IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA, *ex rel.* GERALDINE J. JOHNSON,	)	
Plaintiff,	)	
v.	)	Case No. CIV-20-00018-JD
S. BLAKE KELLY, M.D., and KELLY MEDICAL, P.C., d/b/a OKLAHOMA PAIN CENTER,	)	
Defendants.	)	

ORDER

Before the Court is Defendants' Motion to Dismiss Plaintiff's Complaint-in-Intervention ("Motion") [Doc. No. 41]. Defendants seek dismissal of the Complaint-in-Intervention ("CII") [Doc. No. 27] filed by the United States of America under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. The United States responded in opposition ("Response") [Doc. No. 44]. For the reasons stated below, the Court denies the Motion.

I. INTRODUCTION

This is a qui tam action under the False Claims Act ("FCA"), 31 U.S.C. § 3730. The action was originally filed by relator Geraldine J. Johnson on January 7, 2020. [Doc. No. 1]. After numerous extensions of time to intervene were granted, the United States filed its CII on January 17, 2023, against Defendants Kelly Medical, P.C., d/b/a Oklahoma Pain Center ("OPC"), and its sole owner, Stephen Blake Kelly, M.D. ("Dr. Kelly"). The CII alleges that Defendants executed a scheme, spanning more than six

years,[1] to defraud three Government Health Benefit Programs ("GHBP") by submitting false or fraudulent claims for urine drug testing ("UDT"). CII ¶ 1. Specifically, the United States alleges that Defendants "billed GHBP for UDT that was not rendered, not medically necessary, not used in the treatment of GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the treating practitioner." *Id.*

Defendants move for dismissal of Counts 1 and 2 of the CII for failure to state a claim, which are counts that allege FCA violations for presenting false claims for payment and use of false statements, in violation of 31 U.S.C. § 3729(a)(1)(A) and § 3729(a)(1)(B), respectively.[2]

[1] The allegations span conduct beginning in 2016 and continuing through January 2022. *See* CII ¶¶ 110, 114.

[2] Counts 3, 4, and 5 are federal common law claims for payment by mistake, unjust enrichment, and fraud. Defendants make only a conclusory reference at page 8 of the Motion that materiality is also an essential element to the United States' common law claims for payment by mistake and unjust enrichment; however, they offer no analysis as to the common law claims. Under Federal Rule of Civil Procedure 7(b)(1), "[a] request for a court order must be made by motion. The motion must: be in writing . . . , state with particularity the grounds for seeking the order; and state the relief sought." *See* Motion at 8; *see also* Fed. R. Civ. P. 7(b)(1). The United States in its Response noted that Defendants' Motion focused "exclusively on the FCA claims" and did not challenge the common law claims. *See* Response at 1 n.1. Defendants did not file a reply indicating this assertion was in error. Thus, in accordance with Rule 7(b)(1) and the parties' briefing, the Court construes the Motion as challenging only Counts 1 and 2 of the CII.

II. BACKGROUND[3]

The CII alleges a fraudulent scheme to submit false claims to Medicare, TRICARE, and the Federal Employees Health Benefits Program ("FEHBP"), collectively GHBP.[4] CII ¶ 1. Dr. Kelly is a physician licensed to practice medicine in Oklahoma; his primary practice is OPC in Oklahoma City. *Id.* ¶ 15. OPC is the medical clinic through which Dr. Kelly implemented the alleged scheme. *Id.* ¶ 16. OPC practitioners provide

[3] The Court recounts the facts based on the well-pled allegations in the CII and construes them in the light most favorable to the United States, as the non-movant. *See Serna v. Denver Police Dep't*, 58 F. 4th 1167, 1169 n.1 (10th Cir. 2023).

[4] Medicare is a federal health insurance program that provides coverage for individuals based on age, disability, or affliction with end-stage renal disease. CII ¶ 18; 42 U.S.C. §§ 426, 426-1. It is funded by premium payments by enrollees and funds appropriated by the federal government. CII ¶ 18. Relevant here is Medicare Part B, which covers certain medical services, including clinical laboratory test services provided by physicians and other providers. *Id.* ¶ 19; *see also* 42 U.S.C. § 1395k(a)(2)(B). The Centers for Medicare and Medicaid Services ("CMS") administers Medicare and uses private contractors, i.e., Medicare Administrative Contractors ("MACs"), to review and pay claims submitted by healthcare providers. CII ¶ 20. Novitas Solutions, Inc. ("Novitas") was the MAC for the UDT services billed to Medicare by Defendants. *Id.*

TRICARE is a government-funded healthcare program for uniformed service members, retirees, and their families. *Id.* ¶ 37; *see also* 32 C.F.R. §§ 199.4, 199.17. It is managed by the Defense Health Agency ("DHA"). CII ¶¶ 12, 37. The conduct at issue here, including the submission of alleged false claims, occurred within TRICARE's East Region; Humana Military is the assigned regional contractor assisting DHA. *Id.* ¶ 37. For beneficiaries eligible for Medicare and TRICARE, Medicare is the primary payer and TRICARE is the secondary payer. *Id.* ¶ 43; *see also* 32 C.F.R. § 199.8.

The FEHBP is a federally funded insurance program for federal employees, retirees, and their dependents under age 26. The Office of Personnel Management ("OPM") administers and oversees FEHBP. CII ¶¶ 13, 46–47; *see also* 5 C.F.R. Part 890. Federal agencies and their employees pay health insurance premiums, and the OPM contracts with private insurance carriers to offer healthcare benefits to federal employees. CII ¶¶ 48–49. The FEHBP plans at issue here are those offered by BlueCross BlueShield ("BCBS") and the Government Employees Health Association, Inc. ("GEHA"). *Id.* ¶ 50.

pain management treatment that includes prescribing opiates and other controlled substances to patients suffering from chronic pain. *Id.* Defendants use UDT to monitor and treat patients. *Id.* Dr. Kelly oversaw OPC's daily operations, its in-house UDT laboratory, and submission of claims for payment to GHBP. *Id.*

Providers and suppliers enrolled in Medicare must certify their compliance with the applicable Medicare laws, regulations, and program instructions. *Id.* ¶ 22; 42 C.F.R. § 424.516(a). To that end, a healthcare provider 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." CII ¶ 23. Dr. Kelly signed the certification statement multiple times as the authorized official for OPC. *Id.* ¶ 24.

Providers submit claim forms to obtain reimbursement from Medicare for medical services they administer; this includes UDT services. *Id.* ¶ 25. Providers can submit either a CMS 1500 form or its electronic equivalent, the 837P format. *Id.* To submit electronic claims using the 837P format, a provider completes, signs, and submits to CMS an Electronic Data Interchange Enrollment Form ("EDI"). *Id.* ¶ 26. By signing the EDI, the provider agrees to "submit claims that are accurate, complete, and truthful" and certifies that his electronic signature for claims submission constitutes "an assurance that services were performed as billed." *Id.* This certification serves as the signature for every electronic claim submitted by the provider thereafter. *Id.* OPC submitted its EDI to Novitas on June 30, 2015. *Id.* ¶ 27.

Providers identify CPT[5] codes on the CMS 1500 or 837P electronic claim forms; CPT codes indicate what services were rendered and certify that such services are reimbursable. *Id.* ¶ 28. Providing accurate CPT codes is material to and a condition of payment of the claim. *Id.* ¶ 29. The UDT claims at issue in this action identified OPC (NPI 1467495226) as the billing provider and Dr. Kelly (NPI 1134167455) as the rendering provider.[6] *Id.* ¶ 33. Defendants submitted UDT claims for payment to Medicare via Novitas. *Id.* ¶ 36.

Defendants also submitted UDT claims for payment to TRICARE. *Id.* ¶ 45. TRICARE also utilizes the CMS 1500 claim form, and providers submitting an electronic claim form to TRICARE make the same certifications as described above. *Id.* ¶ 44.

Like Medicare and TRICARE, "FEHBP plans cover only those medical services that are reasonable and necessary to prevent, diagnose, or treat an illness, disease, injury, or condition of the covered beneficiary." *Id.* ¶ 52. In October 2016, the BCBS Federal Employee Program adopted FEP 2.04.98, Drug Testing in Pain Management and Substance Use Disorder Treatment, which is a policy outlining when certain types of UDT are medically necessary. *Id.* ¶¶ 54–55. Defendants submitted UDT claims for payment to FEHBP via BCBS and GEHA. *Id.* ¶ 56.

[5] CPT codes are Current Procedural Terminology Codes.

[6] NPI, or National Provider Identifier, is a unique 10-digit number that corresponds to a specific healthcare provider. Claims for laboratory services must include the NPI for the billing and rendering provider. CII ¶ 32.

The CII alleges that two types of UDT are relevant in this case: (1) presumptive (qualitative) drug testing; and (2) definitive (quantitative) drug testing. *Id.* ¶¶ 60–62. Presumptive drug testing specifies a negative or positive result and is used when medically necessary to determine the presence of drugs in a urine sample. *Id.* ¶ 61. Presumptive UDT methods range from point-of-care dipstick tests to mass spectrometry, with reimbursement rates that correspond with the complexity of the test. *See id.* Conversely, definitive drug tests report results in concentrations and are medically necessary to identify specific medications, illicit substances, and metabolites. *Id.* ¶ 62. Definitive UDT is reimbursed at a higher rate than presumptive UDT. *Id.*

If a presumptive test provides the physician with sufficient information to treat and diagnose a patient, then a definitive test "is not reasonable and necessary and not covered by Medicare." *Id.* ¶ 66. "[O]nly *inconsistent or unexpected* results should be referred for subsequent definitive testing." *Id.* ¶ 67. The medical necessity of definitive testing, therefore, "depends on the unique presentation and condition of each patient, each patient's drug abuse history, and/or whether the results of a preceding presumptive test, if rendered, are expected or unexpected." *Id.* ¶ 65.

The CII acknowledges that presumptive immunoassays, or initial qualitative drug tests, have specific limitations; thus, at times, subsequent targeted definitive testing may be reasonable and necessary to ensure the treating physician has the information he needs to treat and manage a patient's care. *Id.* These limitations, however, do not apply to UDT done with High Performance Liquid Chromatography and Mass Spectrometry ("LC-MS"). *Id.* ¶ 68. "LC-MS is a complex technology that . . . . test[s] . . . for numerous drugs

and metabolites during a single run of [a portion] of a urine sample through the LC-MS machine." *Id.* ¶ 69. Unlike other UDT, the results from LC-MS are not available immediately. *Id.* ¶ 70.

When a definitive test is performed on a LC-MS device, the CII alleges that there "is no medical purpose or reason for the LC-MS simultaneously to report 'presumptive results' because definitive results contain the same information . . . and more." *Id.* ¶ 71. The LC-MS oftentimes runs the same tests on all samples regardless of whether such tests are medically reasonable and necessary; the lab, however, may only bill GHBP for tests that are medically reasonable and necessary to treat the patient. *Id.* ¶ 72.

Under Medicare Part B, no payment may be made for any expenses incurred for items or services that are not reasonable and necessary to prevent illness. *Id.* ¶ 73; *see also* 42 U.S.C. § 1395y(a)(1)(B). When a provider submits a claim for payment to GHBP, he certifies that the services were provided, as billed, and were medically reasonable and necessary. CII ¶ 73. To determine whether services were reasonable and necessary, Medicare requires complete documentation of services rendered. *Id.* ¶ 75. Thus, a provider must supply sufficient documentation in a patient's medical record to establish the need for diagnostic tests like UDT. *See id.* Additionally, all diagnostic testing, including UDT, "must be ordered by the physician who is treating the beneficiary . . . . Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.* ¶ 76. Thus, Medicare will not reimburse a provider for services unless these requirements are met. *Id.*

Additionally, to qualify for coverage, UDT claims must comply with Novitas' policy on drug testing, Local Coverage Determination L35006, Controlled Substance Monitoring and Drugs of Abuse Testing ("LCD"). *Id.* ¶ 77. The LCD covers services performed on or after October 1, 2015. *Id.* Under the LCD, blanket orders are ineligible for reimbursement. *Id.* ¶ 78. Blanket orders are test requests that are not specific to a patient but are for all patients in the practice. *Id.* The LCD requires the treating physician to order all drug tests "in writing" and to indicate on the order, which "drugs/drug classes [are] to be tested." *Id.* ¶ 80.

From 2011 to 2015, Medicare's accepted CPT codes for presumptive UDT were G0431 and G0434. *Id.* ¶ 81. In 2016, Medicare's accepted CPT code for presumptive UDT was G0479. *Id.* The codes changed in 2017 to 80305–80307, and those codes are still operative today. *Id.* Defendants billed for presumptive UDT services using either CPT codes G0479 or 80307. *Id.* ¶ 82. Beginning on January 1, 2016, Medicare required labs to bundle definitive UDT services using CPT codes G0480–G0483. *Id.* ¶ 83. The more drug classes associated with a code, the larger the reimbursement rate. *Id.* ¶ 84.

Initially, Defendants used a third-party laboratory to perform its definitive UDT services. *Id.* ¶ 86. By January 1, 2016, Defendants moved all UDT in-house and used a LC-MS machine to run the tests. *Id.* ¶ 87. Despite the LC-MS machine's technological capabilities to test for numerous drugs and metabolites during a single run, Dr. Kelly limited the information in the presumptive results section to "arbitrarily exclud[e] certain substances and direct[ed] that such results be reported at the drug class level." *Id.* ¶¶ 69, 89. He then "falsely represented that a presumptive test" had been rendered and claimed

the "information [received] was inadequate to treat" the patient "to justify definitive UDT." *Id.* ¶ 89.

For example, at Dr. Kelly's direction, the LC-MS device was programmed to not provide presumptive UDT results for synthetic opiates, such as fentanyl, although the LC-MS machine had that capability. *Id.* ¶ 90. In turn, Defendants would claim that definitive UDT for fentanyl was medically necessary in each instance because there was no "qualitative [presumptive] test available." *Id.*

Additionally, Dr. Kelly, regardless of whether he was the patient's treating physician, would direct when to run UDT and what testing would be billed for all OPC patients. *Id.* ¶ 91. OPC billed GHBP for UDT services pursuant to blanket orders by Dr. Kelly, not based on individual patient determinations or whether UDT was medically reasonable and necessary. *Id.* ¶ 92. To that end, Dr. Kelly directed that definitive UDT for all OPC patients be billed to Medicare using the G0481 CPT code, "irrespective of the needs of any individual patient" or the treating physician's clinical assessment and regardless of whether such testing was medically necessary. *Id.* ¶¶ 93, 95.

For example, in 2018, Dr. Kelly ordered and billed for definitive UDT for alcohol irrespective of whether the individual patient had a history of alcohol abuse or consumed alcohol. *Id.* ¶ 96. In 2014, OPC allegedly billed for definitive UDT despite no written orders for it. *Id.* ¶ 97. In 2014, Novitas performed an audit of OPC, which resulted in a 100 percent denial rate because of the lack of patient-specific documentation showing definitive UDT was medically necessary. *Id.* ¶ 98.

By 2017, OPC began using an intake form "to paper the file." *Id.* ¶¶ 100–01. Intake forms were completed by OPC employees "*after* the LC-MS test was run and based on blanket instructions from Dr. Kelly, irrespective of the patients' individualized needs and . . . whether Dr. Kelly was the treating practitioner." *Id.* ¶ 102. Dr. Kelly ordered certain options on the intake form be designated for all patients in every instance; other selections were based on the test results the OPC employee already had in hand. *Id.* ¶ 103.

For instance, under the "drugs to be tested" category for definitive UDT, Dr. Kelly directed that fentanyl, ketamine, methylphenidate, gabapentin, alcohol, and acetaminophen always be checked. *Id.* ¶ 104. This was done for all UDT patients at OPC regardless of their condition, presentation, or prescribed medications. *Id.* Additionally, if a sample was positive for opiates, the OPC employee completing the intake form, at Dr. Kelly's direction, would order definitive UDT for all opiate drug classes in every instance irrespective of whether the patient was historically compliant and had only one prescription for a specific opiate. *Id.* ¶ 105.

Moreover, Dr. Kelly would direct OPC lab technicians to always check "[t]here is no qualitative test available" to justify billing for definitive UDT. *Id.* ¶ 106. Further, he would direct that "G0481 (8–14 Drug Classes)" always be selected on the intake form regardless of the patient's condition, presentation, or prescriptions. *Id.* ¶ 107. Once the UDT was performed and the intake form completed, Dr. Kelly or another OPC physician signed the intake forms in batches without referencing patient files. *Id.* ¶ 108. The intake form was always filled out and signed several days after the patient visited the office, but

falsely backdated to the visit date to give the impression it was a legitimate order completed by a physician before services were rendered. *Id.* ¶ 109. At times, the intake form was completed and signed after the claim for UDT was submitted to GHBP for payment. *Id.*

From 2016 through January 2022, Defendants billed GHBP for presumptive UDT services that were never performed by manipulating the test results from the LC-MS machine to appear as if two distinct services were rendered as opposed to one test by splitting the test results into a "presumptive result" section and a "definitive result" section. *Id.* ¶¶ 110–13. In reality, only one test was performed on the LC-MS machine. *Id.* ¶ 111.

From January 1, 2016, through October 31, 2021, Defendants' policy and practice was to bill GHBP for definitive UDT services using CPT code G0481 based on blanket orders from Dr. Kelly without regard to whether such services were medically necessary. *Id.* ¶¶ 114–15. The CII alleges that Defendants knew, recklessly disregarded, or deliberately ignored the billing requirements for UDT. *Id.* ¶ 118. In a letter written by Dr. Kelly on July 14, 2014, Dr. Kelly indicated that OPC's "platform" was to provide quantitative/definitive testing for patients. *Id.* ¶ 119. Thus, the CII alleges that Dr. Kelly "knew there was no medical reason to perform, let alone bill, [for a] LC-MS presumptive test." *Id.*

Defendants received provider-specific education from Novitas in the form of a letter dated September 9, 2014. *Id.* ¶ 120. The letter outlined when services are medically necessary, and specifically with respect to definitive testing, it described when to follow

up a qualitative (presumptive test) with quantitative (definitive) testing. *Id.* ¶¶ 120–21. OPC received additional provider-specific education in a letter dated September 7, 2018. *Id.* ¶ 123.

The CII alleges that because of Defendants' conduct, "GHBP paid millions of dollars for . . . thousands of false and/or fraudulent claims for non-covered UDT services." *Id.* ¶ 126. UDT performed in-house at OPC was Defendants' primary source of revenue. *Id.* ¶ 125.

The United States provides three examples in its CII that it alleges are representative of Defendants' fraudulent scheme: (1) involving Beneficiary F.M.; (2) involving Beneficiary S.H.; and (3) involving Beneficiary C.M.

(1) Beneficiary F.M.

F.M. was seen at OPC on September 26, 2017. *Id.* ¶ 129a.i. The progress note was electronically signed by Dr. Kelly, but OPC's records indicate that the treating practitioner for F.M. that day was an advanced practice registered nurse. *Id.* According to claims data, F.M. had been OPC's established patient since December 2014. *Id.* ¶ 129a.ii.

The September 26 progress note falsely stated that "[q]uantitative testing will be performed based on test results from the highly complex LC-MS screen." *Id.* ¶ 129a.iii. OPC performed definitive UDT on the sample provided by F.M. on September 26, 2017; the test results were split into a "presumptive result" section and a "definitive result" section and first disclosed in a report dated October 2, 2017. *Id.* ¶ 129a.iv. The corresponding intake form filled out by an OPC lab technician indicated, pursuant to Dr. Kelly's blanket instructions, that there was no qualitative test available and definitive

confirmation was needed, noting a CPT code of G0481, which corresponds to 8–14 drug classes. *Id.* ¶ 129a.v. The intake form was backdated to September 26, 2017, and signed by Dr. Kelly. *Id.* ¶ 129a.vi.

On September 29, 2017, OPC submitted the claim for payment to GHBP before a corresponding intake form was completed and signed by Dr. Kelly and before the test was completed. *Id.* ¶ 129a.vii. OPC requested reimbursement for services using CPT codes 80307 and G0481. *Id.* OPC was listed as the billing provider on the claim, and Dr. Kelly was the rendering provider. *Id.*

On October 13, 2017, GHBP paid OPC for the 80307 service in the amount of $78.21. *Id.* ¶ 129a.viii. The CII alleges that had GHBP known the 80307 presumptive test was not rendered, it would not have reimbursed OPC for the billed service. *Id.* Additionally, GHBP paid OPC for the G0481 service in the amount of $157.77. *Id.* ¶ 129a.ix. Had GHBP known the G0481 service was billed pursuant to a blanket order, not ordered by the treating physician, and not medically necessary, it would not have reimbursed OPC for the billed service. *Id.* As a result, OPC received $235.98 from GHBP; OPC was not entitled to these funds. *Id.* ¶ 129a.x.

(2) Beneficiary S.H.

S.H. was seen at OPC on December 22, 2017. *Id.* ¶ 129b.i. The progress note was electronically signed by Dr. Kelly, but OPC's records indicate that a physician's assistant was the treating practitioner for S.H. that day. *Id.* According to claims data, S.H. had been OPC's established patient since October 2016. *Id.* ¶ 129b.ii.

The December 22 progress note falsely stated that "[q]uantitative testing will be performed based on test results from the highly complex LC-MS screen." *Id.* ¶ 129b.iii. OPC performed definitive UDT on the sample provided by S.H. on December 22, 2017; the test results were split into a "presumptive result" section and a "definitive result" section and first disclosed in a report dated January 2, 2018. *Id.* ¶ 129b.iv. The corresponding intake form filled out by an OPC lab technician indicated, pursuant to Dr. Kelly's blanket instructions, that there was no qualitative test available and definitive confirmation was needed, noting a CPT code of G0481, which again corresponds to 8–14 drug classes. *Id.* ¶ 129b.v. The intake form was backdated to December 22, 2017, and signed by Dr. Kelly. *Id.* ¶ 129b.vi.

On December 28, 2017, OPC submitted the claim for payment to GHBP before a corresponding intake form was completed and signed by Dr. Kelly and before the test was completed. *Id.* ¶ 129b.vii. OPC requested reimbursement for services using CPT codes 80307 and G0481. *Id.* OPC was listed as the billing provider on the claim, and Dr. Kelly was the rendering provider. *Id.*

On January 11, 2018, GHBP paid OPC for the 80307 service in the amount of $78.21. *Id.* ¶ 129b.viii. The CII alleges that had GHBP known the 80307 presumptive test was not rendered, it would not have reimbursed OPC for the billed service. *Id.* GHBP also paid OPC for the G0481 service in the amount of $157.77. *Id.* ¶ 129b.ix. Had GHBP known the G0481 service was billed pursuant to a blanket order, not ordered by the treating physician, and not medically necessary, it would not have reimbursed OPC for

the billed service. *Id.* Thus, OPC received $235.98 from GHBP of which it was not entitled. *Id.* ¶ 129b.x.

(3) Beneficiary C.M.

C.M. was seen at OPC on March 30, 2018. *Id.* ¶ 129c.i. The progress note was electronically signed by Dr. Kelly, but OPC's records indicate C.M. was instead seen by an advanced practice registered nurse that day. *Id.* According to claims data, C.M. had been OPC's established patient since March 2016. *Id.* ¶ 129c.ii.

The March 30 progress note falsely stated that "[q]uantitative testing will be performed based on test results from the highly complex LC-MS screen." *Id.* ¶ 129c.iii. OPC performed definitive UDT on the sample provided by C.M. on March 30, 2018; the test results were split into a "presumptive result" section and a "definitive result" section and first disclosed in a report dated April 6, 2018. *Id.* ¶ 129c.iv. The corresponding intake form was filled out on April 6, 2018, by an OPC employee and included Dr. Kelly's same blanket instructions as the two examples above. *Id.* ¶ 129c.v. The intake form was backdated to March 30, 2018, and signed by Dr. Kelly. *Id.* ¶ 129c.vi.

On April 9, 2018, OPC submitted the claim for payment to GHBP. *Id.* ¶ 129c.vii. OPC requested reimbursement for services using CPT codes 80307 and G0481. *Id.* OPC was the billing provider on the claim, and Dr. Kelly was the rendering provider. *Id.*

On April 23, 2018, GHBP paid OPC for the 80307 service in the amount of $70.39. *Id.* ¶ 129c.viii. The CII alleges that had GHBP known the 80307 presumptive test was not rendered, it would not have reimbursed OPC for the billed service. *Id.* GHBP further paid OPC for the G0481 service in the amount of $153.46. *Id.* ¶ 129c.ix. GHBP

would not have paid OPC for the G0481 service had it known it was billed pursuant to a blanket order, not ordered by the treating physician, and not medically necessary. *Id.* The CII alleges that OPC received $223.85 from GHBP and that OPC was not entitled to those funds. *Id.* ¶ 129c.x.

The United States asserts two FCA claims: (1) presenting false claims for payment, in violation of 31 U.S.C. § 3729(a)(1)(A); and (2) use of false statements, in violation of 31 U.S.C. § 3729(a)(1)(B). Specifically, with respect to Count 1, the CII alleges that Defendants "knowingly presented, or caused to be presented, materially false and fraudulent claims . . . for reimbursement by GHBP, for services not rendered, not medically necessary, not used in the treatment of GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the treating practitioner." *Id.* ¶ 133. The United States further alleges that "GHBP would not have paid these false and fraudulent claims had they known" this, and that Defendants presented these claims "with actual knowledge of their falsity," "with reckless disregard," or in "deliberate ignorance of whether or not [the claims] were false," resulting in the United States sustaining damages. *Id.* ¶¶ 134–35, 137.

With respect to Count 2, the CII alleges that "Defendants knowingly made, used, or caused to be made or used, false records or statements . . . to obtain approval for and payment by the United States for [the] false or fraudulent claims as detailed above." *Id.* ¶ 140. The alleged false statements "were material to the payment of the false claims" and included certifications and representations on claim forms, the EDI, and other Medicare forms. *Id.* ¶¶ 140–41. The United States would not have otherwise approved or

paid these claims, and has sustained damages. *Id.* ¶¶ 143–44. Defendants allegedly made these false statements, certifications, and representations "with actual knowledge of their falsity," "with reckless disregard," or in "deliberate ignorance of whether or not [such statements] were false." *Id.* ¶ 142.

III. STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although a complaint does not need detailed factual assertions, a pleading that offers only "labels and conclusions" or "pleads facts that are merely consistent with a defendant's liability" will not suffice. *Id.* (internal quotation marks and citations omitted). The burden is on the plaintiff to plead factual allegations that "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

Under this standard, the Court accepts all well-pled factual allegations as true and views the allegations in the light most favorable to the nonmoving party. *Peterson v. Grisham*, 594 F.3d 723, 727 (10th Cir. 2010). Conclusory statements, however, are not entitled to the assumption of truth and courts are free to disregard them. *Khalik v. United Air Lines*, 671 F.3d 1188, 1191 (10th Cir. 2012). The Rule 12(b)(6) standard does not require that a plaintiff establish a prima facie case in its complaint, but the elements of each cause of action help to determine whether the plaintiff has set forth a plausible

claim. *Id.* at 1192. "The court's function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted." *Smith v. United States*, 561 F.3d 1090, 1098 (10th Cir. 2009) (citation omitted).

A plaintiff alleging FCA violations must also satisfy the heightened pleading standard of Rule 9(b) of the Federal Rules of Civil Procedure. *See Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 195 n.6 (2016) ("*Escobar II*") ("False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) . . . ."). Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud . . . . Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Rule 9(b)'s purpose is to provide defendants with "'fair notice of [a] plaintiff's claims and the factual ground upon which [they] are based.'" *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 745 (10th Cir. 2018) (second alteration in original) (quoting *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010)).

FCA claims satisfy Rule 9(b)'s requirements when they "provid[e] factual allegations regarding the who, what, when, where and how of the alleged claims." *See id.* For most FCA claims it is necessary to allege "actual submission[s] of a specific request for payment to the government," but it is unnecessary to allege such specific requests for payment when the government's complaint demonstrates the "'specifics of a fraudulent scheme and provide[s] an adequate basis for a reasonable inference that false claims were

submitted as part of that scheme.'" *United States ex rel. Wagner v. Care Plus Home Health Care, Inc.*, Case No. 15-CV-260-GKF-JFJ, 2017 WL 6329850, at *4 (N.D. Okla. Dec. 11, 2017) (quoting *Lemmon*, 614 F.3d at 1172).

IV. DISCUSSION

Liability under the FCA attaches to anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "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)(A), (a)(1)(B). It defines "knowingly" as a person who "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). "[N]o proof of specific intent to defraud" is required. *Id.* § 3729(b)(1)(B). "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

"False or fraudulent" encompasses "both factually false and legally false requests for payment." *Polukoff*, 895 F.3d at 741 (citing *Lemmon*, 614 F.3d at 1168). Claims that are factually false usually "require a showing that the payee has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1168 (10th Cir. 2016) (internal quotation marks and citations omitted). Conversely, legally false claims normally entail "knowingly false

certification of compliance with a regulation or contractual provision as a condition of payment." *See id.* (internal quotation marks and citations omitted).

Legally false claims are premised on one of two theories: express false certification and implied false certification. *Polukoff*, 895 F.3d at 741. The former applies when a payee falsely certifies compliance with a particular statute, regulation, or contractual term, and compliance is a prerequisite to payment. *See id.* The latter theory does not require a false representation. Instead, under the implied false certification theory, liability attaches "when the defendant submits a claim for payment . . . [and] knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement," and "the omission renders those representations misleading." *Escobar II*, 579 U.S. at 181.

The United States alleges both factually false and legally false claims in Count 1. *See* CII ¶ 133; *see also United States ex rel. Troxler v. Warren Clinic, Inc.*, 630 F. App'x 822, 823–24 (10th Cir. 2015) (unpublished) (factually false claims include services not actually provided); *Polukoff*, 895 F.3d at 741 (explaining that non-compliance "with Medicare's 'reasonable and necessary' requirement" constitutes an allegation of a legally false request for payment). It alleges factually false and express false certification claims in Count 2. *Id.* ¶ 140. Claims under § 3729(a)(1)(A) may be based upon an express false certification theory or an implied false certification theory, while only factually false and express false certification claims are actionable under § 3729(a)(1)(B). *See Lemmon*, 614 F.3d at 1168; *United States ex rel. Wagner v. Care Plus Home Health Care, Inc.*, Case

No. 15-CV-260-GKF-JFJ, 2017 WL 6329850, at *6 (N.D. Okla. Dec. 11, 2017) (explaining that an implied false certification claim does not exist under § 3729(a)(1)(B)).

To state a claim under the FCA for a false claim under § 3729(a)(1)(A), the United States must allege facts to show that Defendants (1) made a claim; (2) to the government; (3) that was materially false or fraudulent; (4) knowing it was false; and (5) requesting payment from the government. *See United States ex rel. Tra v. Fesen*, 403 F. Supp. 3d 949, 957 (D. Kan. 2019) (citing *United States v. Boeing Co.*, 825 F.3d 1138, 1148 (10th Cir. 2016)). Additionally, the United States must plead with particularity the underlying scheme that allegedly resulted in the false claims. *See United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006), *abrogated on other grounds by Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 587 U.S. ----, 139 S. Ct. 1507, 1511 (2019). "A claim for relief under § 3729(a)(1)(B) has three elements: (1) the defendant makes a false statement, (2) the defendant knows that the statement is false, and (3) the false statement is material" to the government's decision to pay. *United States ex rel. Brooks v. Stevens-Henager Coll., Inc.*, 359 F. Supp. 3d 1088, 1109 (D. Utah 2019); *see also Lemmon*, 614 F.3d at 1170.

In their Motion, Defendants assert that: (1) the United States does not plead materiality with particularity in accordance with 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B) and Rule 9(b); (2) the United States' continued payment of claims despite knowledge of the alleged violations is strong evidence any noncompliance was immaterial; (3) the United States "cannot prove Defendants acted with the requisite knowledge, or scienter,"

required under § 3729(a); and (4) the United States does not "allege any TRICARE or FEHBP requirements relating to UDT." Motion at 4–11.

In response, the United States asserts that Defendants' Motion should be denied because: (1) extraneous information and summary judgment arguments cannot be considered under Rule 12(b)(6); (2) the CII pleads materiality with particularity; (3) Defendants' scienter argument sounds almost entirely in summary judgment; and (4) the CII expressly pleads the requirements for reimbursement under TRICARE and FEHBP. Response at 3–11.

A. Extraneous information and summary judgment arguments are not proper under Rule 12(b)(6).

Defendants cite to the standard adopted in *Escobar II*, 579 U.S. at 195, and a post-payment audit conducted by Novitas in 2018 to support their argument regarding materiality. Motion at 6. Defendants assert that this post-payment audit demonstrates that Defendants' "services were completely supported" by documentation. *See id.* Defendants do not attach the audit to their motion, but they assert that the audit is referenced in the CII as an educational letter and that it "would have included a review of the physician progress notes, prescription history, [i]ntake [f]orms, test results, and physician order." Motion at 7. "[A]rmed with this information, [Defendants assert that] Novitas paid for all services associated with the 2018 audit and continues to pay for these services, a factor strongly indicative of the fact the conduct alleged was immaterial." *See id.*

The Court declines Defendants' arguments, particularly at this procedural stage, for several reasons. First, the post-payment audit conducted by Novitas in 2018 goes

beyond the confines of the CII. This is not a motion for summary judgment, and the Court's review "on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial, but to assess whether the [United States' CII] alone is legally sufficient to state a claim for which relief may be granted." *Smith*, 561 F.3d at 1098 (internal quotation marks and citation omitted). Additionally, "centrality to a defense—rather than a claim—does not permit the court to consider material outside of the pleadings." *See United States ex rel. Street v. Genentech, Inc.*, Case No. 17-CV-00293-GKF-JFJ, 2024 WL 1143513, at *8 (N.D. Okla. Mar. 14, 2024) (first citing *Scanlan v. Texas A&M Univ.*, 343 F.3d 533, 537 (5th Cir. 2003); then citing *Burke v. Holdman*, 750 F. App'x 616, 622–23 (10th Cir. 2018) (unpublished); and then citing *Becher v. United Healthcare Servs., Inc.*, 374 F. Supp. 3d 1102, 1106 (D. Kan. 2019) ("At the motion to dismiss stage, the court cannot properly consider extrinsic evidence that isn't central to a plaintiff's claim. This is the rule even if the extrinsic evidence is central to the defendant's 'theories of defense.'")). Even if the Court could consider the post-payment audit, the Court would decline to exercise its discretion to do so, and Defendants have not attached a copy of the audit to their Motion. *See Prager v. LaFaver*, 180 F.3d 1185, 1189 (10th Cir. 1999).

Finally, the CII "does not allege that [Novitas or the United States] knew that the [UDT] was medically unnecessary. Rather, the allegations are that if the government would have known, the government would not have paid." *Tra*, 403 F. Supp. 3d at 961. There are also allegations that Defendants attempted to conceal their conduct from GHBP. *See* CII ¶¶ 2, 87–90, 100–09 (i.e., moving UDT in-house, manipulating the

technology and results, and papering the file with backdated intake forms). "While continued payment after learning of facts that the treatment was not in compliance with the standards could support a finding that the requirement was not material, there are no allegations here that [the United States or Novitas] had such knowledge." *Tra*, 403 F. Supp. 3d at 961. Defendants are free to raise such arguments, along with any related evidence, on summary judgment.

B. The CII pleads materiality with particularity.

The Supreme Court in *Escobar II* explained that materiality is a "holistic" inquiry that examines "'the *effect on the likely or actual behavior of the recipient* of the alleged misrepresentation.'" *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 541 (10th Cir. 2020)[7] (quoting *Escobar II*, 579 U.S. at 193) (emphasis added in *Janssen*). Materiality does not "rest on a single fact or occurrence." *Escobar II*, 579 U.S. at 191 (citation omitted). "[R]elevant factors include, but are not limited to

> (1) whether the Government consistently refuses to pay similar claims based on noncompliance with the provision at issue, or whether the Government continues to pay claims despite knowledge of the noncompliance; (2) whether the noncompliance goes to the 'very essence of the bargain' or is only 'minor or insubstantial;' and (3) whether the Government has expressly identified a provision as a condition of payment."

Janssen, 949 F.3d at 541 (quoting *Escobar II*, 579 U.S. at 194–95 & n.5). "None of these factors alone are dispositive." *Id.*

[7] The Court notes that *Janssen* was decided on summary judgment grounds, and that Defendants' argument that the United States continued to reimburse OPC is more suitable at the summary judgment stage, if supported by evidence of record. *See Janssen*, 949 F.3d at 542.

Defendants contend that the government has not satisfied the materiality requirement. But here, there are specific allegations that span at least eighteen pages of the CII. *See* CII at 20–37. The government has specifically identified that Dr. Kelly and OPC billed for presumptive drug testing that was never rendered, and that if GHBP had known the presumptive drug tests were not rendered, or that services were billed pursuant to a blanket order, not ordered by the treating physician, and not medically necessary, it would not have reimbursed OPC for the billed services. "[A] doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." *Polukoff*, 895 F.3d at 743 (concluding that there were sufficient allegations to support the conclusion that the provider had performed unnecessary procedures and then knowingly submitted false certifications to the government that the procedures were necessary to obtain federal reimbursement). The allegations in the CII clearly state that Medicare, TRICARE, and FEHBP do not pay claims that are not medically necessary. Construing the facts in the light most favorable to the government, the allegations in this case are that certain UDT services were not medically necessary and that the claims would not have been paid had the government known the facts.

Here, the certifications by OPC and Dr. Kelly, as pled in the CII, appear to go to the "very essence of the bargain" between GHBP and Defendants. The CII alleges that Defendants in the June 30, 2015 EDI expressly certified that claims were "accurate, complete, and truthful" and "services were performed as billed," and this EDI certification served "as the signature for every electronic claim submitted by the

provider" thereafter. CII ¶¶ 26–27. The CII also alleges that claims submitted by OPC and Dr. Kelly were false because UDT was either not performed, but billed, or because the services amounted to unnecessary care, and that OPC and Dr. Kelly made certifications to the contrary that were material to the government's decision to pay.

Additionally, the CII alleges express conditions of payment that Defendants violated over the span of six years, including GHBP requirements that services be medically necessary, actually rendered, ordered by the treating physician, and specific to the patient. CII ¶¶ 31, 40–41, 52–55, 73–74, 76–80. Accepting the well-pled allegations as true, the Court finds that materiality is pled here with particularity under § 3729(a)(1)(A) and Rule 9(b). The United States has provided details identifying particular false claims for payment that were submitted to the government by OPC and Dr. Kelly. *Cf. Sikkenga*, 472 F.3d at 727. Additionally, the United States has provided "details concerning the dates of the claims, the content of the forms or the bills submitted, their identification numbers, the amount of money charged to the government, the particular goods and services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims." *See id.* at 727–28 (explaining that at least some of this information must be pled to satisfy Rule 9(b)) (citations omitted); *see also* CII at 28–34.

The Court also finds that the United States has alleged a sufficient factual basis that Defendants made false statements and that the statements were material to the government's decision to pay. The United States' allegations are that Dr. Kelly and OPC filed with the government express certifications of compliance with applicable federal

healthcare program requirements. The United States also alleges specific examples of express certifications accompanied by names, dates, and the specific language used by OPC in its orders, intake forms, EDI, claim forms, and requests for reimbursement to GHBP. *See, e.g.*, CII ¶¶ 129a–129c. When viewed alongside the United States' allegations with respect to Count 1, which the Court concludes have met Rule 9(b)'s pleading requirements, the United States' allegations with respect to Count 2 are also sufficient to state a claim.

C. The well-pled allegations in the CII regarding Defendants' scienter or knowledge satisfy Rule 9(b) and 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B).

Under Federal Rule of Civil Procedure 9(b), "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "The purpose of Rule 9(b) is 'to afford defendant[s] fair notice of plaintiff's claims and the factual ground upon which [they] are based.'" *Polukoff*, 895 F.3d at 745 (quoting *Lemmon*, 614 F.3d at 1172). Thus, "Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of fraud be pled with enough specificity to put defendants on notice as to the nature of the claim." *Id.* (internal quotation marks and citation omitted).

Both § 3729(a)(1)(A) and § 3729(a)(1)(B) require that Defendants act "knowingly." The FCA defines "knowingly" to "mean that a person, with respect to information[:] (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the

truth or falsity of the information . . . .” 31 U.S.C. § 3729(b)(1)(A). “[N]o proof of specific intent to defraud” is required. *Id.* § 3729(b)(1)(B).

Thus, as explained by the Supreme Court, the definition “encompass[es] three mental states” and “either actual knowledge, deliberate ignorance, or recklessness will suffice.” *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749–50 (2023). “[T]he FCA standards focus primarily on what [defendants] thought and believed.” *Id.* at 751. “‘[A]ctual knowledge’ refers to whether a person is ‘aware of’ information.” *Id.* (quoting *Intel Corp. Inv. Pol’y Comm. v. Sulyma*, 589 U.S. ----, 140 S. Ct. 768, 776 (2020)). “Deliberate ignorance” applies to a defendant who is “aware of a substantial risk that [his] statements are false, but intentionally avoid[s] taking steps to confirm the statement’s truth or falsity.” *See id.* Finally, “reckless disregard” refers to a defendant who is “conscious of a substantial and unjustifiable risk that [his] claims are false, but submit[s] the claims anyway.” *See id.* Here, the well-pled allegations regarding Defendants’ scienter satisfy those requirements and are sufficient to state a claim under Rule 12(b)(6).

For example, the CII alleges that Defendants moved all UDT in-house in 2016, and manipulated the testing equipment to manufacture a claim that definitive testing was necessary. CII ¶¶ 86, 89–90, 110–13. It also alleges that OPC billed GHBP for UDT services pursuant to blanket orders by Dr. Kelly irrespective of the patient’s condition, presentation, or prescribed medications and whether such services were medically necessary and despite receiving provider-specific education from Novitas to the contrary. *See id.* ¶¶ 91–99, 102–07, 120–23. Additionally, the CII alleges that Dr. Kelly indicated

in a letter that OPC's "platform" was to provide definitive testing for patients, but that he billed GHBP for presumptive tests that were not medically necessary. *Id.* ¶¶ 118–19, 129. Finally, the CII alleges that Defendants "paper[ed] the file" with backdated intake forms completed by OPC employees several days after the patient visited the office to "falsely [give] the appearance that OPC practitioners were . . . making patient-specific determinations as to whether definitive UDT was medically necessary." *Id.* ¶¶ 100–03, 109, 129. This conduct coupled with other allegations in the CII—including the certification on the EDI that "services were performed as billed" and the claims were "accurate, complete, and truthful"—provides enough factual matter (taken as true) to suggest, at least, "reckless disregard of the truth or falsity of the information" to state a claim. *Id.* ¶¶ 25–27; *see also* 31 U.S.C. § 3729(b)(1)(A).

To the extent Defendants argue that medical necessity is a question of "opinion" and not actionable under the FCA, that argument was considered and rejected by the Tenth Circuit in *Polukoff*. 895 F.3d at 742–43. The *Polukoff* decision also expressly distinguishes *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980 (10th Cir. 2005) (unpublished), which is the case Defendants rely on for their scienter argument. *See Polukoff*, 895 F.3d at 742 (explaining that *Morton* involved application of the FCA to ERISA, not Medicare, that the Tenth Circuit "explicitly cabined *Morton* to the facts in that case," and that it "did not create a bright-line rule that a medical judgment can never serve as the basis for an FCA claim"). Finally, Defendants' remaining arguments regarding scienter appear to be better suited for summary judgment and reference publications and fact sheets not of record. Motion at 9–11.

D. The CII expressly pleads the requirements for reimbursement under TRICARE and FEHBP.

Finally, Defendants assert that the United States has "failed to allege any TRICARE or FEHBP requirements relating to UDT" and, as a result, the United States' claims based on TRICARE and FEHBP "are unsupported by the [CII]." Motion at 11.

However, the CII alleges that TRICARE reimburses providers for services that are "medically necessary and required in the diagnosis and treatment of illness or injury." CII ¶ 40. Specifically, "UDT that is routine, not based on patient-specific medical decision-making, and/or does not impact the medical management of the patient is not medically necessary and therefore not reimbursable under TRICARE." *Id.*; *see also id.* ¶¶ 41–45.

The same is true for FEHBP. *Id.* ¶¶ 52–55. The CII alleges that "FEHBP plans cover only those medical services that are reasonable and necessary to prevent, diagnose, or treat an illness, disease, injury, or condition of the covered beneficiary." *Id.* ¶ 52. Under the BCBS Federal Employee Program plan, for example, "instances when UDT is not medically necessary include but are not limited to routine presumptive or definitive UDT . . . and standing orders." *Id.* ¶¶ 54–55. Additionally, the CII alleges that "Defendants submitted claims to GHBP for UDT services that they knew were not rendered, not medically necessary, not used in the treatment of GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the treating practitioner." *Id.* ¶ 124; *see also id.* ¶¶ 110–17. Thus, the CII expressly pleads the requirements for reimbursement under TRICARE and FEHBP.

V. CONCLUSION

For these reasons, the Court concludes that the United States has alleged enough facts with particularity to state claims for relief that are plausible on their face under the FCA, Rule 12(b)(6), and Rule 9(b). Consequently, the Court DENIES Defendants' Motion to Dismiss Plaintiff's Complaint-in-Intervention [Doc. No. 41].

IT IS SO ORDERED this 29th day of April 2024.

JODI W. DISHMAN
UNITED STATES DISTRICT JUDGE