IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA ex rel. KRISTA NICHOLSON,	)	
Plaintiff,	)	
v.	)	**Case No. 3:20-cv-00309**
	)	**Judge Aleta A. Trauger**
CLARKSVILLE PAIN INSTITUTE, LLC, PAIN INSTITUTE OF NASHVILLE, PLC, MICHAEL COX, and DEBBIE COX,	)	
Defendants.	)	

MEMORANDUM

The United States (the "government") asserts claims under the False Claims Act ("FCA") and federal common law claims for payment by mistake and unjust enrichment against defendants Clarksville Pain Institute, LLC, Pain Institute of Nashville, PLC, Michael Cox, and Debbie Cox.

Before the court are two Motions to Dismiss the government's Complaint-in-Intervention ("Complaint") (Doc. No. 65): one filed by the Clarksville Pain Institute and the Pain Institute of Nashville (Doc. No. 75), and the other filed by Michael Cox and Debbie Cox (Doc. No. 79), each supported by a separate Memorandum of Law (Doc. Nos. 76, 80).[1] The government has filed a

[1] The court rejects as without merit the government's assertion that the two sets of defendants—who happen to be represented by the same counsel—filed separate Rule 12(b)(6) motions to circumvent the page limitations for dispositive motions set forth in Local Rule 7.01(a)(2). The cases cited by the government are inapposite, and the filing of two separate motions in this case does not implicate the Local Rule. Even if there were some requirement that all four defendants join in filing a single motion simply because they are represented by the same attorneys, given that the Complaint is seventy pages long and comprised of nearly four hundred paragraphs, the court would readily have granted a motion to exceed the page limitation set forth in the Local Rule. Moreover, the filing of separate motions in this situation does not create more work for the court. Raising unjustified arguments does.

consolidated Response in opposition to both motions. (Doc. No. 81.) The two sets of defendants filed separate Reply briefs in further support of their motions. (Doc. Nos. 84, 85.)

For the reasons set forth herein, the Cox defendants' Motion to Dismiss will be granted in its entirety, and the entity defendants' motion will be granted in part and denied in part, with the common law claims permitted to proceed.

I. LEGAL STANDARDS

A. False Claims Act

This case involves the defendants' submission of requests for reimbursement for medical services from federal health care programs, specifically Medicare and the United States Department of Veterans Affairs, Veterans Health Agency ("VA") (collectively with Medicare, the "Federal Health Benefit Programs" or "FHBP"). Medicare is a federal health insurance program that provides coverage for individuals based on age, disability, or affliction with endstage renal disease. (Doc. No. 65 ¶ 33 (citing 42 U.S.C. §§ 426, 426-1.) It is funded by premium payments from covered individuals and funds appropriated by the government. (*Id.*) Medicare Part B, which provides outpatient coverage for, among other things, diagnostic laboratory tests (*see* 42 C.F.R. § 410.32), only covers medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Similarly, the VA offers medical benefits to some honorably discharged veterans and their families through TRICARE or, if they do not qualify for TRICARE, potentially through the Civilian Health and Medical Program of the VA ("CHAMPVA"). (Doc. No. 65 ¶¶ 67–68.) Like Medicare, CHAMPVA provides for coverage of allowable medical services and supplies so long as they are "medically necessary and appropriate for the treatment of a condition and . . . are not specifically excluded from program coverage." (*Id.* ¶ 70 (quoting 38 CFR § 17.272(a)).)

The parties' primary focus is on Medicare claims. To participate in the Medicare program as a provider, the "provider," which the Complaint defines as an individual medical practitioner (Doc. No. 65 ¶ 35 n.2), must submit a Medicare Enrollment Application, Form CMS-855B. Enrolled providers must complete a new Form CMS-855B to change their enrollment information or to reactivate or terminate Medicare enrollment. (*Id.* ¶ 39.) Providers must certify that they will comply with all Medicare laws, regulations, and program instructions. (*Id.* ¶ 40 (citing 42 C.F.R. § 424.516(a)).) Any services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are excluded from coverage, and a provider submitting a claim for payment to FHBP necessarily certifies that the services were both provided as billed and medically reasonable and necessary. (*Id.* ¶¶ 41, 42.)

Medicare also requires that providers include documentation in patients' medical records that establish that services provided were reasonable and necessary, and a provider's claim for a diagnostic test is not medically reasonable and necessary if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. (*Id.* ¶ 43 (citing 42 U.S.C. §§ 1395l(e), 1395u(c)(2)(B)(i); 42 C.F.R. § 410.32(d)(3)).) In addition, diagnostic testing of a patient must be ordered by the treating provider, and tests that are not ordered by the treating provider are not reasonable and necessary and are not reimbursable. (*Id.* ¶ 44 (citing 42 C.F.R. § 410.32(a); Medicare Benefit Policy Manual, Ch. 15, § 80.1).)

In addition, although the government elsewhere defines "provider" as an individual practitioner, it alleges that a provider's "authorized official" must sign the "Certification Statement" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to the laws, regulations and program instructions of the Medicare program." (Doc. No. 65 ¶ 47.)

A provider (or entity) seeking reimbursement for services provided to Medicare patients must submit a CMS Form 1500, or its electronic equivalent, known as the 837P format, to the appropriate Medicare Administrative Contractor ("MAC"). (Doc. No. 65 ¶¶ 36, 52.)[2] To submit electronic claims via the 837P format, a provider must first complete and submit to CMS an Electronic Data Interchange Enrollment Form ("EDI"). The EDI may be completed by the provider or an authorized individual who has the legal authority to commit the provider to abide by the laws, regulations, and the program instructions of Medicare. On the EDI, the provider agrees in advance to "submit claims that are accurate, complete, and truthful" and certifies that the use of the provider's National Provider Identifier on a claim "constitutes the provider's legal electronic signature and an assurance that services were performed as billed." The provider's EDI certification serves as the provider's signature for every electronic claim submitted by the provider thereafter. (Doc. No. 65 ¶ 53.)

In addition to Medicare laws and regulations, providers are also subject to Local Coverage Determinations ("LCDs") issued by MACs, which identify, for the states within their jurisdiction, procedures and services that are reasonable and necessary and therefore eligible for payment under Medicare. (*Id.* ¶ 38 (citing 42 U.S.C. §§ 1395ff(f)(2), 1395m-1(g)).) When submitting the CMS 1500 to Medicare, providers certify that the claim is truthful, accurate, and complete and complies with Medicare rules and regulations and applicable LCDs, that the provider is familiar with the applicable law, and that the services on the claim form were medically necessary. (*Id.* ¶ 59.) Generally, after a provider electronically submits the claim to the MAC, the claim is paid directly to the provider without any review of supporting documents, including medical records. (*Id.* ¶ 63.)

[2] At all times relevant to this Complaint, Palmetto GBA, LLC and its predecessor, Cahaba Government Benefit Administrators, LLC were the MACs for the services billed to Medicare by the defendants. (Doc. No. 65 ¶ 37.)

The FCA imposes civil liability on any person who knowingly submits false claims to the government. As relevant in this case, 31 U.S.C. § 3729(a)(1)(A) creates liability for "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." To state a "presentment" claim under this provision of the FCA, the government must sufficiently plead that (1) the defendant presented, or caused to be presented, a claim for payment or approval; (2) the claim was false or fraudulent; and (3) the defendant's acts were undertaken "knowingly," meaning with actual knowledge of the information, or with deliberate ignorance or reckless disregard for the truth or falsity of the claim. *United States ex rel. Prather v. Brookdale Senior Living Cmties., Inc.*, 838 F.3d 750, 761 (6th Cir. 2016); 31 U.S.C. § 3729(b)(1).

Subsection 3729(a)(1)(B) imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). To state a claim under this provision, the plaintiff must sufficiently plead

> [1] that the defendant [made] a false statement or create[d] a false record [2] with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information; [3] that the defendant . . . submitted a claim for payment to the federal government; . . . and [4] that the false statement or record [was] material to the Government's decision to make the payment sought in the defendant's claim.

U.S. ex rel. Sheldon v. Kettering Health Network, 816 F.3d 399, 408 (6th Cir. 2016) (alterations in original) (quoting *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 618 F.3d 505, 509 (6th Cir. 2010)).

B. Standard of Review

Two standards of review govern the consideration of a motion to dismiss claims under the FCA. First, under Rule 12(b)(6), the court must accept as true all well pleaded material allegations of the pleadings, and those allegations must "be sufficient to give notice to the defendant as to what claims are alleged, and . . . plead 'sufficient factual matter' to render the legal claim plausible, *i.e.*, more than merely possible." *Fritz v. Charter Twp. of Comstock*, 592 F.3d 718, 722 (6th Cir. 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009)). That is, under the general pleading

standards of Rule 8, the factual allegations in the complaint need not be detailed, although "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

As with any motion under Rule 12(b)(6), if "matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d). At the same time, it has long been the rule that a court may consider not only the complaint and exhibits attached to it, but also exhibits attached to a defendant's motion to dismiss, "so long as they are referred to in the Complaint and are central to the claims contained therein." *Brent v. Wayne Cty. Dep't of Hum. Servs.*, 901 F.3d 656, 694 (6th Cir. 2018) (citation omitted). A court may also consider public records without converting a Rule 12(b)(6) motion into a Rule 56 motion, but it cannot take judicial notice of the facts set forth in a public record unless they "are not subject to reasonable dispute." *Jones v. City of Cincinnati*, 521 F.3d 555, 562 (6th Cir. 2008) (citation omitted); *see also Bailey v. City of Ann Arbor*, 860 F.3d 382, 386 (6th Cir. 2017) ("[A] court ruling on a motion to dismiss '*may* consider materials in addition to the complaint if such materials are public records or are otherwise appropriate for the taking of judicial notice.'" (emphasis in original) (quoting *New Eng. Health Care Emps. Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003))). In this case, the defendants refer to documents outside the pleadings that are neither referred to in the Complaint nor central to its claims. To the extent they are public documents, the facts therein are clearly subject to dispute. The court has not

considered these documents in addressing the Motions to Dismiss.[3]

In addition to Rule 12, complaints alleging FCA violations must comply with Federal Rule of Civil Procedure 9(b), "because defendants accused of defrauding the federal government have the same protections as defendants sued for fraud in other contexts." *Prather*, 838 F.3d at 760 (quoting *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011)) (internal quotation marks omitted). Under that rule, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). To satisfy Rule 9(b)'s particularity requirement, "a plaintiff, at a minimum, must 'allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.'" *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.* ("*Bledsoe II*"), 501 F.3d 493, 504 (6th Cir. 2007) (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161–62 (6th Cir. 1993)). In the Sixth Circuit, the complaint must identify specific false claims; it is not sufficient to simply allege a false scheme with particularity. *Id.*[4]

Because this case involves multiple defendants, it implicates another aspect of Rule 9(b). That is, the particularity requirement prohibits plaintiffs from relying on "group pleading." *See*

[3] These documents include, for example, the Tennessee Department of Health's Chronic Pain Guidelines (*see* Doc. No. 76 at 8 & n.2), the CDC Guideline for Prescribing Opioids for Chronic Pain (*id.* at 9 & n.5), and internet articles on allergy testing and chronic pain (*id.* at 12 & n.10).

[4] There is a circuit split on this issue, with the Fourth, Sixth, Eighth, and Eleventh Circuits applying the stricter rule, while the Second, Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits "have overtly adopted a more lenient pleading standard," allowing a "complaint that does not allege the details of an actually submitted false claim to pass Rule 9(b) muster by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 89 (2d Cir. 2017) (internal quotation marks and citations omitted).

Sugarlips Bakery, LLC v. A&G Franchising, LLC, No. 3:20-cv-00830, 2022 WL 210135, at *10 (M.D. Tenn. Jan. 24, 2022) ("Mere 'group pleading' . . . fails to meet . . . [Rule] 9(b)'s specificity requirements . . . . " (citation omitted)). More specifically, the Sixth Circuit has explained that "[a] complaint may not rely upon blanket references to acts or omissions by all of the defendants." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.* ("*Bledsoe I*"), 342 F.3d 634, 643 (6th Cir. 2003). Rather, under Rule 9(b), "each defendant named in the complaint is entitled to be apprised of the circumstances surrounding the fraudulent conduct with which he individually stands charged." *Id.* (citation omitted); *see also Bledsoe II*, 501 F.3d at 510 ("[I]mproperly pled allegations of fraud do not become adequate merely by placing them in the same complaint with allegations that are sufficient . . . . Allowing such a complaint to go forward *in toto* would not provide defendants with the protections that Rule 9(b) was intended to afford them . . . ."). Thus, under Rule 9(b), a plaintiff cannot "simply lump[] multiple defendants together without explaining each defendant's culpable role." *Sugarlips Bakery*, 2022 WL 210135, at *10.

The "knowingly" element of FCA claims is not subject to the particularity requirement and may instead, be alleged "generally," subject only to Rule 8. To determine whether a plaintiff's factual allegations give rise to an inference of fraudulent intent, "the court must conduct an inquiry of the competing plausible inferences and must find scienter has been sufficiently pled as long as a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *United States v. Quicken Loans Inc.*, 239 F. Supp. 3d 1014, 1024–25 (E.D. Mich. 2017) (quoting *Chamberlain v. Reddy Ice Holdings, Inc.*, 757 F. Supp. 2d 683, 701 (E.D. Mich. 2010)).

II. FACTS AND PROCEDURAL HISTORY

A. Background

Relator Krista Nicholson filed a *qui tam* complaint under seal on April 10, 2020. (Doc. No. 1.) The relator's *qui tam* complaint alleged numerous fraud schemes and FCA violations, including the submission of false claims for various categories of medically unnecessary services, as well as violations of the Anti-Kickback Statute and the Stark law.

In July 2024, after numerous extensions of the deadline, the government elected to intervene in part, with respect to the relator's claims under 31 U.S.C. § 3729(a)(1)(A) and (B) concerning the medical necessity of Urine Drug Testing ("UDT"), allergy testing, and psychological testing. (*See* Doc. No. 60.) It declined to intervene with respect to the other claims in the *qui tam* complaint. (Doc. No. 61.) The government filed its intervenor Complaint on September 11, 2024 (Doc. No. 65), and the court subsequently dismissed the relator's non-intervened *qui tam* claims. (Doc. No. 71.)

Defendant Clarksville Pain Institute, LLC ("CPI") was a single-member limited liability company formed in 2012 with its principal place of business in Clarksville, Tennessee. CPI's registered agent was Michael Cox. Debbie Cox was its sole member. (*Id.* ¶ 17.)

Pain Institute of Nashville, PLC ("PIN") is a professional limited liability company formed in 2017 with its principal place of business in Clarksville, Tennessee, at the same address as that previously used by CPI. PIN's registered agent and secretary is Michael Cox. When PIN was formed on February 15, 2017, Debbie Cox held a 99% membership interest, and non-party John Stanton held a 1% membership interest. Stanton withdrew his membership interest on February 15, 2022. (*Id.* ¶ 18.) Another individual was a member of PIN until August 7, 2023, when she transferred her membership interest to a professional limited liability company of which Debbie Cox is the sole member. (*Id.* ¶ 20.)

CPI and PIN—to which the government refers collectively as the "Pain Institute"—are separate entities, but they operated a single business, a medical clinic ("the clinic") at 1849 Madison Street in Clarksville, Tennessee during the relevant time, overlapping for at least some period after PIN was formed in 2017 until CPI and PIN merged on November 1, 2018, with PIN as the surviving entity.[5] (*Id.* ¶ 19.) Practitioners at the clinic provide pain management treatment that often involves prescribing opiates to chronic pain patients. (*Id.* ¶ 29.)

Michael Cox and Debbie Cox are married and reside in Franklin, Tennessee. Michael Cox was formerly a sales representative in the healthcare industry. Debbie Cox is a licensed nurse anesthetist. (*Id.* ¶¶ 23–25.) The Coxes directed and controlled the clinic's daily operations, including the operation of an in-house UDT laboratory and the submission of claims for payment to FHBP. (*Id.* ¶ 30.) According to the government, the Coxes "implemented their fraudulent schemes on FHBP" through their operation of the clinic. (*Id.* ¶ 29.)

The government alleges generally that CPI and PIN, entities "owned or managed" by Michael Cox and Debbie Cox, billed FHBP for false and/or fraudulent claims for three kinds of medical testing administered to FHBP beneficiaries: UDT, allergy tests, and psychological tests. (*Id.* ¶¶ 1–2.) According to the government, the defendants billed FHBP for tests that

> were not rendered, not medically necessary, not used in the treatment of FHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the treating practitioner. These services did not comply with material requirements of FHBP laws, regulations, and program instructions, and as the Pain Institute and the Coxes knew, were not reimbursable.

(*Id.* ¶ 3.) The government alleges that the defendants "knew, acted in deliberate ignorance, or acted in reckless disregard of FHBP requirements" and "submitted claims to FHBP for payment anyway

[5] The court refers to them as separate entities, to the extent the allegations in the Complaint make that possible.

thereby presenting false claims and making materially false express and implied certifications to get such claims paid." (*Id.* ¶ 4.) These practices allegedly continued from "at least April 2014 through May 2024," during which period the defendants "knowingly submitted and caused to be submitted millions of dollars in false claims to FHBP for services that were not reasonable and necessary for treatment of their patients," thus causing the government to incur millions of dollars in damages when FHBP paid the false or fraudulent claims. (*Id.* ¶ 9.)

Debbie Cox, through CPI, opened the clinic in February 2012, and Michael Cox eventually quit his medical sales job to work as an employee of the clinic on the "business side." (Doc. No. 65 ¶¶ 150–42.) The Coxes ran a second location in Whitehouse, Tennessee, which eventually moved to Springfield, Tennessee. They also started the Cox Family Pharmacy, which operated from the same suite as the in-house UDT lab in the same suite of offices at 1849 Madison Street, in Clarksville, Tennessee. (*Id.* ¶¶ 148–51.) After Tennessee passed a law in 2017, prohibiting pain clinics from owning a pharmacy within 1,000 feet of a pain clinic, the Coxes sold the Cox Family Pharmacy to an entity owned by an employee of the pharmacy and an employee of the Coxes' in-house UDT lab. (*Id.* ¶¶ 152–54.)

Michael Cox ran the "business side" of the clinic, including finances, payroll, and ordering supplies. (*Id.* ¶ 156.) Debbie Cox performed procedures as a nurse anesthetist at the clinic until November 2016. (*Id.* ¶ 157.)

Michael Cox signed the Certification Statement in Section 15 of Form CMS-855B on behalf of CPI in 2014, in his capacity as both the "delegated official" and "office manager." Debbie Cox, as CPI's "authorized official," signed the "Certification Statement" in Section 15 of Form CMS-855B on behalf of CPI in 2014, 2015, 2016, and 2018. She signed the "Certification Statement" in Section 15 of Form CMS-855B on behalf of PIN in 2017, 2021, and 2022. She

signed a Certification Statement on a Form CMS-855B in her personal capacity as a practitioner in 2017. (Doc. No. 65 ¶¶ 48–51.) CPI submitted one of its EDI certifications, signed by Debbie Cox, to the MAC in April 2013. PIN submitted one of its EDI certifications, signed by Debbie Cox, to the MAC in January 2021. (*Id.* ¶¶ 54–55.)

The government asserts that the medical clinic's "business model" relied on "extracting revenue from its patients" based on a "'tests-for-pills' *quid pro quo*," pursuant to which patients underwent excessive and unnecessary testing and other services to get their prescribed pain medications. (*Id.* ¶¶ 159, 161–62.) Although not involved with the medical side of the clinic's practice, Michael Cox allegedly "would often try to manipulate processes and influence/intimidate providers into treating patients in more profitable ways." (*Id.* ¶ 163.)

Debbie Cox, in solicitating a physician to join the clinic as a provider, described the clinic's patient population as "mainly Medicare and [T]ricare patients" who were "very compliant." (*Id.* ¶ 164.)

As an example of its assertion that the Coxes made patient-care decisions based on profit, the government quotes a text exchange between Michael Cox and John Pritchard, then an employee of the Cox Family Pharmacy, which the Coxes still owned at that time. Pritchard sent Michael Cox a text stating that the profit for Movantik, a laxative often prescribed with opioids, was "between $7 and $11" per prescription, to which Cox responded, "Let's buy just kidding." (*Id.* ¶¶ 165–66.)

The government maintains that the Coxes' alleged greed played out through their operation of four distinct "schemes" as identified by the government, two of which concern UDT: the Standing/Blanket Orders Scheme and the Reflex Testing Scheme. The third was the Allergy Testing Scheme, and the fourth was the Psychological Testing Scheme.

B. The UDT Schemes

The government acknowledges that UDT is often used in the management of chronic pain patients taking prescribed opioids for long periods of time. UDT is "used both to confirm that patients are taking, rather than diverting, the drugs that are prescribed to them, and that they are not taking other drugs not prescribed by the treating physician." (Doc. No. 65 ¶ 91.) When used correctly, UDT can be reasonable and medically necessary. (*Id.* ¶ 92.)

To be a "covered service" and eligible for payment by Medicare, UDT claims must comply with the MAC's Local Coverage Determination L35724, *Controlled Substance Monitoring and Drugs of Abuse Testing* ("LCD"), which covers services performed on or after October 1, 2015. (Doc. No. 65 ¶ 108.) The LCD defines the term "standing order" as a "[t]est request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits." (Doc. No. 65 ¶ 110 (quoting LCD L35724 at 4).) By definition, "[r]outine standing orders for all patients in a physician's practice are not reasonable and necessary." (*Id.* (quoting LCD L35724 at 13).)

The LCD defines "blanket order" as a "[t]est request that is not for a specific patient" but is instead "an identical order for all patients in a clinicians' practice without individualized decision making at every visit." (*Id.* ¶ 111 (quoting LCD L35724 at 5).) The LCD states that any UDT performed pursuant to a blanket order is not reasonable and necessary and therefore not eligible for reimbursement. (*Id.*)

Reflex testing is "[l]aboratory testing that is performed 'reflexively' after initial test results to identify further diagnostic information essential to patient care," meaning that it is "not necessarily based on a specific physician's order." (*Id.* ¶ 112 (quoting LCD L35724 at 5).) "Reflex definitive UDT" is deemed not reasonable and necessary when "presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient." (*Id.*

¶ 113 (quoting LCD L35724 at 13).) In sum, the LCD requires that all UDT orders be "individualized based on clinical history and risk assessment, and must be documented in the medical record." (*Id.* ¶ 115 (quoting LCD L35724 at 8).)

The government alleges that, "[t]hrough standing and blanket orders, the Coxes pressured providers to order more UDT with higher rates of reimbursement." (*Id.* ¶ 169.) The defendants also allegedly profited from reflex testing by requiring "mandatory patient re-visits every 28 days and consistently conducting presumptive and definitive UDT simultaneously." (*Id.*)

The clinic has always had an on-site lab for testing UDT samples, located in the same building as the clinic but in a different suite. (*Id.* ¶¶ 173, 175.) The clinic performs UDTs at its on-site lab using a complex machine that conducts High Performance Liquid Chromatography coupled with Mass Spectrometry ("LCMS machine"), which the clinic has owned since 2014. (*Id.* ¶¶ 102, 177–78.) Unlike point of care ("POC") tests, LCMS test results are often not available for several days after the test is performed. (*Id.* ¶ 104.) The government also explains that,

> [w]hen a definitive test is performed on an LC-MS device, there is no medical purpose or reason for the LC-MS simultaneously to report "presumptive results" because definitive results contain the same information that a presumptive test provides, and more.

(*Id.* ¶ 105.) In addition, even if the LCMS machine runs "the same set of tests on all samples" simply for convenience and cost-effectiveness, irrespective of medical necessity, the lab may only bill FHBP "for those tests that are medically reasonable and necessary to treat the beneficiary." (*Id.* ¶¶ 106–07.)

Debbie Cox told a physician whom she was soliciting to join the practice that the LCMS machine was "a game changer and will pay for itself within a few months. There is special chart

verbiage and [CPT] codes[6] not to over or under bill or be put on CMS' radar." (*Id.* ¶ 179.)

Michael Cox tracked the clinic's UDT on a weekly basis, using an Excel spreadsheet demonstrating how many tests per month were conducted and how those tests broke down by payor. (*Id.* ¶¶ 180–81.)

According to the government, the "defendants" collectively "articulated a policy of blanket and standing orders" for UDT at the medical clinic. (*Id.* ¶ 182.) The Coxes allegedly disseminated the blanket and standing orders over the years through text messages, office policies, email, and verbal in-person communications. (*Id.* ¶ 183.) The "defendants" have also implemented a policy of reflex testing since 2014, pursuant to which patients "would be tested for presumptive and definitive UDT on the same date of service every 28 days." (*Id.* ¶ 184.) These "schemes," rather than individualized patient care, allegedly drove providers' testing decisions. (*Id.* ¶ 185.) The "schemes" are manifested by "medical records that are often incomplete or lack documentation of test results, provider orders, and patient discussions." (*Id.* ¶ 186.) Providers at the clinic purportedly "knew the drill and followed the Coxes' instructions to bill UDT in accordance with these two schemes." (*Id.* ¶ 188.) The government also asserts that the schemes "taint all of the Pain Institute's claims for UDT since 2014." (*Id.* ¶ 189.)

The government alleges that, irrespective of whatever written policies and treatment guidelines providers possessed, "the real policy was articulated by the Coxes: testing was mandatory every 28 days." (*Id.* ¶ 194.) As a result, providers' UDT orders were not based on specific patient needs and individualized decision making at each patient visit. (*Id.* ¶ 197.)

[6] Current Procedural Terminology Codes ("CPT codes") precisely identify the services rendered, and providing accurate CPT codes in claims is material to, and a condition of, payment for FHBP. (Doc. No. 65 ¶¶ 56, 57.)

The medical director for CPI from 2014 through 2016 signed an undated "Urine Drug Screen Policy" for patients on opioid therapy that directed providers to designate patients as high, medium, or low risk, based on factors identified in the policy. (*Id.* ¶¶ 282, 285.) High-risk patients were to undergo UDT on every visit; medium-risk patients would receive UDT eight times a year; and low-risk patients would receive UDT four times a year. (*Id.* ¶ 285.) Patients could be designated as high risk for many reasons, including being on a certain amount of opioids or being prescribed benzodiazepines, but providers were to "classify a high risk patient using their level of experience and comfort level while dealing with a patient on opioid therapy." (*Id.*) According to the government, this policy is inconsistent with the applicable LCDs and meets the definition of both a blanket order and a standing order for UDT. (*Id.* ¶ 286.)

PIN's 2018 written policies and procedures specifically state that "Urine drug screens are mandatory at the Institute." (*Id.* ¶ 199.) Each new patient had to sign a form acknowledging that urine drug screens were mandatory. (*Id.* ¶ 200.)

On September 1, 2015, a CPI employee emailed Michael Cox. The email's subject heading was "medical necessity for UDT's for chronic pain patients," and the body of the email stated:

> HI Michael [sic], See below. Kerri.
>
> > This patient is a chronic pain patient that is using opiates/opioids and or on other schedule 2 and 3 medications. Because of the risk of abuse with other prescribed medications of the same nature not prescribed by this clinic and illicit drugs of abuse, I am ordering this drug test out of medical necessity for this patients safety and efficacy and to prevent to the best of my ability this patient to abuse any prescribed or illicit/illegal drugs.

(*Id.* ¶¶ 201–02 ("[sic]" in original).) Michael Cox replied, "Thanks!" (*Id.* ¶ 203.)

No additional information about this exchange exists, but the government infers from it that the employee was drafting for Michael Cox's review "language for standing orders in a patient's medical record so that UDT could be billed with more frequency." (*Id.* ¶ 204.)

Michael Cox tracked the profitability of UDT closely, and the Coxes knew that "more testing meant more money." (*Id.* ¶ 209; *see id.* ¶¶ 205–08, 210–13.)

In February 2016, Michael Cox exchanged emails with CPI's third party medical billers, Ron Wood and Michelle Sandlin of Medical Data Services, regarding CIGNA's new UDT policy, the maximum number of dates and units for which CIGNA would reimburse UDT, the CPT codes that CIGNA had declared not medically necessary, and strategies for maximizing reimbursement for UDT. (*Id.* ¶¶ 214–20.)

In June 2017, Sandlin notified Michael Cox that Medicare was "conducting a widespread review" of a specific UDT CPT code, G0483, for medical necessity. (*Id.* ¶¶ 222–23.)

In November 2017, Sandlin notified Michael Cox of the Medicare LCD applicable to the same CPT code (G0483); she sent Cox a marked-up copy of the LCD, noting which issues did or did not apply to the medical clinic. (*Id.* ¶¶ 224–25.) She pointed out: "Blanket Orders . . . this is the actual office policy to test each patient across the board. This is NOT [sic] medically necessary per Medicare Guidelines." (*Id.* ¶ 226 ("[sic]" in original).) Sandlin also noted that routine standing orders were not "necessary" and that "Confirmation UDS is NOT [sic] medical necessary UNLESS [sic] the POC/Analyzer is negative when it should be positive." (*Id.* ¶¶ 226–27 ("[sic]" in original); *see also id.* ¶ 228.) Among other things, Sandlin emphasized that "[d]ocumentation is key to all of this . . . . The providers need to make sure to get specific about the wording of WHY the UDS is needed." (*Id.* ¶ 228.)

Despite Michael Cox's thus being notified about what would and would not be considered medically necessary, the clinic's providers allegedly "continued billing in accordance with the Standing/Blanket Orders and Reflex Testing Schemes." (*Id.* ¶ 229.)

In October 2018, Ron Wood sent Michael Cox the LCD on UDT again, again outlining the "Medical Necessity Guidance" for UDT. (*Id.* ¶¶ 230–31.)

Later the same month, Debbie Cox sent a text message to several individuals (whose roles at the clinic are not identified), notifying them that she and Michael Cox, after talking with CPI providers, had decided to require all patients receiving an opioid prescription be furnished with Narcan[7] and that is "mandatory just like a drug screen." (*Id.* ¶ 236.) Patients refusing to comply by their third visit would be discharged. (*Id.*) She noted, "This way if there is ever an OD we are covered and they are taught what to do to prevent a death." (*Id.*)

In August 2019, Humana Military sent PIN an "education letter" regarding its UDT program, specifically noting that it had found that the clinic "bill[ed] an excessive volume of the highest level of definitive drug testing" and requiring all future definitive drug test claims to be submitted with "the corresponding medical records and physician orders." (*Id.* ¶ 237–38.)

In March 2022, Michael Cox, Debbie Cox, and another third-party biller, Megan Rabbitt, exchanged text messages about the fact that TRICARE was "pulling charges on every patient" but was still denying UDT claims as medically unnecessary. (*Id.* ¶¶ 243–44; *see id.* ¶ 248.) Debbie Cox asked Rabbitt if she was "respond[ing] that the patient is high risk for overdosing or that they're on a benzo antidepressant or sleep aid" that "put[] them at high risk for overdosing." (*Id.* ¶ 245.) Rabbitt told her that it was because they were using "too high of a code for what is done" and that they had changed the code and were "hoping this will take down the denials." (*Id.* ¶ 246; *see also id.* ¶ 248.)

[7] Narcan, the brand name for the medication naloxone, is an opioid antagonist that "rapidly reverses an opioid overdose." *See* https://nida.nih.gov/publications/drugfacts/naloxone.

In June 2022, an integrity contractor for CMS sent PIN a notice of overpayment in the amount of $16,708.38, pertaining to claims that had been denied for lack of documentation. (*Id.* ¶¶ 249–50.) The letter also notified the clinic that

> interviewed Medicare beneficiaries "stated that you set his/her appointment schedule every 28 days, which provides for 13 office visits per year instead of 12 . . . you conducts [sic] the highest level of urine drug tests at every visits and do not explain the medical necessity for the [t]ests nor do you alter the beneficiary's medications or plan of care based upon the results of the extensive drug testing.

(*Id.* ¶ 252 (alterations in original).) Despite this notice, the clinic continued to bill UDT in the same manner that it had been doing. (*Id.* ¶ 253.)

Bill Heckle, a consultant for the UDT lab, sent invoices to Michael Cox for his services for May, June, July, and August 2022, reflecting that the number of presumptive and confirmatory tests conducted those months were almost identical (960 and 942 for each in May; 1,112 and 1,114 in June; 841 and 880 in July; and 880 and 879 in August). (*Id.* ¶¶ 254–55, 257–60.) According to the government, these numbers were so close each month "because the Pain Institute's practice was to bill both presumptive and definitive/confirmatory UDT on the same day." (*Id.* ¶¶ 256.)

In October 2022, Heckle emailed Michael Cox to tell him:

> Regarding reflexing, it looks like reflex testing for your practice lab is not going to work out. CMS has determined that reflex testing is "not Reasonable" other than at reference labs. You can still use the guidelines for reflex testing which should satisfy the medical necessity (for example to verify presumptive Positives UTD). You can't just automate it without a provider order.

(*Id.* ¶ 262.) According to the government, this is the defendants' "*Reflex Testing Scheme* in action." (*Id.* ¶ 263.)

In August 2023, another consultant engaged by the medical clinic notified Michael Cox that CMS had implemented a policy change effective July 1, 2023, pursuant to which claims for definitive drug testing would automatically be denied "when billed on the same claim with presumptive tests." (*Id.* ¶ 266.) The consultant also provided advice on how to "bypass this edit."

(*Id.*) At some point, audits conducted by private insurers Blue Cross and United Healthcare "reflected overpayments and denied claims for UDT." (*Id.* ¶ 267.)

Nonetheless, the government claims, Michael Cox "intimidate[d] providers into ordering more UDT," telling them things like, "it's your license" and "it's on you if you don't order a drug screen." (*Id.* ¶ 268.)

The government asserts that all of these communications reflect the Coxes' understanding of Medicare billing and coding for UDT, that "blanket and standing orders existed at the [medical clinic] since at least 2014," and that the clinic "engaged in reflex testing whenever it could." (*Id.* ¶¶ 269–71.)

For example, between January 2, 2014 and October 31, 2023, approximately 67% of all visits to the medical clinic by Medicare patients included a presumptive and definitive UDT on the same day. (*Id.* ¶ 274.) It is "improbable" that all of these patients required presumptive and definitive UDT on the same day. In addition, a large number of the clinic's patients had return visits every 28 days. The clinic's practice model was "to test patients every 28 days regardless of medical need, with both presumptive and definitive UDT on the same day at almost every visit." (*Id.* ¶¶ 277–80.)

Based on all of these allegations, the government asserts that the defendants "recklessly disregarded, or were deliberately ignorant of the requirements for billing UDT to FHBP" and nonetheless "submitted claims to FHBP for UDT services that they knew were not rendered, not medically necessary, not used in the treatment of FHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the treating practitioner." (*Id.* ¶¶ 290–91.)

C. The Allergy Testing Scheme

The medical clinic began its allergy testing program in September 2016 and continued through July 2019. (*Id.* ¶¶ 296, 301.) The government alleges that the allergy testing program

"served no pain management objective." (*Id.* ¶¶ 297.) Neither patients nor providers understood why the clinic offered allergy testing. (*Id.* ¶ 300.) The government avers that "[a]llergy testing has nothing to do with pain management." (*Id.* ¶ 304.)

Many patient medical records include "handwritten blank sheets" with the heading "Alternative Pain Management." (*Id.* ¶ 302.) The form includes a list of treatment modalities, apparently as possible alternatives to opioid pain medications, in one column and "dates" in a second column. (*Id.* ¶ 303.) The alternative modalities listed include pain cream, DME brace, allergy test, physical therapy, chiropractic, weight loss, TPI and facet injections, and radiology. (*Id.*) The government alleges that the only reason allergy testing shows up on this list of alternative modalities was because the clinic's "practice was to get as many patients to do the allergy testing as possible for money." (*Id.* ¶ 305.)

In November 2017, Michael Cox exchanged emails with Kathy Hartman, National Director of Allergy Programs at Medela Remedium Solutions ("MRS"), regarding reducing the costs of MRS Allergy Kits if the clinic bought the "entire MRS program" in bulk for its three locations. (*Id.* ¶¶ 306–08.) The Complaint references a series of emails a clinic employee sent herself in April, May, and July 2018 showing lists of allergy test recipients. The government concludes that these emails establish that the clinic was "tracking how many patients it could convince to do allergy tests." (*Id.* ¶¶ 309–14.)

The government interprets training documents created by the same employee in early 2019 as showing that the clinic was "training employees to push and perform allergy tests on everyone with insurance regardless of medical need." (*Id.* ¶ 322.) One document contained bullet points stating that allergy intake should be "included with new patient paperwork"; "Allergy tests and adjunct therapies to be pushed (new patient visit, write on pain level to be transferred to their next

office visit 'fill out AT ppwk.' . . . The MA's will ask patient if they would like to have the test conducted (push this, tell them it counts as an adjunct therapy and it will not be an additional cost to them.)" (*Id.* ¶ 316.)

A second training document reflected the following:

Allergy Tests- Counts as an adjunct therapy

- Insurance patients only
- Fill out intake
  - If intake is filled out by assistant, patient must sign the bottom of the intake form.

1. Is patient eligible for the test?
   a. Patient has to have allergy symptoms
   b. If patient has COPD; they are not eligible
   c. If patient has taken an antihistamine or a sleeping aide, test must be rescheduled. Fill out reschedule form, patient gets copy of reschedule form. Note needs to be written on pain level "DO AT" for their next visit.
   d. If patient denies allergy test or is not eligible for test, have patient sign decline form.
2. Conduct test. Make sure patient signs both consent forms.
3. Record results on form. Must be filled out completely.
4. Do superbill for test.

(*Id.* ¶ 321.) Notably, among the criteria listed is the requirement that the patient "have allergy symptoms." (*Id.*) The same document includes "Make sure allergy tests are being conducted" under "Manager Duties." (*Id.* ¶¶ 323–24.)

On March 26, 2019, a clinic employee sent a text message to co-workers Debbie Cox, Melissa Moore, relator Krista Nicholson, and Macy Hargis, congratulating them on the "allergy test today" and noting that, "[o]nce we have all of our established patients taken care of we will only have to do them on our newer patients!" (*Id.* ¶¶ 325–26.) Debbie Cox responded, "I know 4 of them . . . impressive!!!" (*Id.* ¶ 327; *see also id.* ¶ 328.) According to the plaintiff, these documents confirm that the clinic was "conducting allergy tests on everyone" and that the "Coxes'

goal was to test everyone," irrespective of individual patients' medical need and not based on individualized decision-making. (*Id.* ¶¶ 329–32.)

Based on these allegations, the government avers that the defendants knowingly submitted claims to FHBP for allergy testing services that they knew or should have known were not medically necessary, were not used to treat FHBP beneficiaries, and/or were billed "pursuant to impermissible blanket orders." (*Id.* ¶ 334.)

D. The Psychological Testing Scheme

The government alleges that the defendants had a scheme to "bill reflexively" for as much psychological testing as possible, irrespective of individual patients' medical needs. (*Id.* ¶ 338.) "Patients would be tested when they came to the Institute on an iPad, and the results of those screenings were often never discussed with the patient." (*Id.* ¶ 339.) Michael Cox purportedly "pressure[d] providers to order psychological tests," telling them "there was a state law requiring them to order testing," even though he himself was not a medical practitioner. (*Id.* ¶ 340.) As a result, providers ordered testing, but their orders "were not specific to the medical needs of patients and were not based on individualized decision-making at each patient's visit." (*Id.* ¶ 342.)

Humana Military notified the medical clinic in August 2019 that it would require medical records to substantiate any future claims billed for substance abuse assessments or psychological testing. (*Id.* ¶¶ 343–44.) In January 2022, Blue Cross Blue Shield of Tennessee denied payment for 124 claims under CPT code 96136 (for psychological or neuropsychological test administration) because the providers were not qualified to administer and interpret the test results for this type of test. (*Id.* ¶¶ 345–46.)

In January 2022, a clinic medical provider texted a clinic employee a photo of a document titled, "CPI Tablet Schedule 2022," which showed for each month of the year the specific psychological tests CPI would be "running that month," along with the statement: "So the months

96138 [CPT code] is written in the box is the months we're doing that specific test." (*Id.* ¶¶ 347–49; *see id.* ¶ 343.)

In February 2022 and August 2023, Blue Cross denied payment for claims for which the providers had "improperly billed for psychological testing performed by nurse practitioners." (*Id.* ¶¶ 354, 355.) Other audits by Blue Cross and United Health similarly denied claims for psychological testing performed at the clinic. (*Id.* ¶ 356.)

Based on these allegations, the government avers that the defendants submitted claims to FHBP for psychological testing services that they knew were not medically necessary, were not used in the treatment of FHBP beneficiaries, and/or were billed pursuant to impermissible blanket orders. (*Id.* ¶ 358.)

From April 2010 through May 9, 2024, FHBP compensated the pain clinics nearly $15 million for UDT, allergy testing, and psychological testing. On May 13, 2024, CMS suspended all Medicare payments to the clinic. (*Id.* ¶¶ 360, 362.)

E. Examples of False Claims

The government provides examples of what it characterizes as "illustrative samples of the types of false claims" the defendants submitted to FHBP between February 2015 and June 2021. (*Id.* ¶ 364.)

The Complaint states that Patient A, a Medicare beneficiary, became a CPI patient in September 2015. This patient's progress note for October 21, 2015 states: "POC [point of care] WNL [within normal limits] for meds prescribed," but despite the initial test results' being within normal limits, "definitive lab was ordered today for quantitative results that are necessary for proper treatment." (*Id.* ¶ 365(A)(i)–(ii).)

Billing records for November 18, 2015 show that Patient A received a preliminary screen followed by a confirmatory test for fourteen drug classes ordered on the same day, less than a

month after the presumptive and definitive testing ordered on October 21, 2015. (*Id.* ¶¶ 365(A)(vi)–(vii).) The progress note for November 18, 2015 again notes: "WNL [within normal limits] for meds prescribed, but definitive lab was ordered today for quantitative results that are necessary for proper treatment." (*Id.* ¶ 365(A)(vii).)

The medical clinic billed Medicare $167 for the preliminary screen and $512 for the confirmatory testing and was reimbursed by Medicare in the amount of $679 on or about November 25, 2015. (*Id.* ¶¶ 365(A)(vii), (xii).) The defendants allegedly knew that this amount was not properly reimbursable, because the testing "was not medically necessary, [was] not used in the treatment of [Patient A], or [was] billed pursuant to impermissible blanket/reflex/standing orders." (*Id.* ¶ 365(A)(xii).)

Patient A's progress note for March 10, 2016 states:

> This patient is a chronic pain patient that is using opiates/opioids and or on other schedule 2 and 3 medications. Because of the risk of abuse with other prescribed medications of the same nature not prescribed by this clinic and illicit drugs of abuse I am ordering this drug test out of medical necessity for this patient's safety and efficacy and to prevent to the best of my ability this patient to abuse any prescribed or illicit / illegal drugs.

(*Id.* ¶ 365(iii).) The government points out that this language essentially mirrors the language in an email to Michael Cox on September 1, 2015, which suggests that the "defendants" were cutting and pasting patient notes in Patient A's records. (*Id.* ¶ 365(iv)–(v).)

The government alleges that Patient B became a patient at PIN in September 2019. Billing data reflects that PIN billed Medicare under CPT codes 80307 and G0483 for UDT on the same dates of service for Patient B on September 11, 2019, September 25, 2019, October 23, 2019, November 20, 2019, January 20, 2020, March 16, 2020, April 13, 2020, and May 11, 2020. (*Id.* ¶ 365(B)(i)–(ii).) Medicare paid PIN approximately $2,439 for this series of claims, which the defendants allegedly knew was not reimbursable because the UDT services "were not medically

necessary, not used in the treatment of the beneficiary, or billed pursuant to impermissible blanket orders." (*Id.* ¶ 365(B)(ii).)

Patient B's record also contains a progress note for February 17, 2020 showing that, on that day, the patient "answered various questions for a psychological test called COMM for aberrant behavior." (*Id.* ¶ 365(B)(iv).) The progress note, signed by provider Meghan Anderson, includes the following statement:

> Per the Tennessee State Requirements and Tracy Alcott, General Sessions Attorney, we will perform psychological testing at every visit for a patient on benzodiazepine therapy and every other visit for all other patients to screen for risk of depression and misuse of opioid therapy.

(*Id.*) The note also states: "Risk Assessment: High risk – behavioral – for potential medication misuse or abuse due COMM score of 11 on 2/17/2020, we will continue with definitive UDS at least six time per year[.]" (*Id.*) However, Patient B's psychological test results for April and May 2020 showed lower risk, but the provider did not scale back the frequency of psychological testing. (*Id.* ¶ 365(B)(v)–(vi).) CMS was billed and reimbursed the clinic in the amount of $29.77 for psychological testing that the defendants knew was not medically necessary, not used in the treatment of Patient B, or was billed pursuant to a blanket order. (*Id.* ¶ 365(B)(vii).)

Patient D was another PIN patient who received UDT presumptive and definitive testing. According to the treatment records, he regularly received presumptive testing and occasionally also received definitive testing. However, when the patient's presumptive test was positive for benzodiazepines in September 2019, his progress note for that day states, "Urine drug screen completed today; POC," and "Benzo Use: none," and, although the patient had in fact tested positive for benzodiazepines, no definitive test was ordered. (*Id.* ¶ 365(D)(i)–(viii).) His treatment notes for October 2019 similarly states, "Benzo Use: None," but that his POC UDT in September had been positive for "Opi." (*Id.* ¶ 365(C)(ix).) In other words, the government says, the medical

clinic was "billing for UDT and not even looking at the results to inform decisions on how much UDT to order and when." (*Id.* ¶ 365(D)(xi).) Medicare reimbursed the medical clinic more than $1,000 on this series of claims for services that, according to the government, the defendants knew or should have known were not medically necessary, were not used in the treatment of the beneficiary, or were billed pursuant to impermissible blanket orders. (*Id.* ¶ 365(D)(xii).)

Likewise, Patient E, also a Medicare beneficiary, received presumptive and definitive UDT, billed under CPT codes 80307 and G0483, on the same day at roughly monthly visits from July 2019 through June 2021. (*Id.* ¶ 365(E)(i)–(iii).) Upon beginning treatment in July 2019, the patient signed a document titled "Three Strike Policy," which notified the patient that the "practice" had a policy pursuant to which a patient could be discharged for misuse of narcotics medication. (*Id.* ¶ 365(E)(iv).) In September 2020, the patient signed another document agreeing not to use illegal drugs while on prescriptions from PIN. (*Id.* ¶ 365(E)(v).) The patient subsequently received UDT test results that were inconsistent with prescribed medications in March 2020 for which no written warning was issued. The patient received written warnings about noncompliance after visits in May 2020, June 2020, and February 2021, but he was not discharged. He received a verbal warning in June 2021. According to the government, Medicare reimbursed PIN more than $6,700 for UDT for this patient which the defendants knew "was not reimbursable because the billed services were not medically necessary, not used in the treatment of the beneficiary, or billed pursuant to impermissible blanket orders." (*Id.* ¶ 365(E)(xiii).)

Only one of the examples cited by the government involved a patient who received allergy testing. Patient C, a patient at the medical clinic beginning in May 2016, underwent allergy testing (CPT code 95004) on October 30, 2017, purportedly based on a diagnosis of allergic rhinitis. (*Id.* ¶ 365(C)(i)–(ii).) The "Chief Complaint" on that date was recorded as "Med 13(Y)–ONLY

ALLERGY TEST PERFORMED THIS DOS [date of service]." (*Id.* ¶ 365(C)(iii).) According to the government, no justification for the test is found in the record, no follow-up was noted, no test result or interpretation is in the record, and the treatment note does not reflect the finding of any symptoms consistent with allergy. (*Id.* ¶ 365(C)(iv).) Medicare reimbursed the medical clinic in the amount of $290 for medically unnecessary and otherwise non-reimbursable allergy testing. (*Id.* ¶ 365(C)(v).)

Patient F, a clinic patient in 2018 and 2019, received UDT and psychological testing on a monthly basis, despite being designated as "low risk" for both substance abuse and psychological issues. (*Id.* ¶ 365(F)(i)–(xvi).) Patient G was a clinic patient from February–June 2015. The patient underwent both presumptive and definitive UDT on three dates in February 2015 despite a clear lack of need, and the patient's progress notes do not reflect an individualized assessment of the necessity for the UDT. (*Id.* ¶ 365(G)(i)–(vii).). These services resulted in the billing of Medicare or the VA for unnecessary services that were reimbursed by the government. (*See also* Summary of Claims, Doc. No. 65-1.)

F. The Government's Claims

The government's First Claim for Relief asserts that the defendants collectively violated 31 U.S.C. § 3729(a)(1)(A) by knowingly, as that term is defined by the statute, presenting or causing to be presented materially false and fraudulent claims for payment or approval to the United States, specifically claims for reimbursement for UDT, psychological tests, and allergy tests performed on FHBP beneficiaries, when the claims were not payable either because the services were not rendered,[8] the services were not medically necessary (including because they

[8] The government provides *no* examples, and no allegations, of claims relating to tests or other services that were not actually performed.

were being billed pursuant to impermissible blanket orders and not being ordered by the treating provider), "and/or" the tests were not being used in the treatment of the FHBP beneficiaries. (Doc. No. 65 ¶ 367.)

Its Second Claim for Relief asserts that the defendants violated § 3729(a)(1)(B) by knowingly submitting the false statements, certifications and representations on claim forms, the EDI, and multiple CMS-855b forms to obtain approval for, and payment by, the United States on the false or fraudulent claims that also violated § 3729(a)(1)(A). (Doc. No. 65 ¶ 370.)

The factual allegations supporting the federal common law claims for payment by mistake and unjust enrichment are essentially the same as those supporting the FCA claims, but payment by mistake and unjust enrichment do not require fraud on the part of the defendants. (*Id.* ¶¶ 373–74, 376–77.)

III. THE COXES' MOTION TO DISMISS FCA CLAIMS

A. Allegations Supporting FCA Claims

The individual defendants argue that the Complaint fails to allege particularized facts as to each of them establishing that they caused any providers to submit false claims and instead "relies on the broadest possible allegations of ownership and alleged responsibility for practices, procedures and financial performance untethered from any specific false claim or false statements." (Doc. No. 80 at 12.)

In response, the government points to the following as "just examples" of the particular facts establishing the Coxes' individual liability:

> 30. At all times relevant to this Complaint, Michael and Debbie Cox directed and controlled the Pain Institute's daily operations, including the operation of an in- house UDT laboratory and the submission of claims for payment to FHBP.
>
> 163. Despite having no medical training, Michael Cox would often try to manipulate processes and influence/intimidate providers into treating patients in more profitable ways.

179. In a text message soliciting a physician to join the Pain Institute, Debbie Cox stated regarding the LCMS machine, "That machine is a game changer and will pay for itself within a few months. There is special chart verbiage and cpt codes not to over or under bill or be put on CMS' radar."

183. These blanket and standing orders were disseminated by various ways by Debbie and Michael Cox over the years, sometimes in text messages, sometimes expressed in office policies, sometimes in person, and sometimes in emails.

232. On October 25, 2018, Debbie Cox sent a text message to John Stanton, John Prichard, Stacie Broadbent Wyatt, and six other individuals. In that message, she communicated a new policy requiring all patients to have Narcan, regardless of medical need.

233. The text message stated that Narcan "is mandatory just like a drug screen."

234. In other words, urine drug screens were mandatory for everyone at each office visit.

235. As stated in the text message, Michael and Debbie Cox were making decisions about the clinic's practices together, and then communicating those decisions to staff.

245. Debbie Cox responded, "Do you respond that the patient is high risk for overdosing or that they're on a benzo antidepressant or sleep aid.? [sic] Which puts them at high risk for overdosing?"

246. Rabbitt stated: "It was because we were using the code G0483. They state it is too high of a code for what is done. We have changed the code to G0482 and I am hoping this will take down the denials."

247. Debbie Cox's answer about a suggested response ignores the medical needs of any specific patient – it wholesale classifies people as high risk based on factors that may or may not be specific to any one patient.

268. Michael Cox would intimidate providers into ordering more UDT, telling providers things like "it's your license" and "it's on you if you don't order a drug screen."

325. On March 26, 2019, Stacie Broadbent Wyatt sent a text message to her co-workers Debbie Cox, Melissa Moore, Krista Nicholson, and Macy Hargis.

326. In that text message, Ms. Wyatt stated: "Great job on the allergy test today, girls! I will continue to put notes in. Once we have all of our established patients taken care of we will only have to do them on our newer patients!"

> 327. Debbie Cox responded, "I know 4 of them . . . impressive!!!" followed by the emoji inspired by Edward Munch's noted painting, The Scream.
>
> 340. Michael Cox would pressure providers to order psychological tests, telling providers that there was a state law requiring them to order testing, though he himself was not a medical clinician.

(Doc. No. 81 at 17 –19 (quoting Doc. No. 65).)[9]

The government maintains that these allegations are sufficient to establish the Coxes' individual liability, that the cases on which the Coxes rely are distinguishable, and that other cases decided within the Sixth Circuit have repeatedly held that similarly pleaded complaints alleged sufficient facts to establish clinic owners' and managers' liability.

B. Discussion

The FCA applies to individual defendants who "cause" submission of false claims, even if they were not personally involved in submitting the claims at issue. *United States ex rel. Kramer v. Doyle*, No. 1:18-CV-373, 2022 WL 1186182, at *12 (S.D. Ohio Apr. 21, 2022). However, the FCA is generally understood to require "some action by the defendant whereby the claim is presented or caused to be presented." *Id.* (quoting *United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991)).

In *Kramer*, the government brought claims against the owner of several dental practices based on a theory that he had caused the submission of false claims for reimbursement by

[9] The only additional substantive allegation involving Debbie Cox that the court has located in the Complaint is this:

> 164. In a text message soliciting a physician to join the Pain Institute, Debbie Cox stated, "Our patients are very compliant[,]" and explained that the practice's referrals were "mainly Medicare and [T]ricare patients."

(Doc. No. 65 ¶ 164.) The Complaint also contains a few additional allegations about Michael Cox, including that he appeared to approve standardized language for "standing orders" for UDT in a September email exchange with a clinic employee and that he closely tracked how much money the clinic made on UDT and on the different types of tests. (*Id.* ¶¶ 201–13.)

Medicare. In support of the claims against the owner, the operative complaint alleged that he set financial goals for the practices and pursued them by making telephone calls to employees who did not meet them. It did not, however, allege that any employee who "treated one of the example patients ever received a phone call . . . about revenue, nor. . . provide even approximate timing, content, or participants in any specific phone call." *Id.* at *13. The complaint did not allege specifics about how the owner personally set or communicated revenue targets; nor did it allege that he instructed employees to provide unnecessary services or created incentives related to the provision of specific services. *Id.* Under these circumstances, the court found the allegations in the complaint "too general and conclusory to state with particularity that [the defendant owner] proximately caused the submission of any of the identified false claims" submitted by the dental practices he owned, as the complaint failed to "identify the 'who, what, when, where, and how' of [the owner's] role in the submission of any identified false claim." *Id.* (quoting *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006)).

Conversely, in *United States ex rel. Norris v. Anderson*, 271 F. Supp. 3d 950, 955 (M.D. Tenn. 2017), Judge Crenshaw of this court rejected arguments advanced by an individual and his management company "that they simply managed" the pain clinics that they controlled and that they could not be liable for any allegedly wrongful "upcoding" in claims submitted by the clinics to Medicare. There, the complaint alleged, among other things, that defendant Anderson personally instructed billing employees at the clinics to bill using a specific CPT code, instead of a lower code that would have provided less in reimbursement, for all established patient office visits, despite actual knowledge that clinics had not provided the patients with services that were reimbursable under that CPT code. *Id.* When questioned by employees, the individual defendant reiterated that employees were to "upcode." *Id.* The government also alleged that the defendants oversaw all

billing at the four clinics, caused the submission of false claims for reimbursement, and did so improperly, insofar as they knew that the upcoding caused the submission of claims for services that were not provided.

Likewise, in *United States ex rel. Odom v. SouthEast Eye Specialists, PLLC*, 570 F. Supp. 3d 561, 583 (M.D. Tenn. 2021) (Crenshaw, C.J.), the court recognized that a defendant may be liable under the FCA if it pursues a scheme that ultimately results in the submission of a false claim, even if the defendant does not participate in the actual submission of the claim. Under such a theory, "a complaint is adequate where it alleges that the defendants set company policy and implemented the 'financial incentives designed to induce the submission of false claims.'" *Id.* (quoting *United States ex rel. Alt v. Anesthesia Servs. Assocs., PLLC*, No. 3:16-cv-0549, 2019 WL 7372510, at *18 (M.D. Tenn. Dec. 31, 2019)). In *Odom*, the government expressly alleged that the individual defendants were not only the co-founders, part owners, and officers of the corporate defendant, they were "directly and personally involved" in implementing the "co-management model"—which is described at length—knowing that this model violated the Anti-Kickback statute, knowingly caused the submission of false claims in violation of the Anti-Kickback statute, personally marketed the illegal co-management scheme at seminars designed to induce others to engage in the scheme, personally delivered kick-back payments to "high referring optometrists," and so forth. *Id.* at 580.

1. Debbie Cox's Individual Liability

The allegations regarding Debbie Cox's involvement in the alleged schemes are sparse. The government alleges that she was the sole member of CPI, held a 99% ownership interest in PIN, "controlled" both entities, and "directed and controlled" their daily operations and the submission of claims for payment to FHBP. (Doc. No. 65 ¶¶ 17, 18, 21, 30.) She signed EDIs and Certification Forms on the CMS-855B forms. (*Id.* ¶¶ 48, 50, 54, 55.) Otherwise, the government

alleges that "defendants" collectively articulated a policy of blanket and standing orders and that Debbie (and Michael) "disseminated" these orders in "various ways . . . over the years, sometimes in text messages, sometimes expressed in office policies, sometimes in person, and sometimes in emails." (*Id.* ¶¶ 182–83.)

These communications are not described, however. One text message identified as evidence of such policies is the one in which Debbie Cox disseminated a new policy requiring all patients to be furnished with Narcan and informed clinic employees that Narcan would be "mandatory just like a drug screen." (*Id.* ¶¶ 232–33, 236.) While the court must, at this juncture, draw all reasonable inferences in favor of the government, as the plaintiff, this text message cannot plausibly be construed as confirming, as the government claims, that providers were required to order "urine drug screens . . . for everyone at each office visit." (*Id.* ¶ 233.) At most, this text can plausibly be construed to mean that patients receiving long-term opioid treatment must undergo drug screens in certain situations, but the frequency and scope of such screens is not specified.[10] In short, the text message does not confirm or even imply the existence of the UDT schemes alleged in this lawsuit.

Next, the government points to an exchange of emails between Debbie Cox and PIN's medical biller at that time, in which Cox asked questions about why TRICARE was denying UDT claims as medically unnecessary. She asked the biller, Megan Rabbitt, if Rabbitt was explaining that the patients were at high risk for overdosing, and Rabbitt explained that TRICARE had told her that they were using the wrong code for what was done. (*Id.* ¶¶ 243–46.) The government draws the conclusion from Debbie Cox's question that Cox was "ignor[ing] the medical needs of

[10] *Accord, e.g.*, Tenn. Code Ann. § 53-11-308(g) ("Any prescribers of opioids . . . to patients who are in chronic, long-term drug therapy for ninety (90) days or longer shall consider *mandatory urine drug testing*." (emphasis added)).

any specific patient" and "wholesale classif[ying] people as high risk based on factors that may or may not be specific to any one patient." (*Id.* ¶ 247.) Again, this inference is not plausible, since Cox was not actually providing treatment or classifying any patient and was, instead, simply asking questions.

Additionally, Debbie Cox made comments to encourage new practitioners to join the practice, touting the benefits of the LCMS machine and describing the clinic's patients as generally "compliant." (Doc. No. 65 ¶¶ 169, 174.) These comments are not evidence of the alleged schemes. Finally, Debbie Cox was on a text thread about the clinic's efforts to offer allergy testing to clinic patients, and she was enthusiastic about the four allergy tests that had been performed that day.

Cox is not alleged to have actually presented false claims as the provider of services, and the court understands the allegations against her to be based on her having caused the presentment of false claims. Aside from alleging broad oversight and control of the entity defendants, however, the Complaint contains no specific allegations about how Debbie Cox caused the presentment of any false claims. As in *Kramer*, the mere fact that she owned the entities is not sufficient. There is no evidence that she treated any of the specific patients for whom false claims were presented, that she submitted those claims, that she played any role in the submission of the claims, or that she even knew about them. *See Kramer*, 2022 WL 1186182, at *12. While the FCA applies to individuals who "cause" the submission of false claims, even if they are not personally involved in submitting them, the FCA "still requires 'some action by the defendant whereby the claim is presented or caused to be presented.'" *Id.* (quoting *Murphy*, 937 F.2d at 1039). The government's claims against Debbie Cox are entirely conclusory, with no particular fact establishing her involvement in any of the alleged schemes or in pressuring any of the individual providers at either CPI or PIN to submit false claims. In short, the Complaint does not identify the "who, what, when,

where, and how" of Debbie Cox's role in the submission of any identified false claim. *Accord id.* at *13; *see also Sanderson*, 447 F.3d at 877.

The government does not adequately respond to the Motion to Dismiss filed on behalf of Debbie Cox and makes only a half-hearted effort to justify the claims. The allegations against her do not satisfy Rule 9(b) and are subject to dismissal on that basis. The court does not reach the question of Debbie Cox's knowledge of the submission of false claims.

2. Michael Cox's Individual Liability

The claims against Michael Cox fare little better, as the allegations involving him are no less vague and conclusory. He is alleged to have "pressured" providers by telling them things like "it's your license," and "it's on you if you don't order a drug screen." (Doc. No. 65 ¶ 268.) Aside from the fact that these statements are not alleged with the requisite particularity under Rule 9(b), they are also inescapably *true*: providers have responsibility for ordering medically necessary testing, and their failure to do so that results in certain outcomes could jeopardize their licensure. Michael Cox is also alleged to have falsely told providers that state law required psychological testing. This statement, too, is not alleged with the requisite particularity under Rule 9(b): there is no indication as to why it was false, when the statement was made, in what context, or to whom he made that statement.

The fact that a September 1, 2015 email from a clinic employee to Michael Cox containing language regarding the medical necessity of UDT, which Cox appeared to approve, is identical to language found in a patient file dated March 10, 2016 is potentially suspicious. (*See id.* ¶¶ 202–03, 365(A)(iii).) However, to conclude from that single email that Michael Cox personally devised a scheme to bill medically unnecessary services, communicated that scheme to providers, and incentivized them to follow it requires many inferential leaps and does not satisfy Rule 9(b)'s particularized pleading requirement.

Michael Cox is alleged to have closely tracked the financial performance of the clinic and the amount of money the clinic received for each test performed, and the Complaint alleges very generally that he set company policy. But merely tracking financial performance is not sufficient to give rise to an inference that he caused the submission of false claims. Notably, like the defendant in *Kramer*, Michael Cox is not alleged to have set or communicated revenue targets for providers, to have instructed providers to provide unnecessary services, or to have created any incentives related to the provision of specific services. *Kramer*, 2022 WL 1186182, at *13. Unlike in *Odom*, the Complaint here contains no express allegations that Michael Cox "implemented . . . financial incentives designed to induce the submission of false claims." *Odom*, 570 F. Supp. 3d at 583 (citation and internal quotation marks omitted). And, unlike the defendant in *Norris*, Michael Cox is not alleged to have specifically instructed providers to upcode. *Norris*, 271 F. Supp. 3d at 955. The allegations of the supposed "pressure" applied by Michael Cox is nothing like those found sufficient to establish a causal connection to the submission of false claims in *United States ex rel. Hayward v. SavaSeniorCare, LLC*, No. 3:11-00821, 2016 WL 5395949 (M.D. Tenn. Sept. 27, 2016), where employees were "systematically" pressured to meet predetermined billing "goals" "through various devices, including action plans, performance evaluations, calls and visits to facilities, threats of repercussions or termination for poor performers, and bonuses for those that did well."

As with Debbie Cox, the conclusory allegations fail to identify the "who, what, when, where, and how" of Michael Cox's causal role in the submission of any identified false claim and, therefore, fail to state a claim against him under the FCA.

IV. THE ENTITY DEFENDANTS' MOTIONS TO DISMISS FCA CLAIMS

While the Complaint contains few facts concerning the operational structure of the pain clinic operated by CPI and PIN, it clearly alleges that Debbie Cox and Michael Cox controlled the

business operations of the clinic. If the Complaint had alleged facts sufficient to establish the individual defendants' liability under the FCA, it would necessarily have also alleged facts sufficient to state FCA claims against the entity defendants, based simply on the allegations that the Coxes acted on behalf of the entities as well as on their own behalf.

Having concluded, however, that the Complaint fails to state colorable claims against the individuals for violations of the FCA, the question remains whether it plausibly alleges FCA violations against the entities based on other allegations in the Complaint, including those concerning the specific examples of allegedly false claims. The court finds that it does not. Every other opinion to which either party has directed the court's attention (and those the court has located through its own research) that have permitted similar FCA claims to survive a motion to dismiss have involved allegations of specific facts indicating the existence of actual schemes to defraud and the knowing involvement of individuals acting on behalf of the entities in directing employees of the entity to submit false or fraudulent claims. Such detailed allegations are sorely lacking in this case. The government instead relies on conclusory assertions and seeks to have the court draw inferences from vague and ambiguous communications the context for which is not explained. The court finds, in short, that the Complaint sketches a broad theory of fraudulent schemes but fails to plead particularized details of those schemes as required by Rule 9(b), fails to plead facts sufficient to show that any tests ordered by CPI's or PIN's providers (none of whom are identified) were medically unnecessary, and fails to allege facts showing that CPI or PIN acted with the requisite knowledge of the submission of any allegedly false claims, as discussed in greater detail hereafter.

A. The UDT Schemes

Regarding the blanket/standing order scheme specifically, as the defendants point out:

> The Complaint identifies no actual standing or blanket order in any patient's medical record; it alleges no document containing a policy for standing or blanket orders; it points to no emails, text messages, or other communications directing CPI's and PIN's providers to use standing or blanket orders; it cites no instance where Debbie Cox, Michael Cox, or any other individual instructed a provider to order a UDT or CPI's and PIN's third-party biller to submit a UDT claim; it does not contend that providers were rewarded or disciplined based on their UDT ordering patterns; and it mentions not a single instance where any provider believed they were ordering a medically unnecessary UDT. In the absence of the foregoing, the Complaint invites the Court to infer a fraud scheme in lieu of pleading the requisite detailed facts.

(Doc. No. 76 at 16.) This summation fairly identifies the problems in the Complaint.

Instead of details, the Complaint contains conclusory, essentially tautological assertions that CPI and PIN billed FHBP for UDT that was not medically necessary or used in the treatment of patients and was "billed pursuant to impermissible blanket orders and/or not ordered by the treating practitioner." (Doc. No. 65 ¶ 3.) It alleges a *quid pro quo* scheme, pursuant to which patients were required to undergo unnecessary testing in exchange for receiving their opiate prescriptions (*id.* ¶ 162), but the Complaint does not provide actual examples of any such *quid pro quo* interaction; it asserts that providers "knew the drill" (*id.* ¶ 188)—*i.e.*, knew that they were required to order unnecessary testing—but it does not contain any allegations by any actual providers that they were pressured or instructed to conduct, or bill for, unnecessary UDT. It broadly alleges the existence of blanket and standing orders but does not show the existence of any such order in any patient's record and provides no specifics about such orders, such as who articulated them, to whom, what they stated exactly, when the orders were issued, or how they were implemented.

The Complaint alleges that the entities tracked business metrics and accuses Debbie and Michael Cox of being driven by greed and profit (*see, e.g.*, *id.* ¶¶ 159, 168, 180–81, 192, 205–13,

269), but keeping track of profits and even being driven to profit are not illegal and do not equate to evidence of a scheme to defraud.

The Complaint alleges instances in which CPI or PIN sought or received advice from outside consultants and billing companies for assistance with billing and compliance. The government asks the court to infer from these communications the existence of the alleged schemes. While such inferences would arguably be permissible if the government only needed to satisfy Rule 8, the attenuated inferences the government asks the court to draw here do not satisfy Rule 9(b)'s particularity requirement. Likewise, the government's reliance on one CMS contractor audit and several audits by private insurance companies that identified overpayments is misplaced, particularly given that none of these audits is alleged to have found improper billing based on standing orders or blanket orders.

Finally, the statistics on which the government relies, standing alone and even in conjunction with the other allegations in the Complaint, are not sufficient to support the fraud allegations. These statistics certainly give rise to a reasonable inference of an unnecessarily high level of UDT, but a mere "improbability" that all of the testing for which CPI and PIN billed was medically necessary again does not satisfy the government's obligation to plead with particularity the facts showing that the defendants devised and implemented a fraudulent scheme. *Accord, e.g.*, *U.S. ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health*, 816 F. App'x 892, 897-98 (5th Cir. 2020) (noting that statistical data may be used to satisfy Rule 9(b) "when paired with particular details"); *U.S. ex rel. Winnon v. Lozano*, No. CV 17-2433 (RJL), 2023 WL 6065162, at *6 (D.D.C. Sept. 18, 2023) (finding that the relator's "reliance on the comparison of statistical averages . . . , without also pleading 'particular details of a scheme to submit false claims,' does

not meet the particularity requirements of Rule 9(b)" (quoting *U.S. ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015))).

Regarding the reflex testing scheme, the government alleges that, "between January 2, 2014, and October 31, 2023, approximately 67% of all visits to the Pain Institute for Medicare beneficiaries included a presumptive and a definitive UDT on the same day" and that, "[b]etween January 2, 2014, and October 31, 2023, out of all Medicare beneficiary visits for UDT to the Pain Institute, approximately 80% were for presumptive and definitive UDT; approximately 14% were for definitive only, and approximately 5% were presumptive only." (Doc. No. 65 ¶¶ 274, 276.) As the government also alleges, "[i] is improbable that 67% of visits to the Pain Institute for Medicare beneficiaries required presumptive and definitive UDT on the same day." (*Id.* ¶ 275.)

The court accepts that this sheer volume of UDT, particularly the fact that such testing usually included presumptive and definitive testing on the same day, gives rise to a reasonable inference that not all such testing was medically necessary or reasonable. The problem, again, is that the Complaint does not pair these statistics with any details about the existence of a scheme requiring reflexive testing, showing that reflex testing was actually occurring—that is, that the definitive testing was being performed and billed without an order from the provider—or the implementation of such a scheme by CPI or PIN.

The government points to billing invoices submitted by Bill Heckle at PL Consultants to PIN that show a similar number of presumptive and quantitative testing each month for a period of four months in 2022 and an email from Heckle to Michael Cox stating, "it looks like reflex testing for your practice lab is not going to work out. CMS has determined that reflex testing is 'not Reasonable' other than at reference labs. You can still use the guidelines for reflex testing which should satisfy the medical necessity (for example to verify presumptive Positives UTD).

You can't just automate it without a provider order." (Doc. No. 65 ¶ 262.) The government states, "This is the Reflex Testing Scheme in action." (*Id.* ¶ 263.) But again, the details of this scheme are not particularized. The Complaint does not contain detailed allegations showing that the presumptive and definitive testing was for the same patients or even on the same day, that the tests were performed without a provider's order, or that any of them was medically unnecessary. The government, instead, asks the court to draw these conclusions, and it considers Heckle's email to be a smoking gun. But it is not. The government provides no context for the email. For instance, is Heckle responding to a question about whether reflex testing going forward would be permissible? Or is he telling Cox that he can no longer perform reflex testing without a provider's order? Did his invoices change substantially after that email? Absent some detail putting this email in context, it cannot be deemed to allege with particularity a scheme to engage in reflex testing.

B. Allergy Testing Scheme

The government alleges that the "allergy testing program" began in 2016, when PIN was not yet in existence. It asserts in a conclusory fashion that allergy testing "has nothing to do with pain management." (Doc. No. 65 ¶¶ 296, 304.) In 2017, CPI was offered a reduced price from a particular company if it made a bulk purchase of allergy test kits to use at all three of its locations. (*Id.* ¶¶ 306–08.) The Complaint does not allege whether CPI actually accepted the offer. These allegations do not establish that CPI engaged in a scheme involving allergy testing.

As regards PIN, the Complaint alleges that a clinic employee named Stacie Broadbent Wyatt sent herself emails showing how many patients had undergone allergy testing between July 31, 2017 and April 6, 2018 and between May 25, 2018 and July 27, 2018. (*Id.* ¶¶ 309–14.) In February 2019, she sent herself what appeared to be training notes for new employees regarding allergy tests as "adjunct therapy" for "insurance patients only," one of the criteria for which was that the patient had to "have allergy symptoms." (*Id.* ¶ 321.) These allegations do not establish

with particularity the existence of a fraudulent scheme to push and bill for medically unnecessary allergy testing. The text message exchange among Wyatt and other clinic employees, including Debbie Cox, congratulating them on getting allergy tests done, strongly suggests that clinic employees were being encouraged to offer allergy testing to patients with allergy symptoms, but, again, nothing in the exchange suggests a scheme to perform and bill for medically unnecessary allergy testing. The allegations that follow from these facts, including that "Providers' orders for allergy testing were not specific to the medical needs of patients and were not based on individualized decision-making at each patient's visit" are wholly conclusory and not supported with reference to actual facts and patient records.

C. Psychological Testing

The Complaint's allegations regarding the psychological testing scheme are even more vague and conclusory than those concerning the other types of testing schemes. There are no allegations concerning CPI or psychological testing that occurred before CPI's merger with PIN, aside from the single statement that "Defendants" began performing psychological assessments in 2014. (Doc. No. 65 ¶ 336.) The alleged scheme was to "bill reflexively for as much testing as possible." (*Id.* ¶ 338; *see id.* ¶ 341.)

The Complaint contains no allegations showing the existence of such an express policy. It alleges that Michael Cox put "pressure" on providers to perform psychological testing, but the alleged pressure (telling providers that psychological tests were required under state law, even though he was not a provider) is not alleged with any particularity, as discussed above. Nor does this statement appear to be the type of "pressure" that would incentivize reasonable—and reasonably professional—medical providers to perform tests that they did not believe were medically necessary. Certainly there are no allegations of financial pressure to increase billing or adverse consequences for providers who did not meet financial targets. *Compare, e.g.*, *United*

States v. Life Care Ctrs. of Am., Inc., No. 1:08-CV-251, 2014 WL 11429265, at *9 (E.D. Tenn. Mar. 26, 2014) (finding Rule 9(b) satisfied and denying motion to dismiss FCA claims, where the complaint contained "many allegations regarding [the corporate] Defendant's actions to influence and direct its therapists, including setting corporate targets at the Ultra High RUG [Resource Utilization Group] level, pushing for increased Medicare revenue, setting minimum therapy levels, measuring an employee's performance on his ability to bill at an Ultra High RUG level, and rewarding employees who billed at higher RUG levels" and further alleged "that these actions, directing and pressuring therapists to bill at higher RUG levels, resulted in Life Care submitting Medicare billings which were knowingly false").

The government alleges that Humana required medical records to support claims for psychological testing and that Blue Cross Blue Shield auditors denied claims on the basis that providers were not qualified to administer or interpret psychological tests. The auditors are not alleged to have found that the testing was medically unnecessary, however, and these allegations do not establish the existence of a scheme to administer medically unnecessary tests to Medicare patients.

The Complaint alleges a text message exchange between a provider and an unidentified clinic employee in January 2022, discussing a posted monthly schedule as to which psychological tests to run. (*Id.* ¶¶ 347–53.) The Complaint, however, makes no real attempt to explain or contextualize the exchange or the calendar and does not even go so far as to allege that psychological tests were performed according to the schedule, that the provider believed such tests to be medically unnecessary and conducted them anyway, or that any tests were medically unnecessary.

D. Summation—FCA Claims

The allegations in the Complaint in this case allege the existence of fraudulent billing schemes in only the most general terms. These allegations might, at least arguably, be sufficient to allow the FCA claims to proceed if they were governed solely by Rule 8 and the *Twombly* / *Iqbal* pleading standard. Under Rule 9(b), however, the Complaint simply does not allege with sufficient particularity the who, what, when, where or how of the alleged schemes, nor does it allege any causal connection between the adoption and implementation of these schemes by the entity defendants and the submission of false claims by the individual providers. The court finds that the Complaint fails to state a colorable FCA claim under 31 U.S.C. § 3729(a)(1)(A), for causing false claims to be presented.

Specifically regarding the claim under § 3729(a)(1)(B), which gives rise to liability for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim," the government does not expressly explain its theory of recovery. The Complaint alleges that the claims at issue in this case were submitted by "various mid-levels and other physicians as the rendering provider," but with CPI or PIN as the "billing provider." It therefore appears that the subsection (B) claims are premised upon CPI's and PIN's having submitted EDIs in which they agreed to submit "accurate, complete, and truthful" claims. (*See* Doc. No. 65 ¶¶ 53, 370.) The Complaint does not allege, however, that CPI's and PIN's prior submission of EDIs was material to the government's payment of claims later submitted by individual providers with the entity as the "billing provider."

Regardless, the Complaint also does not allege a basis for the entities' knowledge of the purported falsity of individual providers' submissions of claims to Medicare for reimbursement, simply by virtue of the claims' having been submitted through the entities as the billing provider. The tests at issue were ordered by CPI's and PIN's licensed nurse practitioners and physicians.

(Doc. No. 65 ¶ 61.) To the extent the government seeks to establish the entities' knowledge through communications in which Debbie Cox and Michael Cox were involved, as discussed above, none of those communications is sufficient to establish that the individual defendants caused the submission of false statements.

As for the examples of false claims provided in the Complaint, even if the court accepts that the claims set forth therein were for services that were not, in fact, medically necessary, the FCA "does not penalize all factually inaccurate statements, but only those statements made with knowledge of their falsity." *Houston*, 2011 WL 4899983, at *4 (quoting *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 832 (7th Cir. 2011)). Without allegations establishing the existence of a fraudulent scheme, the identification of incorrect claims, standing alone, is not sufficient to give rise to FCA liability.

The Complaint fails to state FCA claims against CPI or PIN with the requisite particularity under Rule 9(b), as a result of which those claims are subject to dismissal under Rule 12(b)(6).

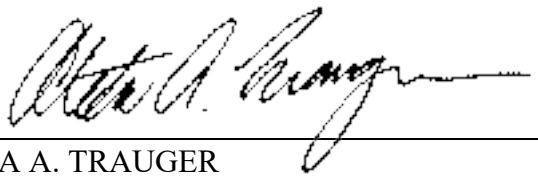
V. THE COMMON LAW CLAIMS

Both sets of defendants also seek dismissal of the federal common law claims of payment by mistake and unjust enrichment on the basis that they are "premised upon the same set of facts as the FCA" and thus "subject to the same heightened pleading standard." (*See* Doc. No. 76 at 25; Doc. No. 80 at 24.) They also assert that the government "does not otherwise separately allege any well-pleaded common law claims against either Defendant." (Doc. No. 76 at 25; Doc. No. 80 at 24.) The government responds only "[p]leading in the alternative is not strange or unusual" and that the "Defendants' arguments on these theories are barely developed, and there is no real dispute that those claims would rise and fall with the sufficiency of the Complaint on the FCA theories." (Doc. No. 81 at 24.)

Given this concession and the court's conclusion that the FCA claims are subject to dismissal, it follows, as the government effectively concedes, that the common law claims are also subject to dismissal.

VI. CONCLUSION

For the reasons set forth herein, both Motions to Dismiss (Doc. Nos. 75, 79) will be granted, and the government's Complaint-in-Intervention (Doc. No. 65) will be dismissed. An appropriate Order is filed herewith.



ALETA A. TRAUGER
United States District Judge