IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA	)	
	)	
Plaintiff,	)	Civil Action No. _____
	)	
v.	)	**COMPLAINT**
	)	
ALPHA CARE MEDICAL, LLC, NIHAR GALA, and BO WANG.	)	
	)	
Defendants.	)	

COMPLAINT OF THE UNITED STATES OF AMERICA

The United States of America, by and through Benjamin L. Wallace, United States Attorney for the District of Delaware, and Elizabeth F. Vieyra, Assistant United States Attorney for the District of Delaware, alleges as follows:

I. INTRODUCTION

1. The United States of America brings this action pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, and under common law and equitable theories of payment by mistake and unjust enrichment, against defendants Alpha Care Medical, LLC ("ACM"), Nihar Gala ("Gala"), and Bo Wang ("Wang") (collectively, "Defendants"), to recover treble damages and penalties resulting from Defendants' unlawful conduct, including the submission of false claims to Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program ("FEHBP") (collectively "Federal Healthcare Programs") for services that were not rendered, were not reasonable and necessary, and/or were not eligible for payment.

2. Beginning no later than July 2021 and continuing to the present, ACM, through its principal Gala and its laboratory director Wang, operated a sham in-house medical laboratory. Rather than providing testing services for the purpose of diagnosing and treating patients, Defendants operated their laboratory for the purpose of enriching themselves. Defendants

routinely billed Federal Healthcare Programs for medical tests that were unnecessary, had no value in the diagnosis or treatment of patients, and frequently were not performed at all. Through these and other practices, from at least July 2021—and, upon information and belief, continuing through the present day—Defendants knowingly submitted, caused to be submitted, and made false records and statements material to, thousands of false claims to Federal Healthcare Programs and knowingly concealed and avoided obligations to repay the United States for such false claims.

3. Defendants acted knowingly. Indeed, in written complaints he lodged with state regulators, Gala acknowledged that ACM conducted testing that was not medically necessary and that ACM billed insurers including the Federal Healthcare Programs for testing ACM never conducted.

4. Defendants' false statements were material to the payment decisions of the Federal Healthcare Programs. Had the Federal Healthcare Programs known the truth about ACM's laboratory claims, thousands of the claims would have been denied or paid at a lower rate.

5. The Federal Healthcare Programs paid ACM for these materially false claims, sustained damages because of Defendants' wrongful conduct, and accordingly demand all available relief.

II. JURISDICTION

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

7. This Court may exercise personal jurisdiction over ACM under 31 U.S.C. § 3732(a) because ACM maintains its principal place of business in the District of Delaware and transacts business in this District.

8. This Court may exercise personal jurisdiction over Gala under 31 U.S.C. § 3732(a) because he can be found, resides, and transacts business in this District.

9. This Court may exercise personal jurisdiction over Wang under 31 U.S.C. § 3732(a) because he can be found and transacts business in this District.

10. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a), because Defendants transact business in this District, and a substantial part of the events giving rise to this action occurred in this District.

III. PARTIES

11. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), which, through the Centers for Medicare and Medicaid Services ("CMS"), administers Medicare and Medicaid; the Department of Defense and its component agency the Defense Health Agency ("DHA"), which administers and supervises TRICARE Health Plans; and on behalf of the Office of Personnel Management ("OPM"), which funds and oversees the FEHBP.

12. At all times relevant to the Complaint, ACM has been a limited liability company authorized and existing under the laws of the State of Delaware, with its principal place of business at 1340 Middleford Road, Seaford, Delaware, 19973, and satellite offices in Dover, Harrington, and Millsboro, Delaware. ACM operates a medical laboratory located at 29787 John J. Williams Highway, Millsboro, Delaware.

13. Defendant Nihar Gala is a resident of Lewes, Delaware. Gala previously held a license to practice medicine in the State of Delaware. By order dated June 4, 2019, the Delaware Board of Medical Licensure and Discipline permanently revoked Gala's medical license. *See Gala v. Bullock*, 250 A.3d 52, 62 (Del. 2021). At all times relevant to the Complaint, Gala, who served as ACM's sole member and president, directed ACM's conduct including hiring and firing of employees, establishment of policies, billing, and submission of claims to insurers.

14. Defendant Bo Wang is a resident of Glen Mills, Pennsylvania and holds a Doctor of Philosophy in Electrical Engineering. At all times relevant to the Complaint, Wang served as ACM's laboratory director.

IV. LEGAL AND REGULATORY FRAMEWORK

A. The False Claims Act

15. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
> (a)(1)(G) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government

is liable to the United States for three times the amount of damages which the Government sustains, plus a mandatory civil penalty of not less than $14,308 and not more than $28,619 per violation. 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5.

16. For purposes of the FCA,

> the terms "knowing" and "knowingly" (A) 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; and (B) require no proof of specific intent to defraud. . . .

31 U.S.C. § 3729(b)(1).

17. The term "claim" includes any

> request or demand . . . for money or property . . . that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program . . . and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(b)(2).

18. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

19. "A claim can be proven 'false' in two ways: factually, when the facts contained within the claim are untrue, and legally, when the claimant falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *United States v. Care Alternatives*, 952 F.3d 89, 96 (3d Cir. 2020) (alterations and quotation marks omitted).

B. The Medicare Program

20. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395 *et seq*.

21. Medicare entitlement is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A. Medicare-insured individuals are commonly referred to as Medicare "beneficiaries."

22. The Medicare program consists of four parts: A, B, C, and D. 42 U.S.C. §§ 1395c–1395i. Medicare Part B covers outpatient care, including, *inter alia*, physician services and ancillary services, such as clinical laboratory services, furnished by physicians and other providers and suppliers.[1] 42 U.S.C. § 1395k.

23. As alleged herein, ACM submitted false claims under Medicare Part B.

24. Medicare Part B covers only those services, including diagnostic laboratory services, which are reasonable and necessary for the diagnosis or treatment of an illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary

[1] In the relevant regulations, physicians and other practitioners are generally referred to as "suppliers" in the Medicare program, rather than "providers." *See* 42 C.F.R. § 400.202. This Complaint nonetheless uses the common term "provider" to refer to individual practitioners.

for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k) (disallowing payment for certain types of services, tests, and examinations that are not "reasonable and necessary"). In order to receive payment, Medicare Part B providers must certify that services for which they bill Medicare are medically necessary. 42 C.F.R. § 424.24(g)(1).

25. The Secretary of HHS ("Secretary") is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a). The Secretary fulfills this responsibility both through formal rulemaking and through other forms of guidance.

26. HHS provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public, including on the Internet. *See generally*, CMS Manuals, *available at* https://www.cms.gov/medicare/regulations-guidance/manuals (last visited June 15, 2026).

27. CMS engages private contractors, referred to as Medicare Administrative Contractors ("MACs"), to review and pay claims submitted by health care providers. 42 U.S.C. §§ 1395u, 1395kk-1. MACs generally act on behalf of CMS within a specified jurisdiction to process and pay Medicare claims submitted by health care providers.

28. At all times relevant to this Complaint, Novitas Solutions, Inc. ("Novitas Solutions") was the MAC responsible for processing Medicare Part B claims in Delaware.

29. MACs also issue Local Coverage Determinations ("LCDs") that identify, for the states within their jurisdiction, procedures and services that are reasonable and necessary, and therefore eligible for payment under Medicare. 42 U.S.C. § 1395ff(f)(2); *see also id.* § 1395m-1(g).

30. Health care providers who wish to submit claims for Medicare reimbursement must enroll in the Medicare program. As part of the enrollment process, and as a condition of

participation in Medicare, providers must certify compliance with Medicare regulations, and program instructions and conditions. *See* 42 C.F.R. § 424.510. Enrolled providers also must certify that they meet, and will continue to meet, the requirements of the Social Security Act as well as Medicare regulations, and the conditions regarding coverage for services for which they seek reimbursement. 42 C.F.R. § 424.516(a)(1).

31. Medicare regulations require diagnostic laboratory testing "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a).

32. Participating providers must properly document in the patient's medical record the service or procedure performed. 42 C.F.R. § 410.32(d)(2)(i).

33. To participate in the Medicare program, group practices and clinical laboratories must submit a Medicare Enrollment Application, Form CMS-855I, which requires, among other things, that signatories certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . . The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . . I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms855i.pdf (last visited June 15, 2026).

34. An authorized official must sign the "Certification Statement" in Section 15 of Form CMS-855I, which includes a statement "I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to [my] organization." *Id.*

35. Once enrolled or credentialed, the provider may submit claims to Medicare for services rendered to beneficiaries.

36. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

37. Typically, physicians are compensated for the services they provide Medicare beneficiaries on a fee-for-service basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, physicians must deliver a compensable service and certify that the service was medically necessary.

38. The Medicare statute requires that each claim submitted for an item or service payable under Medicare Part B include the name and NPI for the referring physician. 42 U.S.C. § 1395l(q)(1).

39. To obtain Medicare reimbursement for certain outpatient items or services, providers must submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent, known as the 837P format. 42 C.F.R. § 424.32.

40. Among the information the provider must include on a CMS 1500 or through the 837P format are certain codes, including Current Procedural Terminology Codes ("CPT codes"), that identify the services rendered and for which reimbursement is sought. Each code corresponds to a specific service.

41. When submitting claims to Medicare on the CMS 1500, providers must certify, *inter alia*, that (a) "the services on this form were medically necessary and personally furnished

by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE;" (b) the information on the claim form is "true, accurate, and complete;" and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." CMS 1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties." *See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf (last visited June 15, 2026).

42. Health care providers who submit claims electronically using the 837P format must also execute an Electronic Data Interchange Enrollment Form ("EDI Enrollment Form") with CMS. At all times relevant to the Complaint, an EDI Enrollment Form to electronically bill Medicare executed by ACM was on file with Novitas Solutions. By executing the EDI Enrollment Form, ACM certified that it would "be responsible for all Medicare claims submitted to CMS or a designated CMS contractor by itself, its employees, or its agents," and to "submit claims that are accurate, complete, and truthful."

43. By executing an EDI Enrollment Form, ACM also acknowledged "that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim as required by this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *Id.*

44. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage and reimbursement for the Medicare services it provides. *See Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

45. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

46. ACM billed Medicare under Part B for medical services including, but not limited to, clinical laboratory services, by submitting claims for reimbursement on the CMS 1500 or the 837P format to Novitas Solutions. ACM received payment from Medicare as a direct result of these submissions.

C. The Delaware Medicaid Program

47. Delaware's Medicaid program, known as the Delaware Medical Assistance Program ("DMAP"), is authorized by Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq*. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. Each state must have a single state agency to administer the Medicaid program. 42 U.S.C. § 1396a.

48. Delaware's Department of Health and Social Services, Division of Medicaid and Medical Assistance ("DMMA") administers the DMAP and receives, processes, and pays claims for services under the Medicaid program. HHS reimburses DMMA for the federal share of all qualified Medicaid claims and ensures that the state complies with minimum standards in the administration of the program.

49. Health care providers bill DMAP for services provided to Medicaid beneficiaries by submitting claim forms electronically to DMMA through its fiscal agent, Hewlett Packard Enterprise.

50. To participate in the Delaware Medicaid program and receive payment for services rendered, health care providers must enter into a contract with the DMAP, called the Contract for Items or Services Delivered to Delaware Medical Assistance Program Eligibles in the Department of Health and Social Services ("DMAP Contract").

51. The DMAP Contract provides that when a healthcare service provider submits a claim for payment for items or services rendered under the DMAP, the provider certifies that the items or services comply with DMAP rules, regulations, policies, and procedures. These include requirements that the services rendered were medically necessary and that all information and documentation submitted by the provider in support of a claim for payment is true, accurate, and complete. Providers also certify that non-compliance with DMAP rules, regulations, and policies may result in the denial of payment and the imposition of penalties.

52. DMMA issues Medicaid policies, manuals, and other materials to provide guidance to providers regarding which services are reimbursable by Medicaid and how to bill those services. *See* 42 C.F.R. § 431.18.

53. DMAP's General Policy Manual instructs that providers must direct patients "to the most appropriate, medically necessary, and cost-efficient care possible," and maintain documentation supporting the services rendered. Providers are also "responsible for the accuracy, truthfulness, and completeness of all claims submitted to DMAP." Providers engage in "fraud" and "abuse" in connection with the DMAP if they "attempt to obtain or provide services that are not medically necessary." *See Delaware Health and Social Services Division of Medicaid & Medical Assistance, Delaware Medical Assistance Program General Policy Manual* §§ 1.6, 1.10, 1.14, 1.20, *available at* https://medicaidpublications.dhss.delaware.gov/docs/DesktopModules/Bring2mind/DMX/API/Entries/Download?Command=Core_Download&EntryId=897&language=en-US&PortalId=0&TabId=94 (last visited on June 15, 2026).

54. ACM billed DMAP for medical services including, but not limited to, clinical laboratory services by submitting claims for reimbursement to DMAP through its fiscal agent. ACM received payment from DMAP as a direct result of these submissions.

D. TRICARE

55. TRICARE is a government-funded healthcare program for uniformed services members, retirees, and their families. DHA manages TRICARE by region. Defendants' conduct and submission of false claims occurred within TRICARE's East Region wherein Humana Military is the assigned regional contractor assisting DHA.

56. DHA provides Humana Military with guidance for administering TRICARE through the Code of Federal Regulations and TRICARE manuals.

57. TRICARE presumes "the provider of the services is responsible for the actions of all individuals who file a claim on behalf of the provider." 32 C.F.R. § 199.2.

58. To be eligible for reimbursement by TRICARE, medical services must be medically necessary and required in the diagnosis and treatment of illness or injury. *See, e.g.*, 32 C.F.R. §§ 199.2, 199.4(a)(1)(i), 199.9(b)(3). Medical testing 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.

59. TRICARE defines "abuse" as practices that are "inconsistent with accepted sound fiscal, business, or professional practice which result in a [TRICARE] claim, unnecessary cost, or [TRICARE] payment for services or supplies that are…[n]ot within the concepts of medically necessary and appropriate care." 32 C.F.R. § 199.2. Abuse is "a sufficient basis for denying all or any part" of a TRICARE health claim. One specific example of "abuse" is "[a] pattern of claims for services which are not medically necessary or, if medically necessary, not to the extent

rendered. For example, a battery of diagnostic tests are given when, based on the diagnosis, fewer tests were needed." 32 C.F.R. § 199.9(b)(3).

60. TRICARE also considers "flagrant and persistent overutilization of services without proper regard for results, the patient's ailments, condition, medical needs, or the physician's orders" to be fraud. 32 C.F.R. § 199.9(c)(5).

61. When submitting an electronic claim form to TRICARE, the provider makes the same certifications as on the CMS 1500 claim form.

62. During the time period relevant to this Complaint, ACM submitted claims for diagnostic laboratory services for payment to TRICARE. ACM received payment from TRICARE as a direct result of these submissions.

E. FEHBP

63. Congress established the FEHBP to provide health benefits to civilian federal employees. *See generally* 5 U.S.C. §§ 8901 *et seq.* The FEHBP is administered by OPM, which, in turn, contracts with various health insurance carriers to provide services to FEHBP members and their families. *See id.* §§ 8902, 8909(a). The OPM makes payments to the insurance carriers for services rendered to FEHPB members using funds from the Employee Benefits Fund, which the United States Treasury holds and invests. *Id.* § 8909.

64. As a condition of funding, the FEHBP requires that covered services be medically necessary to prevent, diagnose, or treat an illness, disease, injury or condition.

65. ACM submitted claims to health insurance carriers in the FEHBP program for reimbursement for services rendered to federal government employees and their families. ACM received payment from FEHBP insurers as a direct result of these submissions.

F. Urine Drug Testing Legal and Regulatory Requirements

1. CLIA Compliance Requirement

66. A laboratory that performs testing on human specimen, including diagnostic laboratory testing, must comply with the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, as set forth at 42 C.F.R. Part 493.

67. "No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure." 42 U.S.C. § 263a.

68. Consistent with the basic public health standards CLIA establishes, the Federal Healthcare Programs require CLIA compliance and registration for payment of diagnostic laboratory testing.

69. A "basic condition" for Medicare Part B coverage is that the service be furnished by an appropriate facility or entity. 42 C.F.R. § 410.12. Diagnostic laboratory tests may be performed by "[a] laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter [CLIA]." 42 C.F.R. § 410.32(d)(1)(v).

70. In short, "CLIA mandates that virtually all laboratories, including physician office laboratories (POLs), meet applicable Federal requirements and have a CLIA certificate in order to receive reimbursement from Federal programs." Medicare Claims Processing Manual, Ch. 16, § 70.1.

71. CMS may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program. 42 C.F.R. § 493.551(a).

72. Where a laboratory elects to seek accreditation through an approved accreditation organization, the laboratory must also meet certain proficiency testing requirements. 42 C.F.R. §§ 493.551(b)(3), 493.801.

73. At all times relevant to the Complaint, ACM operated its in-house medical laboratory under CLIA certification number 08D2120854. However, as further described below, ACM routinely violated the terms of the accreditation that enabled it to receive CLIA certification.

74. In addition, and as further described below, ACM failed to meet the proficiency testing requirements for CLIA accreditation. 42 C.F.R. § 493.551(b)(3).

2. Requirement that Services Be Reasonable and Necessary

75. Medicare regulations require that (1) laboratory tests must be ordered by the physician treating the patient for a specific illness or injury; (2) laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services; and (3) claims for such laboratory services that do not meet these requirements are ineligible for payment and must be denied. *See* 42 C.F.R. § 410.32.

76. According to CMS's Medicare Benefit Policy, when ordering diagnostic testing, "the physician must clearly document, in the medical record his or her intent that the test be performed." Medicare Benefit Policy, Ch. 15, § 80.6.1 (issued Aug. 29, 2008).

77. Medicare requires proper and complete documentation of the services rendered to beneficiaries:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e). The Delaware Medicaid program, DMAP, imposes similar requirements.

78. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is insufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3)(ii).

79. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") also published *Compliance Program Guidance for Clinical Laboratories* in the Federal Register. 63 Fed. Reg. 45076 (Aug. 24, 1998), *available at* https://www.oig.hhs.gov/authorities/docs/cpglab.pdf (last visited June 15, 2026). Among other things, the HHS-OIG clinical laboratory guidance directs that providers must conduct and document a patient-specific assessment of necessity for each test ordered: "Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient. . . . Medicare may deny payment for a test . . . which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record . . . does not support that the tests were reasonable or necessary for a given patient." *Id.* at 45079.

80. The Medicare Claims Processing Manual similarly instructs that "[laboratory t]ests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described." *See* Medicare Claims Processing Manual, Ch. 16, § 120.1.

3. Purpose and Use of Urine Drug Tests

81. Medical providers use urine drug testing ("UDT") to determine the presence or absence of drugs or metabolites, *i.e.*, a byproduct of a drug after it is metabolized by the body.

82. In the clinical pain management context—particularly in the case of management through long-term opioid use—medical providers often used UDT to monitor whether patients are taking prescribed drugs and adhering to treatment. Testing may confirm that patients are taking, rather than diverting, the drugs that are prescribed to them, and that patients are not taking other drugs not prescribed by the treating physician.

83. UDT can be divided into two categories: presumptive and definitive. Presumptive UDT (sometimes referred to as "screening" testing) is used to determine the presence or absence of drugs or drug classes in a urine sample. Definitive UDT (sometimes referred to as "confirmatory" testing) is used when necessary to confirm the results of presumptive testing by identifying the presence of specific drugs or metabolites in the urine sample.

84. Presumptive tests can be performed using a point of care ("POC") testing cup or test strips that are dipped into a urine sample. POC testing cups and test strips are relatively inexpensive and typically feature a panel of treated strips, one for each drug or drug class being tested. When the strips are dipped into the urine specimen, a change in color signifies the presence or absence of the specific drug or drug class for which each strip tests. Using POC cups or strips, a provider can receive almost immediate results for the substances tested.

85. Presumptive UDT can be useful in immediate decision making because the results are typically available during the patient visit. It can also be used to determine the necessity of further confirmatory testing through definitive UDT, for instance, to rule out a false positive or to determine the concentration of a particular drug.

86. Definitive or confirmatory UDT is generally conducted in laboratories that can perform mass spectrometry and either gas or liquid chromatography. These testing methodologies can provide quantitative results, identifying the concentration of a drug or metabolite in a sample.

87. Definitive testing is not indicated absent a clinical determination, documented in the patient record, that such testing is reasonable and necessary based on patient-specific indications.

88. "Chromatography generally is reserved for confirmatory or definitive testing when the initial [presumptive] results are unexpected." Raouf et al., *A Practical Guide to Urine Drug*

Monitoring. FEDERAL PRACTITIONER, April 2018, at 41, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6368048 (last visited June 15, 2026).

89. As discussed below, around 2017, ACM acquired a mass spectrometry and liquid chromatography ("LCMS") machine and began performing in-house definitive UDT.

90. Definitive UDT is covered by Federal Healthcare Programs only to the extent it is necessary for an individual patient, based on factors specific to that individual that are considered by the treating provider and documented in the patient's medical records. In other words, to be reasonable and necessary, definitive UDT must be based on an assessment of individual patient risk and cannot be ordered as a matter of course.

91. UDT guidelines published by the American Society of Interventional Pain Physicians ("ASIPP") recommend only a baseline screening or presumptive test at the initial visit and then adherence monitoring with "confirmation for accuracy with chromatography *in select cases.*" Manchikanti *et al.,* PAIN PHYSICIAN 2012; 15:S67-S116, ISSN 1533-3159, "ASIPP Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain."

92. ASIPP published in 2011, and reprinted in 2012, a diagram charting "algorithmic steps in urine drug testing in chronic pain." *Id.* at S92. The diagram recommends baseline POC testing, using an immunoassay test. If there is an inappropriate or unexplained result, definitive testing is warranted for that result. If results are appropriate, no definitive testing is needed, and the algorithm suggests a random POC (*i.e.*, immunoassay screening or presumptive) test in 1–3 months. And if the results of that test are appropriate, the algorithm suggests follow-up presumptive or screening test in 6–12 months. In short, definitive testing is recommended only for unexplained results. *See generally id.*

4. LCD L35006

93. In October 2015, Novitas Solutions issued Local Coverage Determination L35006, titled "Controlled Substance Monitoring and Drugs of Abuse Testing," ("LCD L35006") and provided the document to all providers within its jurisdiction, which included Delaware.

94. LCD L35006 provides guidance regarding the appropriate indications for and expected frequency of presumptive and definitive UDT to be covered by Medicare.

95. With regard to definitive UDT, LCD L35006 states: "[P]hysician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record."

96. LCD L35006 is clear that "Blanket Orders"—defined as "an identical order for all patients in a clinician's practice without individualized decision-making at every visit"—are "non-covered services" for which Medicare may not be billed. The LCD also specified that "[r]outine standing orders for all patients in a physician's practice are not reasonable and necessary."

5. Reimbursements for Laboratory Tests

97. Medicare reimbursement rates for UDT vary depending on the type of UDT and the number of drug classes tested.

98. At all times relevant to the Complaint, Medicare generally reimbursed presumptive UDT based on the methodology used by the physician practice or the complexity of the test under CLIA. During the time period relevant to the Complaint, Medicare reimbursed POC tests at between $12 and $25.

99. Effective January 1, 2016, CMS created four CPT codes for definitive UDT, G0480, G0481, G0482, and G0483, based on the number of drug classes tested. Only one of these four definitive UDT codes may be billed per patient per day. The following table defines these codes and their corresponding 2023 Medicare reimbursement amount:

Definitive UDT Code	Definition	2023 Medicare Reimbursement
G0480	Definitive drug testing for 1-7 drug classes, including metabolites.	$114.43
G0481	Definitive drug testing for 8-14 drug classes, including metabolites.	$156.59
G0482	Definitive drug testing for 15-21 drug classes, including metabolites.	$198.74
G0483	Definitive drug testing for 22 or more drug classes, including metabolites.	$246.92

100. ACM almost always billed UDT under the most expensive code G0483. Indeed, from July 2021 through March 2026, ACM only used code G0483 to bill Medicare Part B, Medicaid, and TRICARE for UDT.

V. DEFENDANTS' FRAUDULENT CONDUCT

101. As detailed below, under the direction and control of Gala, ACM submitted claims for reimbursement to the Federal Healthcare Programs that it falsely certified were reasonable and necessary. The certifications of medical necessity were false because: (i) ACM operated its laboratory in violation of the requirements of its accreditation by routinely testing stale specimen and by failing to conduct required proficiency testing; (ii) ACM did not use UDT results for diagnosis or treatment; (iii) ACM routinely billed for tests with missing and incorrect information; and (iv) ACM ordered UDT on a blanket basis without a medical provider's individualized risk

assessment of the patient. ACM and Gala knew, recklessly disregarded, or were willfully ignorant that their submissions were false.

102. In other cases, and as detailed below, under the direction and control of Gala, ACM submitted claims for reimbursement to the Federal Healthcare Programs that were factually false because ACM had not conducted the services billed. ACM routinely billed the Federal Healthcare Programs for UDT it did not conduct. ACM and Gala knew, recklessly disregarded, or were willfully ignorant that their submissions for such claims were false.

103. Through March 31, 2026, ACM billed the Federal Healthcare Programs for false UDT claims in at least the amounts of $1,795,125 to Medicare Part B, $789,750 to Delaware Medicaid, $127,125 to TRICARE, and $87,150 to FEHB.

104. Through March 31, 2026, ACM received payment from the Federal Healthcare Programs for false UDT claims in at least the amounts of $886,602 from Medicare Part B, $142,695 from Delaware Medicaid, $32,274 from TRICARE, and $23,786 from FEHB.

A. ACM and Wang Established an In-House Laboratory

105. In 2017, ACM established an in-house medical laboratory in coordination with Wang, who ACM engaged as its laboratory director.

106. From the beginning, Wang and Gala were aware of, and discussed, the potential financial benefits of UDT and the risks of liability to federal payors for false claims. Close in time to establishing the laboratory, Wang shared with Gala a Wall Street Journal article entitled *Doctors Cash in on Drug Tests for Seniors, and Medicare Pays the Bill*, and advised, "It's critical to document medical necessity for all prescriptions, treatments, and tests."

107. As provided in ACM's Medical Laboratory Director Services Agreement, Wang was formally responsible to ensure that testing systems at ACM's laboratory "provide quality

services in all aspects of test performance." Beyond this, Wang was instrumental in establishing the laboratory from a practical and business standpoint.

108. Wang provided—on credit—equipment, supplies, and maintenance services to establish the laboratory.

109. In an agreement dated December 23, 2018, Wang agreed that a limited liability company he controlled would provide a loan to ACM "to assist the purchase of LCMS equipment from Thermo Fisher Scientific."

110. Wang coordinated with third-party vendors to establish the information technology infrastructure for the laboratory.

111. ACM compensated Wang for his services as laboratory director. Initially, ACM compensated Wang based on an hourly rate. In 2018, ACM began compensating Wang "per processed patient urine sample."

112. On information and belief, ACM compensated Wang only for urine tests for which ACM received reimbursement from insurance programs, including Federal Healthcare Programs. Thus, Wang's compensation directly related to and derived from the Federal Healthcare Programs payments for UDT.

B. ACM Obtained CLIA Accreditation through False Statements to COLA

1. COLA's Initial Inspection

113. Also in 2017, ACM engaged the Commission on Laboratory Accreditation ("COLA") as its accreditor.

114. COLA is a CMS-approved laboratory accreditation organization. At all relevant times, CMS approved COLA as an organization capable of accrediting laboratories for purposes of establishing their compliance with CLIA requirements, including for the specialty of Chemistry – Toxicology.

115. On November 17, 2017, COLA first inspected ACM's laboratory and found numerous "serious or systemic issues." Based on the inspection, COLA issued 25 citations to ACM, including for failure to conduct proficiency testing, failure to monitor refrigerator and freezer temperatures, and failure to establish reasonable turnaround times for testing. COLA advised ACM that ACM would be required to agree to COLA's Plan of Required Improvement ("PRI") addressing the violations to receive an accreditation.

116. With respect to turnaround time of testing, COLA advised ACM that turnaround times of over a month were unacceptable and issued a citation for a sample collected on October 3, 2017 and run on November 10, 2017. While COLA declined at that time to impose a specific maximum turnaround time, COLA advised ACM that it must "[e]stablish guidelines for what your laboratory and the clinicians you serve consider reasonable turnaround times for reporting test results."

117. On December 6, 2017, ACM agreed to COLA's PRI.

118. COLA agreed to accredit ACM. With COLA's accreditation, ACM obtained a CLIA Certificate of Accreditation No. 08D2120854 for Chemistry Toxicology effective November 22, 2017.

119. As part of enrollment in COLA's laboratory accreditation program, both Gala and Wang agreed to "comply with the requirements for accreditation established by COLA."

120. As the laboratory director, Wang generally served as the primary point of contact for ACM with COLA. Wang received notices from COLA advising of upcoming inspections, received results of inspections, updated laboratory information forms, signed PRIs, and communicated with COLA on behalf of ACM.

2. COLA's Follow-Up Inspections

121. COLA's subsequent inspections of ACM's laboratory continued to identify problems with quality control and turnaround time.

122. During a November 5, 2019 inspection, COLA issued ACM a citation for unreasonable turnaround time based on testing a sample from October 10, 2019 on the day of the inspection (a 26-day turnaround), among other violations. Based on the violations, COLA placed ACM on probation for 150 days and required ACM to document its fulfillment of the PRI to maintain accreditation.

123. Prompt turnaround times for UDT are important to keep results accurate and reliable. Drug levels present in urine can change after collection because of temperature shifts, light exposure, bacteria, and the chemical nature of the drug, among other factors. Delays increase the likelihood that a substance present in the urine may break down and thus drop below testing thresholds, causing false negatives.

124. Clinically, a delayed test result is also less useful. A patient's condition, medications, or circumstances may have changed, making the delayed result a poor guide for current decision-making. As a practical matter, for the result to have any utility, it must be available to the medical provider when the provider reviews the chart at the patient's next appointment.

125. On November 11, 2019, Wang agreed to implement COLA's PRI to address the citations.

126. On December 2, 2019, Wang provided a written letter to COLA advising of the actions he would take to address citations.

127. Additionally, COLA repeatedly advised ACM to enroll in a proficiency testing program as ACM was required to do under 42 C.F.R. § 493.551(b)(3). ACM, Gala, and Wang

represented that ACM had enrolled in proficiency testing with American Proficiency Institute ("API"). While ACM briefly enrolled in proficiency testing with API, ACM never returned any proficiency testing samples and canceled its enrollment in October 2019.

128. On June 29, 2021, COLA conducted another inspection of ACM's laboratory and again cited ACM for unreasonable turnaround time. The inspector noted that "There are currently two large bags of samples all having collection dates from the beginning of June waiting to be tested." Wang told the inspector that the lab had experienced a leak, which caused a slowdown in testing, and that the samples would not be tested. The inspector advised Wang a month-long turnaround time was not reasonable and recommended that samples be sent to a reference lab for testing in the event of problems at ACM's lab.

3. COLA Imposes a 14-Day Turnaround Time Requirement

129. After repeated failures to establish reasonable turnaround times in coordination with clinicians, COLA required ACM to agree to test specimens within 14 days or send those specimens to a reference laboratory.

130. In a letter dated July 13, 2021, COLA noted the slow turnaround time and required ACM to agree to test samples within 14 days:

> Laboratory's testing results must be reported within a reasonable turnaround time. It was noted at time of resurvey that specimens collected on June 2, 2021 was in the refrigerator and still needed to be performed, Resurvey was performed on June 29, 2021 and Laboratory Director, Bo Wang, PhD stated specimens would not be performed; refrigerator stability was 14 days. **Please submit to COLA the signed STAT Agreement enclosed, as Laboratory Director attesting to adhere to specimen stability studies and not hold specimens outside the acceptable range of 14 days in the refrigerator and any specimens unable to be performed within 14 days will be sent to a Reference Laboratory for testing**.

131. COLA further advised ACM that it must submit required documentation addressing the citations by July 27, 2021 or "be at risk of Pending Denial of Accreditation."

132. On July 16, 2021, Wang agreed to COLA's turnaround time requirement. Specifically, Wang signed COLA's Agreement to the Staff Technical Accreditation Team (STAT) Requirements, in which he agreed: "As Laboratory Director of Alpha Care Medical, COLA ID 27625, I agree to implement the Staff Technical Accreditation Team (STAT) Requirement prescribed by COLA and dated July 13, 2021 within the time limits set forth in the STAT Letter."

133. On July 27, 2021, COLA received Wang's signed agreement along with supporting documents "indicating that specimens were tested within the 14 day stability time frame." Based on Wang's agreement to comply, COLA cleared ACM's citations, allowing ACM to maintain its accreditation and consequently, its CLIA registration. ACM's CLIA registration allowed it to continue to submit claims for UDT, including the false claims ACM submitted to the Federal Healthcare Programs detailed herein.

C. ACM Operated its Laboratory Outside the Scope of Accreditation

134. After agreeing on July 16, 2021 to test specimens within 14 days, ACM continued to operate its laboratory with unreasonable turnaround times. Accordingly, Wang's statement in his July 16, 2021 agreement with COLA was false.

135. ACM's laboratory did not process any tests for the remainder of July 2021. On August 4, 2021, the laboratory reopened and processed dozens of specimens it had held for more than 14 days. Among the tests processed on August 4, 2021, were the following tests of Medicare beneficiaries:

a. Four tests of patient K.C. (born in 1975) that ACM collected on June 30, 2021, July 6, 2021, July 13, 2021, and July 20, 2021;

b. Test of patient T.G. (born in 1957) that ACM collected on July 1, 2021; and

c. Test of patient D.H. (born in 1960) that ACM collected on July 1, 2021.

136. ACM, under the direction and control of Gala, submitted claims to Medicare for each of the six tests specifically referenced in the foregoing paragraph. ACM was not entitled to payment for these tests because it processed each test after more than 14 days, in violation of the terms of its accreditation, and because the tests were not medically necessary.

1. ACM Routinely Tested Specimen After More than 14 Days

137. From July 2021, until the present, ACM routinely tested specimens more than 14 days after collection.

138. Among a sample of approximately 2,900 tests for which ACM submitted claims to Medicare Part B for UDT and Medicare paid, ACM processed more than one-third of the tests after more than 14 days.

139. ACM often processed tests after much longer delays. For example, ACM processed the following tests of Medicare beneficiaries after holding the specimen for more than 50 days:

a. Test of patient E.D. (born 1944) that ACM collected on June 6, 2024 and tested on September 11, 2024 (97 days);

b. Two tests of patient V.B. (born 1951) that ACM collected on August 6, 2024 and August 27, 2024 and tested together on November 1, 2024 (87 days and 66 days); and

c. Two tests of patient L.B. (born 1957) that ACM collected on June 17, 2024 and July 17, 2024 and tested together on September 11, 2024 (86 days and 56 days).

140. ACM submitted claims to Medicare for each of the five tests specifically referenced in the foregoing paragraph. ACM submitted the claims and received payment from Medicare before it had processed any of the tests associated with the claims. ACM was not entitled to payment for these tests because ACM processed each test after more than 14 days, in violation of the terms of its accreditation, and because the tests were not medically necessary.

141. Not only was ACM's failure to test specimen within 14 days a violation of the terms of its accreditation, the delay also made the tests less reliable. Metabolites in urine can break down over time, particularly if the specimen was contaminated by bacteria at the time of collection. Upon information and belief, ACM did not take steps to reduce the likelihood of damage to the sample resulting from bacterial contamination.

142. Additionally, ACM's delay made the tests less useful for the treatment of patients. As discussed below, delay in testing frequently meant that, when a patient returned for a subsequent visit, the UDT results from the prior visit were not yet available. Thus, providers were unable to use those test results in assessing patient compliance and patient risk, rendering the tests medically unnecessary.

143. Wang was aware, or at least deliberately ignored or recklessly disregarded, that ACM did not comply with COLA's requirements and routinely tested specimen older than 14 days. Wang had access to ACM's testing results, which reflected the turnaround time, through ACM's laboratory management software. In his role as laboratory director, Wang was responsible for overseeing "all aspects of test performance" as well as managing the laboratory software.

144. In addition, as laboratory director, Wang knew or should have known that delay in testing samples reduced their accuracy. Upon information and belief, Wang took no steps to reduce the likelihood that delays in testing would adversely affect the accuracy and reliability of tests performed by ACM's lab.

145. Wang likewise failed to cause ACM to conduct required proficiency testing. Because such proficiency testing was a requirement for the tests to be medically necessary, 42 C.F.R. §§ 410.32(d)(1)(v), 493.551(b)(3), that failure rendered each of ACM's UDT claims false.

2. ACM Routinely Ordered New Testing for Patients Before It Had Processed Results from Earlier Collected Tests

146. The tests of patients V.B. and L.B. referenced in the foregoing subsection illustrate ACM's practice of ordering additional UDT before it had processed prior tests. This routine practice demonstrates that ACM did not use UDT for any medical purpose and ordered UDT without consulting prior results to determine whether new testing would be medically necessary based on individualized clinical history and risk assessment.

147. ACM's treatment of patient J.B. (born 1965) further demonstrates that ACM ordered UDT without a valid medical purpose.

a. ACM ordered UDT and collected a specimen from J.B. at his initial appointment on February 22, 2022.

b. At a follow-up appointment on March 3, 2022, ACM ordered UDT and collected another specimen from J.B.

c. At a third appointment on March 9, 2022, ACM ordered UDT and collected a third specimen from J.B. On the date of the third appointment, ACM had yet to process any of the previous tests it had ordered for J.B.

d. At a fourth appointment on March 16, 2022, ACM ordered UDT and collected a fourth specimen from J.B. ACM processed the tests from the March 9 and March 16 appointments together on March 27, 2022 (18 days and 11 days). Although the test collected on March 16 was processed within 14 days, the test was not medically necessary because it was ordered without access to the results of prior testing and an individualized assessment of J.B.'s risk.

148. ACM submitted claims to Medicare for each of the four tests of J.B. specifically referenced in the foregoing paragraph. ACM submitted the claims and received payment from

Medicare before it had processed any of the tests associated with the claims. ACM was not entitled to payment for these tests because, as ACM well knew, the tests were not medically necessary.

149. J.B.'s situation was not unusual. ACM regularly ordered additional testing before receiving results from prior tests.

150. Likewise, ACM performed definitive UDT testing far more frequently than was justified by any risk assessment contained in the patient's medical records.

151. Gala, as ACM's managing member, and Wang, as its laboratory director, deliberately ignored or were recklessly indifferent to the fact that ACM providers routinely ordered definitive UDT far more frequently than could be justified by any reasonable individualized assessment of patient risk.

3. ACM's Providers Did Not Use UDT Results in Treatment

152. ACM's medical providers did not use UDT results in diagnosis or treatment of patients, at least in part, because the results were not timely available to them.

153. For example, ACM submitted a claim to Medicare for definitive UDT for patient M.V. (born 1964) collected on July 2, 2021. At his follow-up appointment on July 23, 2021, M.V.'s medical provider noted that testing results were not available: "No new UDS [Urine Drug Screen]." M.V.'s UDT results were not available because ACM did not process the test until August 4, 2021, 33 days after collection.

154. M.V.'s medical record notes that UDT results were not available at three subsequent appointments in January, February, and March 2022 although ACM billed Medicare for the associated testing under CPT code G0483. Instead, as M.V.'s medical record states, the provider performed POC testing, which provided immediate results, because the results from the definitive UDT were not available.

155. M.V.'s situation was not an isolated incident. ACM regularly billed Federal Healthcare Programs for testing even though those tests had no medical value because the results were not available to the providers at the patient's next appointment.

4. Gala Acknowledged the Need for Timely Testing

156. Gala himself was well aware of the need for timely testing and the importance of considering UDT results at subsequent visits.

157. On July 28, 2025, Gala filed a complaint on behalf of ACM with the Delaware Division of Professional Regulation ("DPR") against a nurse practitioner, B.M., who worked at ACM until July 2024. In the complaint, Gala accused B.M. of exhibiting "a sustained pattern of **unethical, negligent, and dangerous clinical behavior** that places patients and the public at serious risk." (Emphasis in original).

158. Gala provided several examples of B.M.'s treatment of patients that he asserted constituted such unethical, negligent, and dangerous clinical behavior. Among those examples, Gala asserted that B.M. had failed to appropriately treat Medicaid patient T.S. (born 1962) because B.M. did not counsel T.S. about the results of her May 8, 2024 UDT at her follow-up appointment on May 29, 2024. However, the results from T.S.'s May 8, 2024 UDT were not available at the subsequent office visit because ACM did not process the UDT until June 12, 2024 (35 days).

159. T.S.'s UDT was not medically necessary because it was not and could not be used by her healthcare provider B.M. to diagnosis or treat an injury or illness.

D. ACM Routinely Billed Federal Programs for Tests It Did Not Conduct and Facially Invalid Tests

160. ACM also billed Federal Healthcare Programs for hundreds of tests that ACM did not conduct at all or were facially invalid.

161. Among a sample of approximately 2,900 UDT claims for which ACM submitted claims to Medicare Part B for UDT, at least 19% of ACM's claims were invalid for these reasons.

162. ACM maintained a general practice of billing for UDT close in time to sample collection—usually within 2 or 3 days. Consequently, ACM almost always billed for UDT before actually conducting testing. In cases where ACM never conducted the testing, ACM nonetheless generally billed Medicare within 2 or 3 days of the purported collection date and frequently received payment from Medicare within a week of claim submission, as detailed below.

1. ACM Submitted Claims for Tests It Did Not Conduct

163. ACM knowingly submitted claims to Federal Healthcare Programs for hundreds of tests it did not conduct.

164. For example, on January 15, 2025, ACM submitted a claim to Medicare under CPT code G0483 for a UDT it claimed to have collected from patient E.B. (born 1953) on January 7, 2025. On January 18, 2025, ACM received reimbursement from Medicare for this claim. However, E.B.'s medical record reveals that her January 7, 2025 appointment occurred "via HIPAA compliant telemedicine platform today due to state of emergency secondary to winter storm." As the medical record further makes clear: "Consequently, UDT and VS [vital signs] not collected."

165. As another example, on February 9, 2022, ACM submitted a claim to Medicare under CPT code G0483 for a UDT it claimed to have collected from patient A.K. (born 1957) on February 4, 2022. On February 12, 2022, ACM received reimbursement from Medicare for this claim. However, A.K.'s medical record contains no results for UDT collected on February 4, 2022, and A.K. medical provider noted at the subsequent appointment on February 25, 2022 that A.K.'s most recent UDT results were from January.

166. These are not isolated incidents. ACM was not entitled to payment for UDT it did not conduct. Yet, ACM nonetheless submitted claims to the Federal Healthcare Programs and wrongfully received payment for hundreds of tests it did not conduct.

2. Gala Acknowledged that ACM Billed for Tests It Did Not Conduct

167. Gala himself was well aware that ACM had billed for tests it did not conduct.

168. On January 12, 2026, Gala filed a second complaint with DPR about former ACM employee B.M. In this complaint, Gala alleged that from "March through July 2024, with the majority of incidents occurring between April and June 2024, . . . [B.M.] instructed clinical staff to discard urine specimen without testing." Gala further asserted that "[u]pon learning of this conduct, Alpha Care Medical immediately initiated an internal investigation, consulted healthcare counsel and compliance experts, corrected internal protocols, and voluntarily refunded identified overpayments to applicable payors."

169. ACM submitted to the Federal Healthcare Programs and was paid for hundreds of claims for UDT ordered by rendering provider B.M.

170. Many of the tests for which ACM submitted UDT claims to the Federal Healthcare Programs for services rendered by B.M. between March and July 2024 were never conducted. For instance, ACM did not conduct tests associated with the following claims, for which ACM received payment from Medicare:

a. Claim for patient A.D. (born 1958) with date of service April 3, 2024 and rendering provider B.M.;

b. Claim for patient J.S. (born 1937) with date of service May 6, 2024 and rendering provider B.M.; and

c. Claim for patient S.V. (born 1954) with date of service May 6, 2024 and rendering provider B.M.

171. Contrary to Gala's statement in his report, ACM has not "voluntarily refunded" any "identified overpayments" to the Federal Healthcare Programs.

3. ACM Submitted Claims for Tests that are Facially Invalid

172. ACM knowingly submitted claims to Federal Healthcare Programs for hundreds of tests that were facially invalid based on missing and obviously incorrect information appearing on the test result.

173. ACM submitted claims to Federal Healthcare Programs for UDT that are invalid because the test results are missing data needed to establish the validity of the test. For instance, ACM submitted a claim for a test for patient T.B. (born 1966) with a date of service of March 15, 2022. The associated test result contains no date for specimen collection and no date for laboratory receipt of the specimen. A provider cannot use the results of a UDT in the treatment of a patient without knowing when the specimen was collected. Thus, such tests necessarily lack medical necessity.

174. ACM also submitted claims to Federal Healthcare Programs for UDT that are invalid because the test results contain obviously wrong data. For instance, ACM submitted a claim for a test for patient I.C. (born 1947) with a date of service of May 9, 2024. The associated test results reflect that the laboratory received the specimen at 11:00 A.M. on May 10, 2024, but tested the specimen 47 minutes earlier at 10:13 A.M.

175. ACM's own internal Procedure Manual for UDT requires that test results include the dates of specimen collection and testing as well as "other information . . . necessary for interpretation."

176. Tests with missing or obviously incorrect data are invalid because such results cannot be used in the diagnosis or treatment of patients. Tests that cannot be used in the diagnosis or treatment of patients are not medically necessary and are not eligible for reimbursement.

E. ACM Conducted Blanket Testing Not Based on Appropriate Medical Criteria and Did Not Use the Results.

177. ACM ordered and billed the Federal Healthcare Programs for UDT that it conducted on a blanket basis for all insured patients. ACM conducted such UDT without medical necessity, documentation in the patient medical file, or individualized risk assessment of the patient.

178. In around 2019, Gala drafted and established a "Drugs of Abuse Testing" policy that he distributed to ACM's medical providers. While the formal policy purported to advise ACM's medical providers to order presumptive and definitive UDT based on medical necessity, the policy was only a pretense. In communications to employees, Gala advised employees to maximize UDT ordering—"We do not want to miss out on UDT charges"; "You can order UDTs as frequently as 12 times a year, you just need to document case-specific justification"—and to order only expensive definitive testing—"We used to do presumptive testing, then we matured to definitive testing."

179. In one text message exchange, Gala advised ACM's medical providers to fabricate medical justifications for UDT to deceive federal payors:

> The game here is meeting Medicare's requirements, since they are in the position of power of accusing fraud and abuse.. so I studied what Medicare considered reasonable and necessary, and I've determined that what we need to do is simply add a line or two of justification.. e.g. patient has persistent pain therefore we will perform UDT this visit, or patient has medical comorbidities that increase risks therefore we will perform UDT this visit [sic]

WhatsApp Messages, Sept. 30, 2019, 8:42 A.M.

180. Consequently, ACM's medical providers ordered the most comprehensive and expensive definitive UDT for their insured patients at nearly every appointment.

181. By contrast, ACM frequently permitted uninsured or "cash-pay" patients to forego UDT or to undergo inexpensive POC presumptive testing.

182. As an example of ACM's testing practices for Medicare beneficiaries, from January 2023 to November 2024, ACM submitted and Medicare paid 24 claims for UDT for patient J.S. (born 1937), although the medical provider's notes for J.S. include no documentation or individualized risk assessment supporting the medical necessity for any of the tests. Treatment notes indicate that J.S. was compliant with the treatment plan, J.S.'s UDT results were consistent, and J.S. never received a violation for noncompliance with the treatment plan.

183. Despite this, J.S. was subject to repeated testing using the most comprehensive panel that included testing for metabolites of drugs including cocaine, ketamine, and MDMA (commonly known as "Ecstasy").

184. Nothing in J.S.'s medical records supports the necessity of testing an octogenarian more than once a month for street drugs.

185. J.S.'s medical records also fail to include any documentation showing that the testing results were ever used for any treatment or diagnosis.

186. ACM submitted false claims for reimbursement for J.S. by certifying to the Federal Healthcare Programs that the UDT ordered for J.S. was reasonable and necessary. ACM knew, recklessly disregarded, or deliberately ignored the fact that the certifications that UDT was reasonable and necessary were false because (i) testing was ordered on a blanket basis and not based on a medical provider's decision that testing was medical necessary; (ii) medical necessity for testing was not documented in J.S.'s patient file; (iii) testing was ordered without appropriately risk assessing J.S.; and (iv) the test results were not used for diagnosis or treatment.

187. In the case of patients whose UDT did reflect unexpected positive results, ACM also did not use the results for any treatment or diagnosis.

188. For example, between December 2023 and May 2024, patient B.S. (born 1949) tested positive for cocaine on six consecutive drug tests. However, the medical provider's notes

for B.S. do not mention the positive results and instead uniformly state at each appointment that "patient is compliant with treatment plan" and additional "UDT will be ordered at this visit r/t COT [related to chronic opioid therapy] compliance."

189. Similarly, patient S.V. (born 1954) tested positive for cocaine on a drug test collected on August 26, 2024. The medical provider's notes for S.V. do not mention the positive result at subsequent appointments and instead uniformly state that "patient is compliant with treatment plan" and additional "UDT will be ordered at this visit r/t COT compliance."

190. ACM's treatment of B.S. and S.V. exemplify its practice, consistent with Gala's direction, of inserting boilerplate justification into patient medical records regarding the ordering and use of UDT. Such boilerplate language, lacking any individualized medical assessment, does not support the medical necessity of testing.

191. ACM submitted false claims for reimbursement for B.S. and S.V. by certifying to the Federal Healthcare Programs that the UDT ordered for B.S. and S.V. was reasonable and necessary. ACM knew, recklessly disregarded, or deliberately ignored the fact that the certifications that UDT was reasonable and necessary were false because (i) testing was ordered on a blanket basis and not based on a medical provider's decision that testing was medical necessary; (ii) medical necessity for testing was not documented in patient files; (iii) testing was ordered without appropriately risk assessing the patients; and (iv) the test results were not used for diagnosis or treatment.

192. These are not isolated examples. Because ACM "[did] not want to miss out on UDT charges," providers routinely ordered blanket testing without appropriate risk assessment or determinations of medical necessity and without using the test results for diagnosis or treatment.

FIRST CAUSE OF ACTION
Against ACM and Gala
False Claims Act: Presenting and Causing False Claims (31 U.S.C. § 3729(a)(1)(A))

193. The United States re-alleges and incorporates by reference all prior paragraphs of this Complaint set out above as if fully set forth here.

194. As detailed above, ACM and Gala presented and/or caused to be presented materially false and fraudulent claims for payment or approval to the Federal Healthcare Programs for UDT that was not reasonable and necessary.

195. Specifically, ACM and Gala submitted and/or caused submission of false claims by seeking payment for UDT that was not reasonable and necessary or was otherwise not covered by Federal Healthcare Programs. The testing was not covered because, among other reasons, (i) ACM operated its laboratory in violation of the requirements of its accreditation by routinely testing stale specimens and failing to conduct required proficiency testing; (ii) ACM did not use UDT results for diagnosis or treatment; (iii) ACM routinely billed for tests with missing and incorrect information; and (iv) ACM ordered UDT on a blanket basis without a medical provider's individualized risk assessment of the patient. ACM and Gala knew, were recklessly indifferent to, or deliberately ignored the fact that testing was not reasonable and necessary or was otherwise not covered by Federal Healthcare Programs.

196. Additionally, ACM and Gala submitted and/or caused submission of false claims by seeking payment for UDT that that ACM did not conduct. ACM routinely billed the Federal Healthcare Programs for UDT it did not conduct. Defendants knew, recklessly disregarded, or were willfully ignorant that their submissions for such claims were false.

197. Gala knowingly caused the submission of these false claims because he directed and controlled ACM's conduct.

198. The Federal Healthcare Programs paid ACM for these materially false claims and thus sustained damages because of this wrongful conduct.

199. Federal Healthcare Programs made these payments without knowledge of material facts and under the mistaken belief that ACM was entitled to receive payment for such claims when it was not. Federal Healthcare Programs' mistaken beliefs were material to the decision to pay ACM for such claims.

SECOND CAUSE OF ACTION
Against ACM, Gala, and Wang
False Claims Act: False Statements Material to False Claims (31 U.S.C. § 3729(a)(1)(B))

200. The United States re-alleges and incorporates by reference all prior paragraphs of this Complaint set out above as if fully set forth here.

201. As detailed above, during the relevant time-period, Defendants made, used, or caused to be made or used, false records and statements, material to a false or fraudulent claim.

202. Specifically, Defendants made, used, and caused to be made or used, false records and statements when they certified that the UDT for which ACM was seeking reimbursement were reasonable and necessary. The certifications were false because (i) ACM operated its laboratory in violation of the requirements of its accreditation by routinely testing stale specimens and failing to conduct required proficiency testing; (ii) ACM did not use UDT results for diagnosis or treatment; (iii) ACM routinely billed for tests with missing and incorrect information; and (iv) ACM ordered UDT on a blanket basis without a medical provider's individualized risk assessment of the patient.

203. Defendants made false records and statements to COLA regarding ACM's compliance with COLA's terms of accreditation. Based on such false records and statements, COLA accredited ACM, which allowed ACM to maintain a CLIA Registration, and consequently to continue to submit false claims for UDT to the Federal Healthcare Programs.

204. Defendants also made, used, and caused to be made or used, false records and statements when ACM submitted claims for UDT that ACM did not conduct.

205. Defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

206. The false records or statements were material to the decision of Federal Healthcare Programs to pay the claims. The false certifications, including the certification that the services provided were reasonable and necessary and the certification that ACM met CLIA requirements, were a necessary condition of payment for the claims.

207. The Federal Healthcare Programs paid ACM for these materially false claims and thus sustained damages because of this wrongful conduct.

THIRD CAUSE OF ACTION
Against ACM, Gala, and Wang
False Claims Act: Reserve False Claims (31 U.S.C. § 3729(a)(1)(G))

208. The United States re-alleges and incorporates by reference all prior paragraphs of this Complaint set out above as if fully set forth here.

209. As detailed above, Defendants knowingly made, used, or caused to be made or used false records and/or statements to conceal, avoid, or decrease obligations to pay or transmit money or property, in the form of payments from the Federal Healthcare Programs to ACM for UDT, to the United States.

210. Specifically, ACM, though Gala and Wang, knowingly retained payments it had received from Federal Healthcare Programs even after it determined that the claims at issue were false because the testing was never conducted or was not medically necessary.

211. The Federal Healthcare Programs sustained damages in the form of payment for false UDT claims that Defendants did not repay to the United States because of this wrongful conduct.

FOURTH CAUSE OF ACTION
Against ACM
Payment by Mistake

212. The United States re-alleges and incorporates by reference all prior paragraphs of this Complaint set out above as if fully set forth here.

213. This is a claim for the recovery of monies paid by Federal Healthcare Programs to ACM as a result of mistaken understandings of fact.

214. Federal Healthcare Programs paid ACM for UDT that did not comply with the requirements of the Federal Healthcare Programs. Federal Healthcare Programs made these payments without knowledge of material facts and under the mistaken belief that ACM was entitled to receive payment for such claims when it was not. Federal Healthcare Programs' mistaken beliefs were material to the decision to pay ACM for such claims. Accordingly, ACM is liable to make restitution to the United States of the amounts of the payments made in error to ACM by the Federal Healthcare Programs.

FIFTH CAUSE OF ACTION
Against Wang
Unjust Enrichment

215. The United States re-alleges and incorporates by reference all prior paragraphs of this Complaint set out above as if fully set forth here.

216. This is a claim for the recovery of monies by which Wang has been unjustly enriched during the relevant time period at the expense of Federal Healthcare Programs.

217. By directly or indirectly obtaining government funds to which he was not entitled, Wang was unjustly enriched and is liable to account for and pay as restitution such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

The United States demands and prays that judgment be entered in its favor against Defendants as follows:

A. On Count I against defendants ACM and Gala, under the False Claims Act, for the amount of the United States' damages, trebled as required by law, plus costs of investigation and prosecution, and such civil penalties for each false claim as are provided by law, plus interest, together with such further relief as may be just and proper.

B. On Counts II and III against defendants ACM, Gala, and Wang, under the False Claims Act, for the amount of the United States' damages, trebled as required by law, plus costs of investigation and prosecution, and such civil penalties for each false claim as are provided by law, plus interest, together with such further relief as may be just and proper.

C. On Count IV for payment by mistake, against defendant ACM, for the damages sustained and/or amounts by which ACM was paid by mistake or by which ACM retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

D. On Count V for unjust enrichment, for the damages sustained and/or amounts by which Wang was unjustly enriched or by which Wang retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

E. Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

BENJAMIN L. WALLACE
United States Attorney

/s/ Elizabeth F. Vieyra
Elizabeth F. Vieyra
Assistant U.S. Attorney

Dated: June 17, 2026