F.3d at 486 n.1 (citing *Wilkins*, 659 F.3d at 305). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government." *Wilkins*, 659 F.3d at 305 (citation omitted). Allstate does not press this theory here. Rather, its theory is one of legal falsity. [See Pl.'s Opp'n at 19.]

"A claim is legally false when it does not comply 'with a statute or regulation the compliance with which is a condition for Government payment.' " *Petratos*, 855 F.3d at 486 (citing *Wilkins*, 659 F.3d at 305). There are two varieties of legal falsity

theories: express false certification and implied false certification. *Wilkins*, 659 F.3d at 305. Under the express variety, "an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *Id.* (citation omitted). Under the implied variety, liability "attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *Id.* (citation omitted); *see also Escobar*, 579 U.S. at 190 (specifically recognizing the implied certification theory as a basis for liability). Under either theory, the question is "simply" "whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 97 (3d Cir. 2020).

Here, Allstate pursues a theory of implied false certification.[2] It alleges that Phoenix Toxicology performed medically unnecessary UDT and sought reimbursement from Medicare, Medicaid, and the Federal Employee Health Benefits

[2] In its Reply Brief, Phoenix Toxicology attempts to cast aspersions on Allstate's pleading by complaining that Allstate did not plead whether it was proceeding under a legal or factual falsity theory, that it never even used the words "implied certification," "condition of payment," or "condition of participation." [Def.'s Reply Br. at 2–3.] This is hardly fatal, *see Skinner v. Switzer*, 562 U.S. 521, 530 (2011) ("[U]nder the Federal Rules of Civil Procedure, a complaint need not pin plaintiff's claim for relief to a precise legal theory. Rule 8(a)(2) of the Federal Rules of Civil Procedure generally requires only a plausible 'short and plain' statement of the plaintiff's claim, not an exposition of his legal argument."), and of no moment therefor, *see United States ex rel. Zwirn v. ADT Security Services, Inc.*, Case No. 10-cv-2639, 2014 WL 2932846, at *5 n.6 (D.N.J. June 30, 2014) (Hayden, J.) (rejecting similar argument in FCA case) (citing *Skinner*, 562 U.S. at 530).

Program. [*E.g.*, Compl. ¶ 6.] By doing so, Allstate submits that Phoenix Toxicology impliedly certified that each UDT performed was medically necessary even though Allstate knew that it was not. [Pl.'s Opp'n at 19.] To determine whether Allstate's allegations of falsity are well-pleaded, the Court must first determine whether the Duplicative Presumptive UDT Scheme, Definitive UDT Standing Order Scheme, and Drug Classes Standing Order Scheme sufficiently identify the "who, what, when, where, and how" of an alleged fraud. *See Majestic Blue Fisheries*, 812 F.3d at 307. The Court then turns to Phoenix Toxicology's principal argument that Allstate has impermissibly based its pleading on facts concerning privately insured patients.

a. Whether the Complaint Describes a Fraudulent Scheme.

First, consider the Duplicative Presumptive UDT Scheme. Allstate alleges that, between 2016 and 2022, Phoenix Toxicology performed presumptive testing of patients' urine samples irrespective of whether the referring provider reported a positive or negative initial screening result. [Compl. ¶¶ 85–86, 88–89.] Because such initial screening tests are asserted to be "CLIA-waived"[3]—or categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result," *see* 42 U.S.C. § 263a(d)(3)—Allstate contends that additional presumptive testing (i.e., secondary screening) was not clinically indicated where the referring provider reported a negative result. [*See* Compl. ¶ 116.] In further support of its theory, Allstate points to Phoenix Toxicology's requisition form, which specifically solicits the

[3] "CLIA" refers to the Clinical Laboratory Improvement Amendments of 1988.

result of the initial screening test. [*Id.* ¶ 90.] Doing so, Allstate maintains, encouraged referring providers to conduct point-of-care testing and to order duplicative testing in all cases, without regard to clinical indication. [*Id.*] Allstate bolsters these allegations by providing representative examples from its review of Phoenix Toxicology's nonpublic documents. [*Id.* ¶¶ 139–81.] It also explains that three New Jersey providers referred the vast majority of Phoenix Toxicology's business. [*Id.* ¶¶ 79–80.]

As to the Duplicative Presumptive UDT Scheme, the Court can discern all the component parts of the "first paragraph of the newspaper story." *See Majestic Blue Fisheries*, 812 F.3d at 307. The "who" is Phoenix Toxicology (and the three referring providers based in New Jersey); the "what" is Phoenix Toxicology's general practice of conducting presumptive testing irrespective of the initial screening result; the "when" is between 2016 and 2022; the "where" is Phoenix, Arizona, at Phoenix Toxicology's laboratory and New Jersey, where the referring providers conduct point-of-care testing; and the "how" of the scheme is adequately described in the preceding paragraph—unnecessarily duplicative testing. If Allstate can prove that claims were submitted to the federal government for UDT performed in this manner, such claims would likely breach Phoenix Toxicology's implied certification that all testing for which it sought reimbursement was medically necessary. *See* 42 U.S.C. § 1395y(a)(1)(A) (excluding from Medicare coverage expenses incurred for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").

Still, Phoenix Toxicology argues that Allstate's Duplicative Presumptive UDT Scheme fails to consider a competing alternative inference: that the New Jersey providers ordered UDT in the exercise of their medical judgment, and Phoenix Toxicology permissibly performed UDT in reliance on such judgment.[4] [*See* Def.'s Br. at 22–23.] True enough, as the court considers whether a relator has pleaded sufficient facts to "establish a 'strong inference' that false claims were submitted," "the possibility of a legitimate explanation undermines the strength of the inference of illegality." *United States v. Omnicare, Inc.*, 903 F.3d 78, 92 (3d Cir. 2018) (citing *Foglia*, 754 F.3d at 158). But there is daylight between a provider's responsibility to determine medical necessity and a clinical laboratory's entitlement to rely on the provider's referral without independent verification of medical necessity for the tests billed. Clinical laboratories are under a statutory duty to ensure that only claims for services that are medically necessary are presented to the federal government for reimbursement. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A). When a laboratory, such as Phoenix Toxicology, files a claim on the CMS-1500 form, it certifies that the tests performed were medically necessary. *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 159, 164 (D.D.C. 2017). It is the ordering

[4] Phoenix Toxicology also argues preliminarily that the Complaint is too "imprecise," "vague," and "opaque." [See Def.'s Br. at 10–12.] It attempts to muddy the waters by identifying inconsistencies in Allstate's use of testing terminology in the pleading. [*Id.*] But this effort falls flat. When a court reviews the allegations of a pleading to ensure that the plaintiff has complied with the heightened requirements of Rule 9(b), it does not look for foot faults; it ensures that a complaint is coherent enough to provide the defendant with notice of the "precise misconduct with which it is charged." *Frederico*, 507 F.3d at 200. Allstate's alleged schemes satisfy this standard.

physician, not the laboratory, that determines whether the test is medically necessary. *Id.* Accordingly, this Court agrees that Phoenix Toxicology "is not required to make an independent determination of medical necessity, but rather may rely on the ordering physician's determination." *Id.* at 163.

Still, this proposition is not without qualification. The "tension" between Medicare's statutory requirement of medical necessity applicable to laboratories, *see* § 1395y(a)(1)(A), and physicians' responsibility for determining medical necessity, must yield to a reasonable degree of due diligence on the laboratory's part. This expectation is addressed in guidance that the Office of the Inspector General ("**OIG**") long-ago issued. *See generally* OFF. INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUM. SERVS., PUBLICATION OF OIG COMPLIANCE PROGRAM GUIDANCE FOR CLINICAL LABORATORIES, 63 Fed. Reg. 45,076 (Aug. 24, 1998). To fulfill a laboratory's "legal duty to ensure that it is not submitting false or incorrect claims to Government and private payors," a laboratory should maintain an effective compliance program. *Id.* at 45,077–78. While "laboratories do not and cannot treat patients or make medical necessity determinations," as OIG recognized, "there are steps that such facilities can take to assure compliance with the applicable statutes, regulations and the requirements of Federal, State and private health plans." *Id.* at 45,079; *see also id.* at 45,079–80 (identifying actions, including appropriately designing requisition forms, appropriately advising providers that Medicare will only reimburse medically necessary tests, and engaging in test utilization monitoring and analysis by CPT or HCPCS code). Therefore, Phoenix Toxicology cannot escape Allstate's well-pleaded

allegations by pointing to the fact that in ordering the UDT that it performed, New Jersey providers determined that they were necessary. As Allstate has sufficiently alleged that Phoenix Toxicology engaged in a scheme to conduct duplicative presumptive testing without regard to medical necessity and to encourage physicians to order additional screening tests as a matter of course, Phoenix Toxicology's contrary inference that such tests were reasonable and legitimate because ordering providers determined that they were necessary is insufficient to defeat the inference alleged by Allstate at the pleading stage and is better raised at summary judgment. *See Groat*, 296 F. Supp. 3d at 166 (finding that relator sufficiently alleged that laboratory submitted false claims by "engaging in a scheme that encouraged non-cardiology physicians to order medically unnecessary tests, and then billing the Government for those tests," even though laboratory was not responsible for making medical necessity determinations).

Next, consider the Definitive UDT Standing Order Scheme. Allstate alleges that Phoenix Toxicology accepted from its New Jersey referring providers UDT orders to perform definitive tests on urine samples that returned a negative screening result. [*See, e.g.*, Compl. ¶¶ 107, 114, 127, 128.] Phoenix Toxicology even accepted such orders when "the referring physician [did] not suspect the patient [was] taking an undetected substance; or when the test [was] not needed to rule out as error as the cause of the negative presumptive UDT result." [*Id.* ¶ 114.] Phoenix Toxicology also performed definitive testing prior to even receiving presumptive testing results. [*Id.* ¶¶ 115, 147, 192.]

The Court finds that the Definitive UDT Standing Order Scheme adequately describes the "who, what, when, where, and how" of fraud. Most of the circumstances remain the same as the Duplicative Presumptive UDT Scheme, but the nature of the scheme is slightly different. In this instance, as Allstate identifies, Medicare Local Coverage Determinations and guidelines from the Substance Abuse and Mental Health Services Administration ("**SAMHSA**") prohibit standing orders to perform definitive UDT to confirm screening results without the clinician having performed an individualized assessment. [*See, e.g.*, Compl. ¶¶ 106–17, 124–29.] For instance, Local Coverage Determination No. 36707 explains that "[p]hysician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use, clinical findings, and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record." CTRS. FOR MEDICARE & MEDICAID SERVS., LOCAL COVERAGE DETERMINATION NO. 36707, at PDF p. 7 (2016), https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36707 [https://perma.cc/8FNW-KH2Q]. Likewise, in setting guidelines for clinical drug testing programs, SAMHSA has explained that "[i]n clinical settings, confirmation is not always necessary. . . . [A] confirmatory test may not be needed; patients may admit to drug use or not taking scheduled medications when told of the drug test results, negating the necessity of a confirmatory test." SAMHSA, TECHNICAL ASSISTANCE PUBLICATION SERIES NO. 32: CLINICAL

DRUG TESTING IN PRIMARY CARE, at 10 (2012), https://store.samhsa.gov/sites/default/files/sma12-4668.pdf [https://perma.cc/Q5RM-87TU].

Here, Allstate has adequately alleged that Phoenix Toxicology performed definitive testing to confirm negative screening test results without regard to need. Moreover, Allstate has alleged that Relievus employed the same stock language in each of the reports that it provided to Phoenix Toxicology concerning its patients' medication use and the medical necessity of performing UDT. [*See, e.g.*, Compl. ¶¶ 130–31.] Without sufficient tailoring, this practice raises the plausible inference that the providers' determination to order definitive testing was not appropriately individualized and clinically indicated. This further supports Allstate's allegations of falsity.

Finally, consider the Drug Classes Standing Order Scheme. Allstate alleges that Phoenix Toxicology performed tests of multiple drug classes that were either not drugs of abuse or were not widely available. [Compl. ¶ 136.] These drug tests are alleged to have been performed without due regard for a patient's individualized circumstances. [*Id.* ¶¶ 136–37.] Allstate specifically identifies Phoenix Toxicology's testing for PCP in the urine of nearly every Medicare patient referred, notwithstanding the fact that use of PCP is especially unlikely among the elderly. [*Id.* ¶¶ 136–38; *see also id.* ¶¶ 189–90.] It supplies several representative examples. [*Id.* ¶¶ 151–88.] The Court finds that the Drug Classes Standing Order Scheme also adequately describes the "who, what, when, where, and how" of fraud. *See Majestic Blue Fisheries*, 812 F.3d at 307.

b. Whether Allstate's Reliance on Schemes Concerning Privately Insured Patients Raises a Strong Inference that False Claims Were Submitted to the Federal Government.

Having concluded that the schemes adequately describe the "who, what, when, where, and how" of an alleged fraud, the Court turns to Phoenix Toxicology's chief argument. It submits that Allstate's Complaint must be dismissed because it has failed to identify reliable indicia raising a strong inference that false claims for reimbursement were, in fact, submitted *to the United States*, as Allstate's allegations of fraud focus exclusively on claims Phoenix Toxicology submitted to Allstate (and other private insurers). [Def.'s Br. at 12–13.]

Opposing Phoenix Toxicology's argument, Allstate identifies the following allegations as "reliable indicia" that false claims were submitted to the federal government. [*See* Pl.'s Opp'n at 11–13.] First, Allstate alleges that Phoenix Toxicology has been engaged exclusively in urine drug testing. [Compl. ¶ 119.] While the fraudulent schemes are based on its review of claims submitted to private insurers, Allstate alleges that Phoenix Toxicology submitted claims to the federal government as well as Allstate. [*See id.* ¶ 45.] It further alleges that its review of Phoenix Toxicology's nonpublic bills, reports, notes, claims, and medical records revealed a similar pattern of claims for presumptive and definitive testing submitted to other private insurers, such as Amica and GEICO. [*Id.* ¶¶ 130, 165–68.]

Second, having identified a pattern of claims based on the CPT and HCPCS codes, Allstate reviewed publicly available CMS data showing that, between 2016 and 2022, the federal government reimbursed Phoenix Toxicology $3,717,500 for UDT.

[*Id.* ¶¶ 46–50.] This sum is more than eight times the amount of money Allstate reimbursed Phoenix Toxicology during the same period. [*Id.* ¶ 51.] The CMS data also demonstrate that Phoenix Toxicology submitted claims for reimbursement for the same CPT and HCPCS codes as Allstate and that the most common code was G0482 and G0483—the most expensive drug classes yielding the highest reimbursement rate. [*See id.* ¶¶ 72, 78, 191–92.]

Third, Allstate alleges that, according to CMS data from 2015, Phoenix Toxicology "submitted bills for 1,441 beneficiaries for testing PCP" despite its allegation that PCP-use is not widely found in the general population and is even less likely to be found among elderly Medicare recipients. [*Id.* ¶¶ 189–90.] Allstate claims that it has an expert opinion that it will produce to demonstrate these allegations. [Pl.'s Opp'n at 13; *see also* Compl. ¶¶ 133–36.]

Fourth, and finally, Allstate asserts that CMS data show that, from 2018 until 2020, Phoenix Toxicology billed the federal government for more definitive testing than presumptive testing. [Compl. ¶¶ 193–97.] In 2018, for instance, claims for definitive testing were nearly twice as many as those for presumptive testing (i.e., 1,247 to 716). [*Id.* ¶ 193.] Allstate again argues that presumptive testing should inform the medical necessity of definitive testing, so there should not be a stark discrepancy in the numbers. [*See* Pl.'s Opp'n at 13.]

Taking these allegations together, Allstate contends that a strong and plausible inference is that Phoenix Toxicology submitted false claims for reimbursement to the federal government just as it did with Allstate. [*See* Pl.'s Opp'n at 12 ("All of this non-

public information, combined, leads to the conclusion that the Fraudulent UDT Scheme was Phoenix's *very business model*.").]

While this case is, perhaps, a close one because it is founded on Allstate's own dispute with Phoenix Toxicology, the Court finds that Allstate has identified "reliable indicia" to raise a plausible inference that Phoenix Toxicology submitted false claims to the United States in the same manner as the allegedly fraudulent schemes described above. The Court is mindful that, at the pleading stage, a relator is not required to identify a false claim that was, in fact, submitted to the federal government. *Wilkins*, 659 F.3d at 308. This makes sense, as the defendant—and usually only the defendant—"has access to the documents that could easily prove the claim one way or another." *Foglia*, 754 F.3d at 158. As both parties here recognize, a relator can satisfy Rule 9(b) by alleging "particular details of a scheme to submit false claims paired with reliable indicia that leads to a strong inference that claims were actually submitted." *Id.* at 156 (citation and quotation marks omitted).

Allstate has met its burden at this stage. Accepting its allegations as true, as the Court must, the most natural inference is that Phoenix Toxicology submitted duplicative, excessive, and medically unnecessary claims to Medicare, Medicaid, and the Federal Employee Health Benefits Program between 2016 and 2022. As Allstate argues, there is no credible reason to believe, at this juncture, that Phoenix Toxicology would submit false claims to Allstate and other private insurers, but not to the federal government. It follows that Allstate's theory raises a strong inference of fraud on the United States because Phoenix Toxicology is engaged exclusively in UDT, depends

almost entirely on three New Jersey providers for referrals, and has reimbursed a substantially larger sum from the federal government than Allstate for similar UDT claims. *See United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 258 (3d Cir. 2016) (recognizing that an "opportunity for fraud," in combination with other allegations, can raise a strong inference that false claims were submitted to the government). Thoughtful, targeted, and proportionate discovery will reveal whether Allstate's claims are, in fact, true. *See id.* (concluding that relator had satisfied Rule 9(b) as to "reverse" FCA claim because, *inter alia*, only the defendant "has access to the documents that could prove or disprove [the relator's] well-pled allegations"). The Court will impose this preliminary limiting procedure so that discovery does not become a "fishing expedition," but rather focuses on the critical disagreement between the parties: whether similarly defective claims were actually submitted to the federal government.

In so holding, the Court finds Phoenix Toxicology's cases unpersuasive. It provides an armada of citations for the proposition that "[a]lleging a private scheme, even if alleged with requisite detail . . . , does not provide a 'reliable indicia' that Phoenix Toxicology submitted claims for medically unnecessary tests to Medicare or any other federal health care programs." [Def.'s Br. at 17; *see also id.* at 13–21 (citing cases).] Not quite. Phoenix Toxicology's cases do not stand for as much as it believes.

Begin with *United States ex rel. Zwirn v. ADT Security Services, Inc.*, Case No. 10-cv-2639, 2014 WL 2932846 (D.N.J. June 30, 2014) (Hayden, J.). There, the court considered allegations of fraud brought by a "leading expert on alarm systems" against

ADT Security Services (ADT). *Id.* at *1. Focusing on allegedly "mission critical" deficiencies in residential security systems, the relator contended that ADT's security systems were similarly deficient at federal courthouses and the homes of federal judges. *Id.* at *1–2. But the court dismissed the relator's claims because his lawsuit was premised on the idea that ADT's contracts with the United States Marshals Service reflected the same flaws as a sampling of residential contracts. *Id.* at *7. The court explained that his allegations were "broad and sweeping" in nature (all contracts with the judiciary for the past 20 years) and were based on his own asserted expertise (speculation). *Id.* at *7–8. The relator failed to tie the residential contract deficiencies to the government contract deficiencies, merely implying a connection between violent acts against judicial officers and ADT's allegedly false claims. *Id.* He also failed to clearly identify a theory of false certification. *Id.*

Zwirn is unlike this case. Here, Allstate has clearly identified theories of false certification as to Phoenix Toxicology's government claims. It provides reasonable grounds to believe that they are similar to its private claims. Furthermore, unlike *Zwirn*, Allstate does not rest on sweeping generalities about flaws that 20 years of government contracts "must have" contained. Its allegations are much more circumscribed. Ultimately, the problem for the relator in *Zwirn* was not that it extrapolated from private contracts to support its theory of fraud; it was that it provided the court with no reasonable grounds to believe there was a connection to government contracts. *See, e.g.*, *id.* at *9 ("The allegations cover more than two decades of possible activity, span the entire country, and involve multiple and

undifferentiated contracts and the invoices billed under them. Zwirn does not provide examples of the contracts in question and, apart from arguing by analogy, he does not allege that they include any particular terms or requirements.").

Consider another case. In *United States ex rel. Frazier v. IASIS Healthcare Corp.*, 812 F. Supp. 2d 1008 (D. Ariz. 2011), the relator asserted an illegal kickback scheme between referring physicians and hospitals involving medically unnecessary procedures in violation of 31 U.S.C. § 3729(a)(1)(A)–(C), (G), and the Stark Act and Anti-Kickback Provision, 42 U.S.C. §§ 1395nn(a)(1), 1320a–7b(b). Considering the relator's allegations under a pleading standard identical to that adopted in *Foglia*, *compare Frazier*, 812 F. Supp. 2d at 1015 (citing *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010)), *with Foglia*, 754 F.3d at 156 (first citing *Grubbs*, 565 F.3d at 190; then citing *Ebeid*, 616 F.3d at 998–99), the court dismissed the relator's claims of fraud. *Frazier*, 812 F. Supp. 2d at 1016–18, 1021. The critical problem for the relator in *Frazier* was his failure to plead facts suggesting that a physician referred Medicare patients to the hospital, that the hospital submitted claims for those patients, and that the hospital expressly certified compliance with the Stark Act/Anti-Kickback Provision when submitting claims for reimbursement. *Id.* at 1016. When considering the relator's attempt to establish representative samples of unnecessary medical procedures performed, the court declined to consider cases involving privately insured patients as "legally irrelevant." *Id.* at 1017. Phoenix Toxicology makes much of this, [*see* Def.'s Br. at 15], but again the critical problem, as illustrated by the representative

cases involving Medicare patients, was the relator's failure to "plead facts showing why the procedures performed . . . were unnecessary." *Id.*

This case is different. Allstate has alleged the circumstances showing why Phoenix Toxicology's urine drug tests were either duplicative, excessive, or performed prior to certain initial screening tests only because they were more expensive (and could generate greater revenues). It has sufficiently outlined fraudulent schemes (i.e., the Duplicative Presumptive UDT Scheme, Definitive UDT Standing Order Scheme, and Drug Classes Standing Order Scheme). Thus, unlike *Frazier*, Allstate has sufficiently pleaded an underlying scheme *plus* reliable indicia suggesting a strong inference that false claims were submitted to the federal government.

The Court applying a similar analysis, Phoenix Toxicology's other Ninth Circuit cases are not to the contrary. *See, e.g.*, *United States ex rel. Puhl v. Terumo BCT*, 2019 WL 6954317, at *3 (C.D. Cal. Sept. 12, 2019) (reasoning that relator "fails to allege an improper scheme because he does not detail the scheme or how it led to improper Medicare reimbursements"); *United States ex rel. Karp v. Ahaddian*, 2018 WL 6333670, at *3–4 (C.D. Cal. Aug. 3, 2018) (explaining that relator had failed to link substantial volume of Medicare claims (defendant being within 89th and 94th percentiles of Medicare payments among psychiatry providers between 2012 and 2015) and similar CPT codes as allegedly fraudulent claims submitted to private insurers with sufficiently detailed underlying schemes).

A final note about *United States ex rel. Clausen v. Lab Corp. of Am.*, 290 F.3d 1301 (11th Cir. 2002). Phoenix Toxicology quotes *Clausen* among its citations. [Def.'s Br.

at 16.] Applying Rule 9(b) to a False Claims Act case, the *Clausen* court explained that because the statute attaches liability to "the *presentment* of . . . a claim," the False Claims Act does not permit a plaintiff "merely to describe a private scheme in detail but then to 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." 290 F.3d at 1311. Two points. First, as explained repeatedly, Allstate has provided reasons "for [its] belief that claims requesting illegal payments must have been submitted." Second, contrasting the rigidity of the Eleventh Circuit's approach (like that of the Fourth, Sixth, and Eighth Circuits), the Third Circuit expressly adopted the "nuanced" standard embraced by the First, Fifth, and Ninth Circuits, which permits a relator to show *why* an allegedly fraudulent scheme should yield to the conclusion that false claims were submitted to the government. *See Foglia*, 754 F.3d at 156. This Court thus declines to apply *Clausen* stringently here.

Accordingly, the Court concludes that Allstate has sufficiently pleaded "falsity" under an implied certification theory. This conclusion applies to its claim under Count I that Phoenix Toxicology submitted bills for medically unnecessary UDT in violation of § 3729(a)(1)(A), and its claim under Count II that Phoenix Toxicology blindly submitted false records from its referring providers as well (*see, e.g.*, Compl. ¶ 130).

2. Scienter.

Phoenix Toxicology also argues that Allstate has failed to adequately plead scienter. [Def.'s Br. at 25–35.] As noted above, to establish a prima facie FCA claim,

a relator must allege that the defendant knew that the claim it submitted to the federal government was false or fraudulent. *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175 (3d Cir. 2019); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). The FCA has an expansive definition of knowledge, permitting a relator to plead that a defendant knew, deliberately ignored, or recklessly disregarded the falsity of its claim. *See* 31 U.S.C. § 3729(b)(1)(A). The FCA's "scienter requirement 'requires no proof of specific intent to defraud.'" *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 187 n.2 (2016) (quoting 31 U.S.C. § 3729(b)(1)(B)).

Here, Allstate has pleaded just enough facts to establish that Phoenix Toxicology had the requisite knowledge of falsity. First, Allstate establishes that Phoenix Toxicology had knowledge of the Duplicative Presumptive UDT Scheme. Allstate has alleged that Phoenix Toxicology was aware that its referring providers performed point-of-care testing. [Compl. ¶ 84.] It further alleges that Phoenix Toxicology's requisition form contained a section requesting the result of such testing when a provider referred a patient for UDT. [*Id.* ¶ 85.] As explained above, Allstate maintains that Phoenix Toxicology encouraged referring providers to order additional UDT irrespective of the result of initial screening tests. "[B]ased upon Phoenix Toxicology's request for point of care results on the requisition form, and its stated opinion that the point of care tests are insufficient and require confirmation testing, Phoenix Toxicology encouraged referring providers to conduct [point-of-care testing], and order testing from Phoenix Toxicology for all patients." [*Id.* ¶ 90; *see also id.* ¶ 120.] Whether Phoenix Toxicology's requisition form, in fact, encouraged providers

to request duplicative UDT will be tested in discovery, but it is sufficient at this stage to raise a plausible inference that Phoenix Toxicology knew these additional screening tests were unnecessary.

Likewise, Allstate has pleaded sufficient facts to establish a plausible inference that Phoenix Toxicology had knowledge of the Definitive UDT Standing Order Scheme and the Drug Classes Standing Order Scheme. Allstate alleges that Phoenix Toxicology performed definitive drug testing without regard to the results of presumptive testing or to confirm negative screening tests. [Compl. ¶¶ 178–88, 193–97.] Allstate is alleged to have been aware of Medicare Local Coverage Determinations and SAMHSA guidelines requiring individualized assessments of the need for definitive / confirmatory testing. [*See id.* ¶¶ 108–17, 125–29.] Allstate suggests that Phoenix Toxicology recklessly disregarded its providers' failure to conduct appropriate assessments, performing definitive UDT as a standard practice. [*See, e.g.*, *id.* ¶¶ 117, 138.] Finally, Allstate also suggests that Phoenix Toxicology knew that performing PCP for nearly all Medicare patients was patently unreasonable. [*Id.* ¶¶ 136–38, 189–90.] Although the Court notes that Allstate's allegations of scienter are perilously sparse, when viewed in their totality they clearly identify an alleged practice of recklessly disregarding the submission of duplicative, excessive, and medically unnecessary claims. *See United States ex rel. Int'l Bhd. of Elec. Workers Local Union No. 98 v. Farfield Co.*, 5 F.4th 315, 348 (3d Cir. 2021) (explaining that "Congress added the 'reckless disregard' prong to the FCA's definition of 'knowingly' to target the defendant who has 'buried his head in the sand' and failed to make an 'inquiry into

the claim's validity' that is 'reasonable and prudent under the circumstances') (quoting *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012)). Allstate should be mindful of what it must ultimately prove up. *See United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023) (holding that the focus of the FCA's scienter element is a defendant's "knowledge and subjective beliefs," not "what an objectively reasonable person may have known or believed").

Accordingly, the Court concludes that Allstate has sufficiently pleaded scienter as to Counts I and II of the Complaint.

3. Materiality.

Finally, Phoenix Toxicology argues that Allstate has failed to plead that the allegedly fraudulent scheme was material to the federal government's decision to pay the reimbursement claims. [Def.'s Br. at 35–37; *see also* Def.'s Reply Br. at 14.] The Court disagrees.

"Material" is defined under the False Claims Act as "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). It is a "holistic, totality-of-the-circumstances examination," *United States ex rel. Int'l Bhd. of Elec. Workers Local Union No. 98 v. Farfield Co.*, 5 F.4th 315, 342 (3d Cir. 2021), that "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 193 (2016) (cleaned up) (quoting 26 R. LORD, WILLISTON ON CONTRACTS § 69:12, p. 549 (4th ed. 2003)). Proof of materiality under

the False Claims Act can include "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 194–95. But materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* at 194; *see, e.g.*, *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (finding misrepresentation immaterial because noncompliance with § 1395y was "minor or insubstantial" as relator acknowledged that "the FDA would not 'have acted differently had Genentech told the truth' ").

Here, Allstate has alleged sufficient facts to raise the plausible inference that the federal government would not have paid Phoenix Toxicology's reimbursement claims had it known that the billed UDT was, in fact, medically unnecessary. Not only does Allstate identify § 1395y as a condition of payment, but also it cites to a Medicare Local Coverage Determination that explains that " '[r]outine standing orders for all patients in a physician's practice are not reasonable and necessary' " and that " '[i]t is not reasonable and necessary for a physician to perform presumptive POCT [point-of-care testing] and order presumptive IA [immunoassay] testing from a reference laboratory.' " [Compl. ¶ 117 (quoting CTRS. FOR MEDICARE & MEDICAID SERVS., LOCAL COVERAGE DETERMINATION NO. 36707, at PDF p. 13 (2016)).] " 'Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.' " [*Id.*] Finally, Allstate identifies that UDT " 'may not be used to confirm or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods.' " [*Id.*] Paragraph 117 is

key to demonstrating that the allegedly fraudulent schemes here were "material" to the federal government's payment decisions because it very likely would not have reimbursed Phoenix Toxicology's claims had it known about its noncompliance with the statutory and regulatory scheme. This case is thus unlike *Petratos* where the court concluded that "CMS would reimburse the[] claims even with full knowledge of the alleged reporting deficiencies." 855 F.3d at 490. Given paragraphs 108 through 117 of the Complaint, this Court cannot conclude similarly. Allstate has pleaded sufficient facts that Phoenix Toxicology's allegedly fraudulent scheme was material. *See Escobar*, 579 U.S. at 192 ("[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act").

Therefore, the Court concludes that Counts I and II of Allstate's Complaint are supported by sufficient allegations to survive dismissal at this juncture.

V. CONCLUSION

Accordingly, the Court having carefully considered the parties' submissions, and for the reasons expressed above, and for good cause shown,

IT IS, on this **30th** day of **May 2024**, hereby:

ORDERED that Defendant Phoenix Toxicology's Motion to Dismiss [ECF No. 19] is **DENIED**.

s/Renée Marie Bumb
RENÉE MARIE BUMB
Chief United States District Judge