IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

UNITED STATES OF AMERICA and THE STATE OF GEORGIA ex rel. REBECCA WILLIAMS, MORGAN VANLUVEN, BILLIE CATHEY, ASHIK RAHMAN, TAYLOR BODIFORD and TRACNESA RANDOLPH,	:	**3:21-cv-00036-CAR**
Plaintiffs,	:	
v.	:	
LANDMARK HOSPITAL OF ATHENS, LLC and ATHENS PULMONARY AND SLEEP MEDICINE, P.C.,	:	
Defendants.	:	

ORDER ON DEFENDANTS' MOTIONS TO DISMISS

Rebecca Williams, Morgan Van Luven, Billie Cathey, Ashik Rahman, Taylor Bodiford, and Tracnesa Randolph ("Relators") brought this action on behalf of the United States of America and the State of Georgia pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and the Georgia False Medicaid Claims Act ("GFMCA"), O.C.G.A. § 49-4-168, against Defendants Landmark Hospital of Athens, LLC ("Landmark") and Athens Pulmonary and Sleep Medicine, P.C. ("Athens Pulmonary") for alleged fraudulent practices. Currently before the Court are Defendants' motions to dismiss Relators' Amended Complaint for failure to state a claim upon which relief may be

granted. Having considered the motions, pleadings, and applicable law, the Court **GRANTS** Defendants' motions to dismiss [Docs. 33, 34].

BACKGROUND

In analyzing Defendants' motions to dismiss, the Court accepts all factual allegations in the Amended Complaint as true and construes them in the light most favorable to Relators.

Rebecca Williams, Morgan Van Luven, Billie Cathey, Ashik Rahman, and Taylor Bodiford are nurses formerly employed by Landmark.[1] Landmark is a for-profit domestic corporation that owns and operates a 42-bed critical care hospital in Athens, Georgia.[2] Tracnesa Randolph is the daughter of a patient treated at both Landmark and Athens Pulmonary.[3] Athens Pulmonary is a for-profit domestic corporation that provides pulmonary care to patients in the Athens area, including at Landmark, Piedmont Athens Regional Hospital ("PARMC"), and St. Mary's Hospital.[4] Approximately seventy percent of Landmark's patients also receive treatment from Athens Pulmonary.[5]

Relators filed a *qui tam* Complaint against Landmark and Athens Pulmonary on April 12, 2021, alleging violations of the FCA and the GFMCA for presenting false or

[1] Am Compl. ¶¶ 3-6 [Doc. 25].
[2] *Id*. at ¶ 9.
[3] *Id*. at ¶ 8.
[4] *Id*. at ¶ 10.
[5] *Id*. at ¶ 31 n.1.

fraudulent claims for payment by Medicare and Medicaid.[6] Pursuant to 31 U.S.C. § 3730(b)(2), the Complaint was placed under seal to permit the United States and the State of Georgia an opportunity to investigate Relators' allegations and to decide whether to intervene in the action.[7] Following a six-month extension of the seal and the time to consider election to intervene, the United States and the State of Georgia declined to intervene.[8] The Court unsealed the Complaint and ordered service on Defendants on December 20, 2021.[9]

Landmark moved to dismiss Relators' Complaint on May, 10, 2022.[10] Athens Pulmonary moved to dismiss Relators' Complaint on May 13, 2022.[11] In response, Relators filed an Amended Complaint as a matter of course pursuant to Federal Rule of Civil Procedure 15(a)(1)(B) on May 31, 2022, effectively mooting the original motions to dismiss.[12] The Amended Complaint modified Relators' claims against Defendants, alleging not only that Landmark presented false and fraudulent claims but also that all requests for payment submitted by Defendants to Medicare and Medicaid were fraudulent under the worthless services theory.[13] Relators included two additional claims

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[6] Comp. [Doc. 3].
[7] [Docs. 1, 2].
[8] [Docs. 10, 11].
[9] [Doc. 12].
[10] [Doc. 17].
[11] [Doc. 21].
[12] Defendant Landmark's motion to dismiss [Doc. 17] and Defendant Athens Pulmonary's motion to dismiss [Doc. 21] are hereby **DENIED as moot**.
[13] Am. Compl. ¶¶ 47-49, 146-160, 187-190, 196-201 [Doc. 25].

against Landmark for (1) alleged violations of the Paycheck Protection Program ("PPP"); and (2) alleged presentation of false claims to the Government between 2017 and 2020 for payment for medications, laboratory charges, therapy, imaging, and medical equipment.[14] Defendants moved to dismiss Relators' Amended Complaint on June 21, 2022.[15]

A. Legal and Regulatory Framework

The FCA[16] provides for an award of treble damages and civil penalties for knowingly presenting or causing to be presented false or fraudulent claims for payment to the Government, and for knowingly making or using, or causing to be made or used, false records or statements material to false or fraudulent claims paid by the Government.[17] The FCA further makes it unlawful to conspire to knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval or to conspire to make or use a false record or statement material to a false or fraudulent claim.[18] For purposes of the FCA, a "claim" includes any request or demand for money or property made to a contractor, grantee, or other recipient if the Government provides any portion

[14] *Id*. at ¶¶ 194-236.

[15] [Docs. 33, 34].

[16] Relators assert claims under both the FCA and the GFMCA. Defendants state, and Relators concede, that the statutory language in the GFMCA mirrors the language in the FCA. [Doc. 34, p. 19; Doc. 38, p. 6]. Accordingly, any ruling on Realtors' FCA claims applies in equal measure to their claims arising under the GFMCA.

[17] Am. Compl. ¶¶ 18-21 [Doc. 25].

[18] *Id*. at ¶¶ 22-23.

of the money or property which is requested or demanded.[19] The terms "knowing" and "knowingly" mean that an individual (1) has actual knowledge of the information; (2) acts with deliberate ignorance of the truth or falsity of the information; or (3) acts with reckless disregard of the truth or falsity of the information.[20]

The Medicare Program is administered by the United States Department of Health and Human Services and provides medical services and durable medical equipment to individuals age 65 and older and others who qualify for Medicare coverage.[21] The Medicaid Program is funded through state and federal taxpayer revenue and assists participating states in providing medical services, durable medical equipment, and prescription drugs to financially eligible participants.[22] The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") is administered by the Department of Defense and provides medical benefits to retired members of the Uniformed Services; the spouses and children of active duty, retired, and deceased members; and reservists ordered to active duty for thirty days or longer.[23] The Civilian Health and Medical Program of the Veterans Administration (CHAMPVN") is administered by the Department of Defense and provides medical benefits for spouses and children of veterans entitled to permanent and total disability benefits and to widows and children

[19] *Id*. at ¶¶ 27-28.
[20] *Id*. at ¶ 29.
[21] *Id*. at ¶ 11.
[22] *Id*. at ¶ 12.
[23] *Id*. at ¶ 13.

of veterans who died from service-related disabilities.[24] Claims submitted to each of these Government health insurance programs require the completion of CMS Form UB-04 or CMS-1450.[25] The submitting party must verify that the claim is "true, accurate[,] and complete" and that the services for which the party seeks payment were "medically necessary and appropriate for the health of the patient."[26]

B. Factual Allegations

COVID-19 Testing Scheme (Counts I through V)

In the early months of the COVID-19 pandemic, the Centers for Disease Control and Prevention ("CDC") issued guidelines for performing COVID-19 testing.[27] As of May 1, 2020, those guidelines provided that initial diagnostic testing for SARS-CoV-2 should be conducted by testing an upper respiratory specimen.[28] The CDC outlined additional procedures for collecting and testing lower respiratory tract aspirate or bronchoalveolar lavage samples as well as tracheal aspirate specimens.[29] The CDC guidelines cautioned: "Proper collection of specimens is the most important step in the laboratory of infectious disease. A specimen that is not collected correctly may lead to false negative test results."[30]

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[24] *Id*. at ¶ 14.
[25] *Id*. at ¶ 16.
[26] *Id*.
[27] *Id*. at ¶ 42
[28] *Id*. at ¶ 44.
[29] *Id*. at ¶¶ 44-46.
[30] *Id*. at ¶ 43.

Medicare and Medicaid require participating laboratories to comply with federal regulations.[31] Those regulations provide, in pertinent part, that laboratories establish and follow written procedures for specimen collection, labeling, and acceptability and rejection.[32] Any request for testing must include the source of the specimen, when appropriate, and any information relevant to a specific test to ensure accurate and timely testing and reporting of test results.[33] The test reports must also include the specimen source, when appropriate, the test result, and any information impacting the laboratory's criteria for acceptability.[34]

Relators allege Defendants performed, or conspired to have performed, fraudulent COVID-19 testing.[35] According to Relators, Defendants submitted tracheal aspirate specimens to the laboratory for testing that (1) were collected with nasopharyngeal swab kits; and (2) falsely identified tracheal aspirate specimens as nasopharyngeal specimens.[36] Relators allege Defendants submitted, or conspired to submit, these specimens with the knowledge that the testing laboratory did not accept tracheal aspirate specimens and the intent to manipulate the testing laboratory into testing specimens that did not comply with approved guidelines.[37] Relators further allege Defendants knowingly submitted

[31] *Id*. at ¶ 34.
[32] *Id*. at ¶¶ 38-39.
[33] *Id*. at ¶ 37.
[34] *Id*. at ¶ 40.
[35] *Id*. at ¶¶ 50, 176-77.
[36] *Id*. at 50.
[37] *Id*. at ¶¶ 51-52.

false lab requisition forms, indicating that tracheal aspirate specimens were nasopharyngeal specimens, and knowingly made false reports to local, state, and national health officials about the presence of COVID-19 in their facilities.[38] Defendants also purportedly created medical records premised on the manufactured COVID-19 test results to avoid detection of the fraudulent testing scheme by nursing staff, state inspectors, or anyone else reviewing the records.[39]

The Amended Complaint outlines anecdotal evidence for three patients whose COVID-19 testing Relators contend was fraudulently performed and reported:

Patient DL

On June 4, 2020, a doctor at Landmark ordered a nasopharyngeal swab for patient DL.[40] The laboratory reported the specimen was positive for COVID-19.[41] The lab report lists the source of the test only as a "swab."[42] Landmark retested DL the next day.[43] This time, the doctor ordered a tracheal secretion suction specimen.[44] Testing of the tracheal specimen produced a negative result.[45] The laboratory test report identifies the submitted specimen as a nasopharyngeal specimen.[46] Relators state they have an audio recording of

[38] Id. at ¶¶163-168, 178-79.
[39] *Id*. at ¶¶ 169, 180.
[40] *Id*. at ¶ 56.
[41] *Id*.
[42] *Id*.
[43] *Id*. at ¶ 57.
[44] *Id*.
[45] *Id*.
[46] *Id*.

Landmark's Chief Executive Officer admitting that the specimen was a tracheal aspirate specimen.[47]

Patient DL tested positive for COVID-19 a second time after a nasopharyngeal swab.[48] Hours later, the hospital ordered a tracheal aspirate specimen test.[49] That specimen, which was labeled for testing as a nasopharyngeal specimen, came back negative for COVID-19.[50]

Patient DD

On June 5, 2020, Landmark ordered a COVID-19 test for patient DD, who was scheduled for a procedure at another facility on June 7, 2020.[51] An unspecified swab taken at 4:30 a.m. on June 7, 2020, returned a positive COVID-19 result.[52] The Nurse Manager ordered the Charge Nurse to suction DD through his trach, swab those secretions, and send them to the laboratory for a second test.[53] Instead, the Charge Nurse directed the performance of a nasopharyngeal swab.[54] The nurse placed the specimen in the testing lockbox, but the specimen was never tested.[55]

A doctor then verbally ordered a sputum specimen, a lower respiratory sample

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[47] *Id*.
[48] *Id*. at ¶ 58.
[49] *Id*. at ¶ 59.
[50] *Id*.
[51] *Id*. at ¶ 60.
[52] *Id*. at ¶ 61.
[53] *Id*. at ¶ 62.
[54] *Id*. at ¶ 63.
[55] *Id*.

that was not approved by the testing laboratory for COVID-19 testing and for which Landmark allegedly did not have or use the appropriate testing kit.[56] The laboratory reported a negative result at 12:49 p.m.[57] At 3:43 p.m., the laboratory reported a specimen taken from patient DD was negative for COVID-19.[58] The laboratory test report indicated that the specimen was a nasopharyngeal specimen, but Landmark's lab results records list the source only as a "swab."[59]

On June 8, 2020, the doctor ordered a tracheal specimen from DD.[60] The lab requisition form, however, shows the specimen was submitted to the laboratory as a "nasal COVID 19" specimen.[61] A notation by an infectious disease doctor treating DD indicates the June 8 test was "negative by tracheal aspirate."[62] Patient DD had a positive COVID-19 antigen test on June 8.[63] The Nurse Manager ordered that the test be discarded and the patient re-swabbed.[64]

Patient TS

Patient TS tested negative for COVID-19 on April 14, 2020, 96 hours before her admission to Landmark. On June 8, 2020, Landmark took a tracheal aspirate specimen

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[56] *Id*. at ¶ 64.
[57] *Id*. at ¶ 65.
[58] *Id*. at ¶ 66.
[59] *Id*.
[60] *Id*. at ¶ 67.
[61] *Id*. at ¶ 68.
[62] *Id*. at ¶ 70.
[63] *Id*. at ¶ 71.
[64] *Id*.

from TS.[65] Relators do not have the laboratory test report for this specimen but state that Landmark's lab results record the source of the specimen only as a "swab."[66]

Patient TS transferred from Landmark to PARMC on June 19, 2020.[67] On June 20, 2020, Relator Randolph, the daughter of patient TS, recorded a telephone call during which a physician with Athens Pulmonary admitted Athens Pulmonary swabs tracheal aspirate and submits it to the laboratory as a nasopharyngeal specimen.[68] The physician opined, "we have more accuracy with a tracheal aspirate than we do with the nasopharyngeal swab."[69]

Relators obtained a list of ten other Landmark patients tested on June 8, 2020.[70] Some of the patients underwent nasopharyngeal swabs and some tracheal aspirate swabs.[71] Of the three known tracheal specimens taken, Relators claim the specimens were labeled on the lab requisition form as "nasal COVID-19."[72] Relators allege Defendants were knowingly engaging in a fraudulent scheme to manipulate COVID-19 test results. Relators claim numerous audio recordings from meetings, text messages, and e-mails in which Defendants openly confess to conducting COVID-19 testing in ways that were

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[65] *Id*. at ¶ 73.
[66] *Id*. at ¶ 73.
[67] *Id*. at ¶ 74.
[68] *Id*. at ¶ 78.
[69] *Id*.
[70] *Id*. at ¶ 80.
[71] *Id*. at ¶¶ 81-90.
[72] *Id*. at ¶ 91.

inconsistent with CDC guidelines and federal requirements for laboratory testing.[73]

Relators contend the purpose of Defendants' fraudulent testing scheme was to ensure the hospital could continue accepting and discharging patients.[74] In other words, Landmark was concerned with profitability.[75] Relators highlight that Landmark is a small hospital without an emergency room.[76] Relators posit that were perspective patients aware of the number of COVID-19 patients at the hospital, those individuals would choose to receive care at a different medical facility.[77]

Landmark further benefitted from publicity generated from participation in COVID-19 drug trials.[78] William Kapp, III, MD is the founder of Landmark Hospitals and manager of Landmark Hospital of Athens, LLC.[79] Dr. Kapp also serves as a medical advisor to Organicell Regenerative Medicine, Inc., which produces Organicell Flow, otherwise known as Zofin.[80] Landmark began enrolling patients in Zofin drug trials in May 2020.[81] Relators claim Landmark included patients who did not qualify for the drug trial and exaggerated the success of the drug trial to unduly influence patient treatment.[82]

Relators allege Defendants' COVID-related fraud extended beyond administration

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[73] *Id*. at ¶¶ 92-106.
[74] *Id*. at ¶ 110.
[75] *Id*. at ¶ 31 n.1.
[76] *Id*.
[77] *Id*.
[78] *Id*. at ¶¶ 123-141.
[79] *Id*. at ¶ 127.
[80] *Id*. at ¶¶ 123, 125-26.
[81] *Id*. at ¶ 123.
[82] *Id*. at ¶¶ 135-36, 138-39.

of COVID-19 tests. According to Relators, at some point Landmark's administration instructed the nursing staff to cease performing extensive COVID-19 testing and instead assume every patient had COVID.[83] Landmark also failed to isolate those patients who tested positive for COVID-19 and frequently relied on false negative COVID-19 tests to prematurely discontinue droplet precautions.[84] From May 2020 until June 17, 2020, the hospital's central air conditioning failed on one of the halls.[85] Landmark placed portable air conditioning units on the hall, including in the rooms of patients with COVID-19.[86] That meant air was being ventilated from the rooms of COVID-19 patients into the hallways and other parts of the hospital.[87] The portable air conditioners could not effectively cool the hospital, so temperatures often rose above ninety degrees.[88] A linen shortage developed because patients then required more frequent bed changes and because the linens were used to clean water leaking from the air conditioners.[89] The elevated temperatures also caused increased skin and wound degradation in patients.[90]

Relators claim Defendants billed Medicare and Medicaid significant sums for services between March 2020 and June 2020.[91] Relators allege based on the fraudulent

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[83] *Id*. at ¶ 107.
[84] *Id*. at ¶¶ 112-114, 122.
[85] *Id*. at ¶ 116, 147.
[86] *Id*. at ¶¶ 116, 119-20, 147.
[87] *Id*. at ¶¶ 118-20.
[88] *Id*. at ¶ 149.
[89] *Id*. at ¶ 150.
[90] *Id*. at ¶ 151.
[91] *Id*. at ¶¶ 143, 145, 146.

COVID-19 testing, which jeopardized effective treatment of patients, and the poor conditions at the hospital, all services rendered by Landmark were worthless.[92] And, because Athens Pulmonary treated patients at Landmark and billed separately for those services, Athens Pulmonary's services were by extension worthless.[93] Relators contend Defendants caused damage to the Government by billing for these worthless or inadequate services.[94] Relators further allege that Defendants' COVID-19 testing scheme caused PARMC and other medical providers to present false or fraudulent claims for payment by the Government.[95]

PPP Fraud (Count VI)

Relators allege Landmark violated the FCA by knowingly presenting a false or fraudulent claim for forgiveness of a Paycheck Protection Program ("PPP") loan.[96] On March 27, 2020, Congress signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act").[97] The CARES Act established the Paycheck Protection Program, a federal loan program designed to incentivize employers to maintain employees during the economic crisis caused by the COVID-19 pandemic.[98] Recipients of PPP loans are eligible for full loan forgiveness provided the recipient adheres to the

[92] *Id*. at ¶¶ 143, 157-60.
[93] *Id*. at ¶ 197-200.
[94] *Id*. at ¶¶ 201-202.
[95] *Id*. at ¶¶ 172-174.
[96] *Id*. at ¶ 220.
[97] Id. at ¶ 204.
[98] *Id*.

following requirements:

a. The business uses at least sixty percent of the loan on payroll expenses. The remainder of the loan may be spent on other qualifying costs, including rent, utilities, and mortgage interest.

b. The business spends the loan within the eight to twenty-four week covered period following loan disbursement.

c. The business maintains employee and compensation levels during the covered period.

d. The business does not reduce employees' wages by more than twenty-five percent for all employees earning less than $33,333 between March 1, 2019, and June 20, 2019, or earning $100,000 or less in 2019.[99]

Landmark received PPP loan #31490567103 for $1,526,300.00 on April 21, 2021.[100] Landmark was required to use $1,221,112.00 of the loan for payroll.[101] Relators claim Landmark did not expend the funds as required nor did Landmark maintain the required employee ratio, having terminated Relators Williams, Van Luven, Cathey, Rahman, and Bodiford during the relevant time period.[102]

Non-COVID-19 False Claims (Count VII)

[99] *Id*. at ¶ 206.
[100] *Id*. at ¶ 209.
[101] *Id*. at ¶ 210.
[102] *Id*. at ¶¶ 211-213.

Relators assert a final count against Landmark for alleged presentation of non-COVID-19 related false claims between 2017 and 2020. Relators claim that during this time period, Landmark billed the Government for medications that either were not administered at the level claimed or were not administered at all.[103] Relators further purport Landmark billed the Government for laboratory charges that were not eligible for reimbursement.[104] Additionally, Relators allege Landmark submitted claims for therapy services that were not given, not medically necessary, or had no reasonable expectation of resulting in patient improvement[105]; for imaging and procedures that were not performed or were performed at other facilities[106]; and for medical equipment that was not utilized.[107]

LEGAL STANDARD

On a motion to dismiss, the Court must accept as true all well-pleaded facts in a plaintiff's complaint.[108] To avoid dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[109] A claim is plausible where the plaintiff alleges factual content that "allows the court to draw the reasonable inference that the

[103] *Id*. at ¶¶ 222-224.
[104] *Id*. at ¶¶ 225-227.
[105] Id. at ¶¶228-230
[106] Id. at ¶¶ 231-232.
[107] *Id*. at ¶¶ 233.
[108] *Sinaltrainal v. Coca-Cola Co.*, 578 F.3d 1252, 1260 (11th Cir. 2009).
[109] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

defendant is liable for the misconduct alleged."[110] The plausibility standard requires that a plaintiff allege sufficient facts "to raise a reasonable expectation that discovery will reveal evidence" that supports a plaintiff's claims.[111]

Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleading is entitled to relief."[112] The purpose of this requirement is to "give the defendant fair notice of what the ... claim is and the grounds upon which it rests."[113] "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions."[114] The complaint must contain enough factual allegations to "raise a right to relief above the speculative level."[115]

In addition, the heightened pleading standard of Federal Rule of Civil Procedure 9(b) applies to causes of action brought under the FCA.[116] Under Rule 9(b), "in 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

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[110] *Id.*
[111] *Twombly*., 550 U.S. at 556.
[112] Fed. R. Civ. P. 8(a)(2).
[113] *Twombly*, 550 U.S. at 554-55 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (internal quotation marks omitted) (alteration in original).
[114] *Id*. at 555 (citations omitted) (alteration in original).
[115] *Id*. at 555-56.
[116] *Hopper v. Solvay Pharm., Inc.,* 588 F.3d 1318, 1324 (11th Cir. 2009).

alleged generally."[117] An FCA complaint must plead not only the "who, what, where, when, and how of improper practices," but also the "who, what, where, when, and how of fraudulent submissions to the Government."[118] Rule 9(b) serves to ensure that a FCA claim has "some indicia of reliability . . . to support the allegation of an actual false claim for payment being made to the Government."[119]

DISCUSSION

Defendants move the Court to dismiss Relators' Amended Complaint for failure to state a claim under the FCA. Defendants argue the Amended Complaint fails adequately to allege Defendants knowingly presented any false or fraudulent claim to the Government for payment for services rendered. Absent specific allegations that Defendants entered into an agreement to defraud the Government, Defendants further argue Relators' conspiracy claim is subject to dismissal. Defendant Landmark additionally submits that Relators' Amended Complaint should be dismissed in its entirety for failure to comply with the FCA's sealing requirements. The Court addresses each argument in turn below.

A. Amended Complaint Violates the FCA Filing Requirements

Defendant Landmark moves the Court to dismiss Relators' Amended Complaint

[117] Fed. R. Civ. P. 9(b).

[118] *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (citation omitted).

[119] *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313 n.24 (11th Cir. 2002).

for failure to follow the procedural requirements of the FCA.[120] The FCA requires compliance with certain mandatory filing rules. Section 3730(b)(2) provides that a relator must serve upon the Government "[a] copy of the complaint and written disclosure of substantially all material evidence and information the person possesses."[121] The complaint then "shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders."[122] The purpose of the sealing requirement is to preserve the Government's interests by ensuring the Government's ability to investigate the allegations and to decide whether to intervene in the case prior to the defendant receiving notification of the lawsuit.[123]

Relators here properly filed their original complaint under seal. The issue raised by Landmark is whether Relators' Amended Complaint, which was filed after the lifting of the seal and service on Defendants, should also have been filed under seal. The answer is not clear. Neither the Eleventh Circuit Court of Appeals nor any other judge in this district has directly addressed this issue.

The FCA does not establish separate procedures for filing an amended complaint. District courts generally agree, however, that the sealing requirements of § 3730(b)(2) do

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[120] Landmark's procedural argument primarily impacts Counts VI and VII of Relators' Amended Complaint. Those claims assert allegations only against Landmark. Accordingly, Athens Pulmonary does not join in the motion to dismiss those claims.

[121] 31 U.S.C. § 3730(b)(2).

[122] *Id*.

[123] *See State Farm Fire and Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26, 35 (2016) (citing S. Rep. No. 99-345, p. 24 (1986) (indicating the seal provision was designed to alleviate any concern that a relator may file a civil complaint that would alert a defendant to a pending federal criminal investigation)).

not apply to amended *qui tam* complaints when the Government has had an opportunity to consider intervention and the proposed amendment expands or explains existing claims but does not add new claims.[124] Where district courts diverge is when an amended complaint endeavors to add new FCA claims not previously presented for the Government's consideration.

Many courts conclude that "[n]either the statute nor any relevant case law impose[s] a duty to file any amendment to that complaint in camera and under seal."[125] The Northern District of Georgia adopted this viewpoint in *Saldivar*.[126] There, the district court reasoned that the statutory language of § 3730(c)(2)(D)(3) alleviated any concerns that the Government lacked an opportunity to review new FCA claims included in the relator's third motion to amend his complaint.[127] Section 3730 provides that when the Government elects not to intervene, the Government may nevertheless request service of

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[124] *See, e.g., E. Bay Mun. Util. Dist. v. Balfour Beatty Infrastructure, Inc.,* No. 13-CV-02032-WHO, 2014 WL 2611312, at *3 (N.D. Cal. June 11, 2014) ("Requiring an amended complaint to be sealed does not benefit the government if the amended complaint relates to the same claims and conduct as the original complaint that the government already had the opportunity to study."); *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 972 F. Supp. 2d 1317, 1325-26 (N.D. Ga. 2013); *United States ex rel. Ubl*, No. 1:06-CV-641, 2009 WL 1254704, at *4 (E.D. Va. May 5, 2009).

[125] *United States ex rel Milan v. Regents of the Univ. of Cal.*, 912 F. Supp. 868, 890 (D. Md. 1995); *United States ex rel. Wisz v. C/HCA Dev., Inc.*, 31 F. Supp. 2d 1068 (N.D. Ill. 1998).

[126] 972 F. Supp. 2d at 1327.

[127] Review of the procedural history in *Saldivar* reveals the relator filed his first amended complaint as a matter of right under Fed. R. Civ. P. 15(a)(1) while the case remained under seal. *Saldivar*, No. 1:10-CV-01614-AT (Jan. 24, 2011). After the court lifted the seal, the relator filed a second motion to amend his complaint pursuant to Fed. R. Civ. P. 15(a)(2) to add an FCA claim for retaliation. *Saldivar*, 972 F. Supp. 2d at 1322. The defendant did not oppose the motion, and the district court granted the relator leave to amend. *Id*. The court did not evaluate the sealing issue until the relator filed his third motion to amend, at which point the case had been ongoing for just short of two years. *Id*. 1322-23. The court expressed concern that requiring a new confidential filing at that point in the case risked stagnation of evidence and unnecessary extension of discovery which had already begun. *Id*. at 1327.

all future court filings and later move to intervene upon a showing of good cause.[128] The court in *Saldivar* opined that this statutory provision creates a "backdoor" for the Government to participate in the proceedings after declining to intervene and eliminates the need to seal amended pleadings, which may unnecessarily prolong the case.[129]

Other courts have found that requiring the Government show good cause to intervene on claims the Government did not have the chance to review while the case remained under seal frustrates the purpose of the FCA's sealing requirement.[130] This Court agrees. The purpose of the sealing requirement is to "allow the [G]overnment to investigate the claims and decide whether to intervene."[131] The "policy behind the sealing requirement . . . is especially implicated when a relator amends a complaint to add completely new FCA claims."[132] Otherwise, "a relator could file an initial complaint with minor fraud allegations, and then once the [G]overnment declines to intervene, the relator could amend the complaint as of right to include additional claims for relief or new and substantially different allegations of fraud."[133] The Government under those

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[128] 31 U.S.C. § 3730(c)(2)(D)(3).

[129] *Saldivar*, 972 F. Supp.2d at 1326 (citing *United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715, 721 (9th Cir. 1994)); *see also United States ex rel. Walle v. Martin Marietta Corp.*, No. 92-3677, 1994 WL 518307, at *2 (E.D. La. 1994) (granting leave to amend to add a new but closely related claim and expressing a lack of concern for the Government as the Government had the statutory authority to intervene at a later time and was not likely to "walk away from any viable allegations that might put money back into the Government's pocket").

[130] *United States ex rel Brooks v. Stevens-Henager Coll., Inc.*, 359 F. Supp. 3d 1088, 1128 (D. Utah 2019).

[131] *United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 262 (D. Mass. 2015).

[132] *United States v. Walgreen Co.*, No. CV09-1293 PSG PJWx, 2017 WL 10591756, at *4 (C.D. Cal. 2017).

[133] *United States ex rel. Davis v. Prince*, 766 F. Supp. 2d 679, 684 (E.D. Va. 2011).

circumstances would be stripped of the "'opportunity to conduct a confidential and unhurried investigation of the new claims in the amended complaint.'"[134] Courts accordingly have required relators abide by the sealing requirements "when filing an amended complaint that is not 'substantially similar' to the original complaint."[135]

Here, Relators' Amended Complaint is not "substantially similar" to the original Complaint. The Amended Complaint adds two additional FCA claims with no apparent connection to Relators' original claims concerning Defendants' allegedly fraudulent COVID-19 testing scheme.[136] In Count VI of the Amended Complaint, Relators assert a new claim against Landmark for alleged PPP fraud. In Count VII, Relators allege Landmark violated the FCA by engaging in a pattern of submitting false claims for non-COVID-19 services and treatment from 2017 through 2020. The original Complaint contains no allegations even alluding to these claims. Because these newly alleged claims were never reviewed by the Government, and therefore could not have formed the basis of the Government's decision to decline intervention, Relators' Amended Complaint

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[134] *Id*. (quoting J. Boese, Civil False Claims and Qui Tam Actions § 4.04[C], p. 4-169 (3d ed. 2006)).

[135] *Walgreen*, 2017 WL 10591756, at *4 (citing *E. Bay Mun.*, 2014 WL 2611312, at *3)).

[136] Landmark also suggests that Relators' inclusion of the worthless services theory significantly modifies Relators' claims and subjects the Amended Complaint to the FCA's sealing requirements. [Doc. 33, p. 7-8]. The Court disagrees. The original Complaint outlines the same conditions Relators allege in the Amended Complaint rendered the services performed by Defendants worthless, including falsified COVID-19 testing; failure to isolate patients who tested positive for COVID; lack of proper ventilation; and removal of droplet precautions. [Doc. 3, ¶¶ 101-111). Relators' original Complaint also includes allegations that Defendants billed the Government for "worthless or inadequate services." [*Id*. at ¶¶ 149, 158]. The Court is satisfied that the Government thus had sufficient opportunity to evaluate whether the services provided by Defendants were worthless prior to declining intervention.

violates the FCA's filing requirements.[137]

The FCA provides no remedy for violations of the seal requirement.[138] The structure of the statute, however, indicates that a violation of that rule does not mandate dismissal.[139] "Because the seal requirement was intended in main to protect the Government's interests, it would make little sense to adopt a rigid interpretation of the seal provision that prejudices the Government by depriving it of needed assistance from private parties."[140] The "question whether dismissal is appropriate should be left to the sound discretion of the district court."[141] When deciding whether dismissal is an appropriate sanction, courts should consider the following factors: (1) whether and to what extent the seal violation harmed the Government; (2) the nature of the violation; and (3) whether the violation was willful or made in bad faith.[142]

Taking these factors into consideration, the Court does not believe the circumstances warrant dismissing Relators' Amended Complaint in its entirety. However, the Court in its discretion determines that Relators shall not be permitted to pursue those claims outlined in Counts VI and VII of the Amended Complaint. Why Relators elected not to raise those claims in their original Complaint is not apparent on

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[137] *See Walgreen Co.*, 2017 WL 10591756, at *5.

[138] *See Rigsby*, 580 U.S. at 34.

[139] *Id*. (explaining, "[i]t is proper to infer that, had Congress intended to require dismissal for a violation of the seal requirement, it would have said so").

[140] *Id*. at 34-35.

[141] *Id*. at 37.

[142] *United States ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242, 245-46 (9th Cir. 1995).

the face of the pleadings. What is clear, though, is that the Government was not afforded an opportunity to conduct a confidential review of these claims prior to declining intervention. The Court accordingly **DISMISSES** Counts VI and VII of Relators' Amended Complaint without prejudice.

B. Amended Complaint Fails to Allege Submission of a False Claim or Use of a False Statement

Counts I and II of Relators' Amended Complaint assert the following FCA claims against Defendants: (1) presentation of false claims under 31 U.S.C. § 3729(a)(1)(A) (Count II); and (2) using false statements to procure payment of false claims under 31 U.S.C. § 3729(a)(1)(B) (Count I). Defendants move to dismiss Relators' claims for failure adequately to allege the actual submission of any false claim or the use of any false statement to secure payment of a false claim.

1. Submission of a False Claim

The FCA imposes liability on any person who "knowingly presents or causes to be presented a false or fraudulent claim for payment or approval."[143] Liability under the FCA does not attach "merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe."[144] The "act of submitting a fraudulent claim to the [G]overnment is the *sine qua non* of a [FCA]

[143] 31 U.S.C. § 3729(a)(1)(A).

[144] *Clausen*, 290 F.3d at 1311 (emphasis in original).

violation."[145] "Without the *presentment* of such a claim, while the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the public fisc as required" under the FCA.[146]

Allegations of an FCA violation must meet the heightened pleading standard of Rule 9(b).[147] As the Eleventh Circuit explained in *Corsello*, submission of a fraudulent claim may not be inferred from allegations of improper practices.[148] Rather, to meet the Rule 9(b) pleading standard, the complaint must include:

> (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.[149]

In short, a relator must "allege the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the [G]overnment."[150]

Relators' Amended Complaint outlines a purported fraudulent scheme whereby Defendants regularly labeled tracheal aspirate specimens as nasopharyngeal specimens before submitting the specimens to the laboratory at PARMC and other medical providers for COVID-19 testing. According to Relators, this practice contravened

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[145] *Corsello*, 428 F.3d at 1012 (quotation and citation omitted).

[146] *Clausen*, 290 F.3d at 1311.

[147] *Estate of Helmly v. Bethany Hospice and Palliative Care of Coastal Ga.*, 853 F. App'x 496, 501 (11th Cir. 2021) (citing *Corsello*, 428 F.3d at 1012; *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006)).

[148] *Corsello*, 428 F.3d at 1013.

[149] *Clausen*, 290 F.3d at 1210 (quoting *Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001)).

[150] *Coresello*, 428 F.3d at 1014.

guidance issued by the CDC for COVID-19 testing and violated federal regulations for laboratory testing. In Count II of their Amended Complaint, Relators allege Defendants' submission of the improperly marked COVID-19 tests to the laboratory caused PARMC and other medical providers "to present false or fraudulent claims for payment or approval to the Government."[151]

Conspicuously absent from the Amended Complaint are any allegations concerning PARMC's billing to any Government healthcare agency for these specific laboratory services. Relators allege only the following:

> The knowingly false records and statements of Landmark Hospital and Athens Pulmonary caused PARMC and other medical providers to present false or fraudulent claims for payment or approval to the Government, including claims for false testing, for ineffective treatment, and for metrics which affect the percentage at which the Government pays or approves claims.[152]

The Amended Complaint contains no information concerning who at PARMC or any other medical facility submitted any requests for payment to the Government; when or to whom those requests were made; for what services PARMC sought payment from the Government; what documentation was presented in support of those claims; or whether the Government rendered payment for those services. The only information Relators offer in support of their claim is an explanation of benefits provided by PARMC

[151] Am. Compl., ¶ 172. [Doc. 25]
[152] *Id*.

to Patient TS.[153] The explanation of benefits lists all services received by TS during hospitalization at PARMC but provides no information regarding which of the voluminous services PARMC actually billed to the Government. Moreover, the explanation of benefits does not indicate which, if any, of the services rendered relates to any purported misstatement by either Defendant. Relators' claim is simply too broad and too conclusory to satisfy the heightened pleading standard of Rule 9(b). Count II of Relators' Amended Complaint accordingly is dismissed for failure to state a claim.

2. Use of False Statements

In Count I of their Amended Complaint, Relators allege Defendants violated the FCA when they knowingly submitted false laboratory requisition forms to PARMC, labeling tracheal aspirate samples as nasopharyngeal samples.[154] These false requisition forms caused PARMC to issue false laboratory test reports and resulted in the recording of false information in patients' medical records.[155] Relators contend the laboratory requisition forms and test reports are material to the false or fraudulent claims submitted by Defendants and PARMC to the Government for payment of COVID-19 testing.[156]

To state a claim under § 3729(a)(1)(B), a relator must show that: "(1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and

[153] Am. Compl., Ex. 8 [Doc. 25-8].
[154] Am. Compl., ¶¶ 163-65 [Doc. 25].
[155] *Id*. at ¶¶ 166-67.
[156] *Id*. at ¶ 168.

(3) the statement was material to a false claim."[157] What § 3729(a)(1)(B) "demands is not proof that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record or statement for the purpose of getting a false or fraudulent claim paid or approved by the Government."[158] If a defendant makes a false statement but does not intend the Government to rely on that false statement "as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim" by the Government, and there is no FCA violation.[159]

Taking the allegations in the Amended Complaint as true, which the Court must at this stage, Relators have sufficiently alleged that Defendants knowingly created false laboratory requisition forms when they mislabeled COVID-19 specimens. However, Relators' claim fails to meet the demanding materiality standard.[160] The FCA defines material as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[161] The Supreme Court has explained that materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation."[162] A misrepresentation "cannot be deemed material because

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[157] *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017).

[158] *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 671 (2008) (internal quotation marks omitted).

[159] *Id*.

[160] *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016).

[161] 31 U.S.C. § 3729(b)(4).

[162] *Escobar*, 579 U.S. at 193.

the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment" nor because the Government would have the option to decline payment if the Government knew of a defendant's noncompliance.[163]

Simply alleging that the laboratory requisition forms and laboratory test reports are material to a claim submitted to the Government for payment is not sufficient to meet the rigorous pleading requirements. Nor is enough to allege that mislabeling the COVID-19 specimens did not comply with labeling and testing standards. Relators must also show that Defendants falsified the reports with the specific purpose of inducing the Government to pay for services the Government would not otherwise owe. Relators fail to allege facts making this connection. The Court therefore grants Defendants' motions to dismiss Count I of Relators' Amended Complaint.

C. Amended Complaint Fails to State a Claim for Conspiracy

Count III of Relators' Amended Complaint alleges Defendants conspired to violate the FCA pursuant to 31 U.S.C. § 3729(a)(1)(C). Section 3792(a)(1)(C) imposes liability on any person who conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.[164] To state a claim for conspiracy to violate the FCA, a relator must show: "(1) that the defendant conspired with one or more persons to get a false or

[163] *Id*. at 194.

[164] 31 U.S.C. § 3792(a)(3).

fraudulent claim paid by the United States; (2) that one or more of the conspirators performed any act to affect the object of the conspiracy; and (3) that the [Government] suffered damages as a result of the false or fraudulent claim."[165] "Where the conduct that the conspirators are alleged to have agreed upon involved the making of a false record or statement, it must be shown that the conspirators had the purpose of 'getting' the false record or statement to bring about the Government's payment of a false or fraudulent claim."[166] A relator does not need to show that the conspirators intended to present any false record or statement to the Government; but a relator must establish that the conspirators agreed that the false statement or record would have a material impact on the Government's decision to pay the claim.[167]

Relators' conclusory statements that Defendants conspired with one another to engage in a false COVID-19 testing scheme are insufficient to establish a claim for conspiracy under the FCA. Relators allege generally that both Landmark and Athens Pulmonary mislabeled COVID-19 tests. However, Relators fail to establish with particularity that the two entities entered into an explicit agreement to do so with the specific purpose of inducing payment from the Government. Relators have shown only that physicians for both Defendants believed tracheal aspirate specimens produced more

[165] *Corsello*, 428 F.3d at 1014.
[166] *Allison Engine*, 553 U.S. at 672-73.
[167] *Id*. at 673.

reliable COVID-19 test results than nasopharyngeal specimens.[168] Absent allegations of more, Relators' conspiracy claim is subject to dismissal.

D. Amended Complaint Fails to State a Claim for Worthless Services

In Counts IV and V of the Amended Complaint, Relators contend Defendants' failure to follow accepted testing protocols for COVID-19, along with allegedly poor conditions in hospital, resulted in patients receiving unnecessary or improper treatment and rendered all services performed by Defendants worthless. Relators allege Defendants' presentation of claims to the Government for payment of these worthless or inadequate services violated 31 U.S.C. §§ 3729(a)(1)(A) and (B).

A worthless services claim is not predicated on a false certification theory but instead "asserts that the knowing request of federal reimbursement for a procedure with no medical value violated the [FCA] irrespective of any certification."[169] Recognized by some district courts as a distinct claim under the FCA, a worthless services claim "is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided."[170] In other words, "the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."[171] To prevail on a worthless services claim, a relator must show that a procedure

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[168] Am. Compl., ¶¶ 78, 92-93 [Doc. 25].
[169] *United States et rel. Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001), *abrogated on other grounds by Escobar*, 579 U.S. 176 (2016).
[170] *Id*. at 703.
[171] *Id*.

had no medical value; negligence is insufficient.[172]

There are a number of issues with Relators' worthless services claims. First, Relators have not alleged Defendants knew that testing tracheal aspirate specimens instead of nasopharyngeal specimens for COVID-19 had no medical value. To the contrary. Relators point to statements from Defendants' employees affirmatively expressing their belief that, while they understood the FDA had not yet granted approval for tracheal COVID-19 tests, tracheal aspirate specimens produced more accurate results.[173] For example, Relators purport to have a recording of Dr. Jakemia Coleman, an Athens Pulmonary physician, saying, "we have more accuracy with a tracheal aspirate than we do with a nasopharyngeal swab."[174] Relators claim to have another recording in which Kimberly Wilson, Landmark's Director of Quality Management, Respiratory Director, and Lab Director, explained that Dr. Mark Visitacion, Landmark's Director of Infectious Disease and Treatment, and Dr. Hugh Jenkins, an Athens Pulmonary physician, stated that in their medical opinions, once the COVID-19 virus entered the lungs, "that's where you get your true test result."[175]

Relators also offer only conclusory allegations that Defendants' purportedly ineffective COVID-19 testing unnecessarily subjected patients to an increased risk of

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[172] *Id*.

[173] Am. Compl., ¶¶ 92-93 [Doc. 25]

[174] *Id*. ¶ 78.

[175] *Id*. at ¶92.

contracting COVID-19 and resulted in patients receiving inappropriate or inadequate medical care. The Amended Complaint offers no context for that assertion. Relators, for example, do not allege the initial condition or treatment plan for any patient hospitalized by Landmark or treated by Athens Pulmonary; how the condition or treatment of the patient changed after the allegedly specious COVID-19 testing; how the patient's medical condition and treatment plan changed following a COVID-19 diagnosis; and how those changes amounted either to unnecessary medical treatment or failure to receive necessary medical treatment.

Relators attempt to categorize the totality of medical care provided by Defendants as "bundled services." The concept of "bundled services" arises largely in the context of nursing home care, where providers bill the Government for overall care of residents on a per diem basis.[176] Often, nursing home care reaches a "very blurry point" where a provider's care falls below the minimal standard of care required to ensure a patient's quality of life. Under those circumstances, when the provider presents claims for reimbursement to the Government, "the provider has simply committed fraud." Relators' classification of the care rendered by Defendants fails for one simple reason: Relators never allege Defendants billed the Government for per diem services.

Relators have failed to allege facts sufficient to show that the COVID-19 testing

[176] *See United States v. Houser*, No. 4:10-CR-012-HLM, 2011 WL 2118847, at *6-7 (N.D. Ga. May 23, 2011) (quoting *United States v. NHC Health Care Corp.*, 163 F. Supp. 2d 1051, 1055-56 (W.D. Mo. 2001)).

scheme, or any other conditions at the hospital, resulted in the performance of services so deficient as to be equivalent to no performance at all. Relators moreover have not adequately alleged that Defendants knowingly sought payment from the Government for services with no medical value. Having failed to state a viable claim for worthless services, the Court dismisses Counts IV and V of Relators' Amended Complaint.

CONCLUSION

For the foregoing reasons, Defendant Landmark Hospital's Motion to Dismiss [Doc. 33] and Defendant Athens Pulmonary's Motion to Dismiss [Doc. 34] are **GRANTED**.

SO ORDERED, this 26th day of April, 2023.

S/ C. Ashley Royal
C. ASHLEY ROYAL, SENIOR JUDGE
UNITED STATES DISTRICT COURT