UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

UNITED STATES OF AMERICA EX REL. [UNDER SEAL],	)	
PLAINTIFFS-RELATORS,	)	**4:20-CV-1110-DPM (Consolidated with 4:21-CV-277-DPM and 4:22-CV-1275-DPM)**
v.	)	
[UNDER SEAL],	)	**IN CAMERA AND UNDER SEAL**
DEFENDANTS.	)	

UNITED STATES' COMPLAINT IN INTERVENTION

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

UNITED STATES OF AMERICA EX REL. BRIAN WATKINS, **PLAINTIFFS,** **v.** **ADVANCED PATHOLOGY SOLUTIONS, LLC; ADVANCED PATHOLOGY SOLUTIONS PLLC; and APS MSO, LLC,** **DEFENDANTS.**	**No. 4:20-CV-1110-DPM** **(Consolidated with 4:21-CV-277-DPM and 4:22-CV-1275-DPM)** **FILED IN CAMERA AND UNDER SEAL** **JURY TRIAL DEMANDED**
UNITED STATES OF AMERICA EX REL. DENISE AUCOIN and BRENT AUCOIN, **PLAINTIFFS,** **v.** **ADVANCED PATHOLOGY SOLUTIONS, LLC; ADVANCED PATHOLOGY SOLUTIONS PLLC; APS MSO, LLC; KEVIN HANNAH; DONELL BURKETT; and DANIEL HUNTER PLEDGER,** **DEFENDANTS.**	
UNITED STATES OF AMERICA EX REL. MICHAEL PAULSEN, **PLAINTIFFS,** **v.** **ADVANCED PATHOLOGY SOLUTIONS, LLC; ADVANCED PATHOLOGY SOLUTIONS PLLC; and**	

APS MSO, LLC,)
)
DEFENDANTS.)

UNITED STATES' COMPLAINT IN INTERVENTION

1. Plaintiff, the United States of America, files this complaint-in-intervention under the False Claims Act (the "FCA"), 31 U.S.C. § 3729, *et seq.*, and the common law, against Defendants Advanced Pathology Solutions, LLC; Advanced Pathology Solutions, PLLC; APS MSO, LLC (collectively, "APS"); Kevin Hannah, Donell Burkett, and Daniel Hunter Pledger.

I. INTRODUCTION

2. From 2015 through at least July 2022, APS and its owners engaged in a nationwide scheme to improperly bill Medicare for gastrointestinal pathology services and reap massive profits. The scheme involved two distinct but related strategies.

3. First, APS provided illegal kickbacks to gastroenterology practices across the United States to induce a nationwide stream of referrals and to stifle competition from other labs. Specifically, APS set up and managed limited-purpose laboratories (known as "lean labs") that were physically located in the same office space as gastroenterology practices and were ostensibly owned and operated by the practices. Through these lean labs, practices could bill for a portion of certain pathology testing services. APS charged little or nothing for its services in setting up and managing the lean labs. In return, APS required those practices to exclusively refer their patients—including Medicare beneficiaries—to APS for pathologist review and additional testing.

4. Second, APS performed medically unnecessary testing on patients' tissue specimens. APS automatically ordered certain tests to be performed on patients' tissue specimens without any determination by a pathologist that those tests were reasonable or

necessary for those patients. APS would perform multiple rounds of tests on the same tissue specimen from a single patient with no explanation in the medical record why serial testing was appropriate. In other instances, APS would test patients for exceedingly rare conditions or diseases without any rationale.

5. Because the scheme enabled both APS and the gastroenterology practices to bill for a portion of the testing, the more tests APS ordered, the more money both APS and the gastroenterology practices stood to make. And the more lucrative APS made its in-house lab offering to the referring gastroenterology practices, the easier APS could secure more patient referrals to its own lab.

6. The scheme worked as intended: APS generated outsized profits from tests that were improperly influenced by kickbacks, were not medically necessary, or both. The business model was a "win-win" proposition for APS and the gastroenterology practices. But it came at significant cost to the Medicare program, which paid out tens of millions of dollars to APS and the gastroenterology practices for services that resulted from kickbacks and were in many cases unnecessary.

7. The United States now brings this suit to recover damages, restitution, and civil penalties from Defendants under the False Claims Act and federal common law.

II. JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 31 U.S.C. §§ 3730(a) and 3732(a) and 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a plaintiff pursuant to the FCA.

9. This Court may exercise personal jurisdiction over all Defendants pursuant to 31 U.S.C. § 3732(a). Defendants Advanced Pathology Solutions, LLC; Advanced Pathology Solutions, PLLC; and APS MSO, LLC, each transact business in this District and committed

some of the actions described herein, which are proscribed by 31 U.S.C. § 3729, in this District. Defendants Hannah, Burkett, and Pledger each reside in this District and committed some of the actions described herein, which are proscribed by 31 U.S.C. § 3729, in this District.

10. Similarly, venue is proper in this jurisdiction under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1935(a). Venue is proper in this jurisdiction because a substantial part of the events or omissions giving rise to these claims occurred in Arkansas. Additionally, all Defendants are subject to the Court's personal jurisdiction pursuant to 31 U.S.C. § 3732(a).

III. PARTIES

11. The Plaintiff in this action is the United States, suing on behalf of the Centers for Medicare and Medicaid Services ("CMS"), which is part of the United States Department of Health and Human Services ("HHS"). CMS is responsible for administering the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, commonly known as Medicare.

12. Relator Brian Watkins is a resident of the State of Arkansas and is a former part owner and managing partner of APS. On September 18, 2020, Watkins filed an action in this Court alleging violations of the FCA on behalf of himself and the United States pursuant to the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b)(1).

13. Relator Denise Aucoin is a resident of the State of Louisiana and is a former sales representative for APS. On April 9, 2021, Denise Aucoin, together with Brent Aucoin, filed an action in this Court alleging violations of the FCA on behalf of herself and the United States pursuant to the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b)(1).

14. Relator Brent Aucoin is a resident of the State of Louisiana and is a former Vice President for Gastrointestinal and Urology Sales at APS. On April 9, 2021, Brent Aucoin, together with Denise Aucoin, filed an action in this Court alleging violations of the FCA on

behalf of himself and the United States pursuant to the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b)(1).

15. Relator Michael Paulsen is a resident of the State of Missouri and is the owner and principal officer of a sales consulting company whose services include marketing laboratory services to hospitals, clinics, and physician groups. On April 1, 2022, Paulsen filed an action in the Southern District of Illinois alleging violations of the FCA on behalf of himself and the United States pursuant to the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b)(1). The *Paulsen* action was subsequently transferred to this District.

16. Defendant Advanced Pathology Solutions, LLC, is an Arkansas corporation with a principal place of business in North Little Rock, Arkansas. Advanced Pathology Solutions, LLC operates an anatomic pathology laboratory and submits claims to insurers, including Medicare, for pathology services performed in its lab.

17. Defendant Advanced Pathology Solutions, PLLC, is an Arkansas corporation with a principal place of business in North Little Rock, Arkansas. Advanced Pathology Solutions, PLLC operates an anatomic pathology laboratory and submits claims to insurers, including Medicare, for pathology services performed in its lab.

18. Defendant APS MSO, LLC, is an Arkansas corporation with a principal place of business in North Little Rock, Arkansas. APS MSO, LLC, is a management service organization for Advanced Pathology Solutions, PLLC.

19. Upon information and belief, prior to January 1, 2023, Advanced Pathology Solutions, PLLC, operated as a limited liability corporation named Advanced Pathology Solutions, LLC. Beginning in 2023, Advanced Pathology Solutions, LLC became Advanced Pathology Solutions, PLLC and the new entity APS MSO, LLC was created. Pursuant to a

contractual management services relationship, Advanced Pathology Solutions, PLLC performs clinical company functions and APS MSO, LLC performs non-clinical company functions. This corporate restructuring was a change on paper only and did not result in any material change to the day-to-day operations of Advanced Pathology Solutions, PLLC, or APS MSO, LLC.

20. Throughout this Complaint, Advanced Pathology Solutions, LLC, Advanced Pathology Solutions, PLLC, and APS MSO, LLC, are collectively referred to as "APS."

21. Defendant Kevin Hannah is a resident of Arkansas. He is the Chief Executive Officer ("CEO") of APS and is a part-owner of the company.

22. Defendant Donell Burkett is a resident of Arkansas. He is the Chief Operations Officer ("COO") of APS and at relevant times was a part-owner of the company.

23. Defendant Daniel Hunter Pledger is a resident of Arkansas. He is the Chief Laboratory Officer ("CLO") of APS and at relevant times was a part-owner of the company.

24. Throughout this Complaint, Defendants Hannah, Burkett, and Pledger are collectively referred to as the "owners" of APS.

IV. LEGAL FRAMEWORK

A. The False Claims Act

25. 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 . . .

is liable to the United States for three times the amount of damages which the United States sustains, plus a civil penalty per violation. 31 U.S.C. § 3729(a)(1).

26. FCA penalties are regularly adjusted for inflation, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. *See* 28 U.S.C. § 2461 note. For

violations occurring after November 2, 2015, the civil penalty amounts currently range from a minimum of $14,308 to a maximum of $28,619. 28 C.F.R. § 85.5.

27. 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).

28. Under the FCA, a "claim" includes direct requests to the United States for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs. 31 U.S.C. § 3729(b)(2)(A).

29. 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).

B. The Anti-Kickback Statute

30. The Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of Congressional concerns involving physicians' conflicts of interest and overutilization of medical services and items. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93. The AKS prohibits kickback payments to protect the integrity of federal healthcare programs, including Medicare.

31. The AKS prohibits any person from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward a person for, *inter alia*, purchasing, ordering, arranging for, or recommending the purchase or ordering of any goods or services for which payment may be made, in whole or in part, under a federal healthcare program.

32. In pertinent part, the AKS provides:

> b. Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.

42 U.S.C. § 1320a-7b(b). "[A] person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." *Id.* § 1320a-7b(h).

33. The AKS defines a "Federal health care program" to mean "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," except for the health insurance program for federal employees. *Id.* § 1320a–7b(f).

34. Referrals or recommendations need not be the sole or primary purpose of a kickback for a violation of the AKS. Instead, courts consider "whether at least one purpose of the payment could be to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program." *Guilfoile v. Shields*, 913 F.3d 178, 189 (1st Cir. 2019) (quotation marks and alterations omitted).

35. Congress reiterated the centrality of the AKS to a claims payment decision in 2010 by amending the AKS to provide that any "claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a–7b(g). Accordingly, claims submitted to federal health care programs that result from violations of the AKS are per se false or fraudulent within the meaning of 31 U.S.C. § 3729(a).

36. Compliance with the AKS is a material condition of payment by Medicare.

37. The United States regularly enforces the AKS and pursues FCA liability based on underlying violations of the AKS.

1. AKS "Safe Harbors"

38. Congress has developed several statutory exceptions to the Federal anti-kickback statute. 42 U.S.C. § 1320a-7b(b)(3). Additionally, the HHS Office of Inspector General ("OIG") has promulgated "safe harbor" regulations that define certain practices that are not treated as an

offense under the AKS because such practices are unlikely to result in fraud or abuse. 42 C.F.R. § 1001.952. The safe harbors assure that arrangements meeting certain specific conditions will not be sanctioned under the AKS. However, safe harbor protection is an affirmative defense that is afforded to only those arrangements that meet all conditions of an applicable safe harbor.

39. The remuneration alleged herein exchanged between APS and the gastroenterology practices hosting lean labs does not satisfy the requirements of any AKS safe harbor, and at all relevant times, Defendants were aware that their conduct was unlawful.

2. OIG Special Fraud Alerts and Related Guidance

40. To alert the public to "trends of health care fraud and certain practices of an industry-wide character," OIG issues special fraud alerts, which are published online and in the Federal Register. 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994). The fraud alerts "provide general guidance to the health care industry" and assist others "in identifying health care fraud schemes." *Id.*

41. In 1989, OIG issued a Special Fraud Alert on Joint Venture Arrangements. OIG warned that physician joint venture arrangements may violate the AKS where the arrangement was "intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for those referrals." OIG, Special Fraud Alert: Joint Venture Arrangements, reprinted in 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

42. In 1994, OIG issued a Special Fraud Alert on transfers of value from laboratories to referral sources. OIG, Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services, *reprinted in* 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994). OIG warned of "inducements offered by clinical laboratories which may implicate the [AKS]," such as providing items, services, and financial benefits. *Id.* OIG warned that "[w]hen one purpose of

these arrangements is to induce the referral of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider may be liable under the [AKS] and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs." *Id.* at 65,377–78.

43. OIG reiterated its concerns in a Special Advisory Bulletin in 2003 about the "proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays." OIG, Special Advisory Bulletin: Contractual Joint Ventures, *reprinted in* 68 Fed. Reg. 23,148, 23,148 (Apr. 30, 2003) (warning that such "questionable contractual arrangements" may violate the AKS).

44. In June 2014, OIG issued a Special Fraud Alert regarding laboratory payments to referring physicians. OIG Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014), *reprinted in* 79 Fed. Reg. 40,115 (July 11, 2014). OIG noted that "[a]rrangements between referring physicians and laboratories historically have been subject to abuse and were the topic of one of the OIG's earliest Special Fraud Alerts." *Id.* at 40,116 (citing 1994 Special Fraud Alert).

45. As OIG recognized, "the choice of laboratory, as well as the decision to order laboratory tests, typically is made or strongly influenced by the physician, with little or no input from patients." *Id.* at 40,116. Transfers of value to physicians "may induce physicians to order tests from a laboratory that provides them with remuneration, rather than the laboratory that provides the best, most clinically appropriate service." *Id.* Such transfers "also may induce physicians to order more laboratory tests than are medically necessary, particularly when the transfers of value are tied to, or take into account, the volume or value of business generated by the physician." *Id.*

C. The Medicare Program

46. Congress enacted the Medicare program in 1965 to pay for the costs of certain healthcare services. 42 U.S.C. § 1395 *et seq.* Eligibility for Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1.

47. HHS is responsible for administration and supervision of the Medicare program. CMS is directly responsible for administering the Medicare program.

1. Medicare Part B

48. Part B of the Medicare program is a federally subsidized, voluntary insurance program that pays for various medical and other health services and supplies, including physician services and laboratory testing. *See* 42 U.S.C. §§ 1395j to 1395w-5.

49. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and by contributions from the Federal Treasury. Eligible individuals who are 65 or older or disabled may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums. Payments under Medicare Part B typically are made directly under assignment to service providers and practitioners, such as physicians, rather than to the patient/beneficiary. In that case, the physician bills the Medicare program directly.

50. CMS provides reimbursement for Medicare Part B claims from the Medicare Trust Fund.

51. To enroll in the Medicare program, suppliers of laboratory services must submit a Medicare Enrollment Application, Form CMS-855B. These providers must also complete Form CMS-855B to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

52. Form CMS-855B requires, among other things, signatories to certify that they will abide by applicable Medicare laws and regulations.

53. The form also requires signatories to certify their understanding that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (Section 1877 of the Social Security Act))."

54. Despite slight variations in language, Form CMS-855B at all times relevant to this Complaint has required the signatory to certify their understanding that payment of claims by Medicare is conditioned upon the claims and the transactions underlying the claims complying with the AKS.

55. Defendants Pledger and Hannah both signed CMS Form CMS-855B as Authorized Officials on behalf of APS.

56. Medicare reimburses only those services furnished to beneficiaries that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(l)(A).

57. The Secretary of HHS is responsible for specifying services covered under the "reasonable and necessary" standard. *See* 42 U.S.C. § 1395ff(a).

58. The Secretary provides guidance to eligible providers about the meaning of the statutory "reasonable and necessary" standard pursuant to a series of Manuals, published by CMS, which are available to the public on the Internet. *See generally* CMS Internet-Only Manuals, *available at* https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html.

59. At all times relevant to this Complaint, CMS contracted with private contractors, known as Medicare Administrative Contractors ("MACs"), to perform various administrative functions on its behalf, including reviewing and paying claims submitted by healthcare providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. MACs generally act on behalf of CMS to process and pay Medicare claims and perform administrative functions on a regional level. MACs may issue Local Coverage Determinations ("LCDs") which identify, for the states within their jurisdiction, procedures and services that are considered reasonable and necessary at the initial determination stage, and therefore eligible for payment under Medicare. 42 U.S.C. § 1395ff(f)(2).

60. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

61. To obtain Medicare reimbursement, healthcare providers[1] (including laboratories) submit claims using paper forms or their electronic equivalents. Providers identify by code on the appropriate form, among other things, the procedures and services rendered.

62. To obtain Medicare reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the "CMS-1500" form or its electronic equivalent, known as the "837P" format.

63. To submit electronic claims via the 837P format, a provider must complete and submit to CMS an Electronic Data Interchange Enrollment Form ("EDI"). The EDI may be

[1] Relevant Medicare regulations use the term "supplier" rather than "provider" to refer to physicians and other practitioners, including laboratories. *See* 42 C.F.R. § 400.202. Since the distinction is not relevant to the issues in this case, the Complaint uses the more colloquial term "provider" to refer generally to persons and entities providing and billing for healthcare services, including individual physicians, physician practice groups, and laboratories.

completed by the provider or an authorized individual who has the legal authority "to commit the provider to abide by the laws, regulations, and the program instructions of Medicare." On the EDI, the provider agrees to "submit claims that are accurate, complete, and truthful" and certifies that the use of the provider's National Provider Identifier on a claim "constitutes the provider's legal electronic signature and an assurance that services were performed as billed." The provider's EDI certification then serves as the signature for every electronic claim submitted by the provider thereafter.

64. Healthcare providers are prohibited from knowingly presenting or causing to be presented claims for items or services that were not "reasonable and necessary…[f]or the diagnosis or treatment of illness or injury," or were false or fraudulent. *E.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1320a-7(b)(7) (providers may be excluded for fraud, kickbacks, and other prohibited activities).

65. Providers have a duty to familiarize themselves with the statutes, regulations, and guidelines regarding coverage for the Medicare services they provide.

66. Because it is not feasible for the Medicare program or its contractors to review medical records corresponding to all of the billion claims for payment it receives from providers each year, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

67. Generally, once a provider submits a claim to the Medicare program, payment is made directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

2. Medicare Advantage

68. Medicare eligible beneficiaries can elect to opt out of traditional Medicare and instead receive their benefits through privately run insurance plans (known as "Medicare

Advantage" or "MA" plans). *See* 42 U.S.C. §§ 1395w-21–1395w-28; 42 C.F.R. § 422.50(a). An individual is eligible to elect a Medicare Advantage plan if he or she is "entitled to Medicare under Part A and enrolled in Part B" of traditional Medicare. 42 U.S.C. § 422.50(a).

69. Today, more than half of all Medicare beneficiaries are enrolled in Medicare Advantage plans.

70. Medicare Advantage plans are operated and managed by Medicare Advantage Organizations ("MAOs") that contract with CMS. *E.g.*, 42 C.F.R. §§ 422.2, 422.503(b)(2).

71. MAOs are obligated to cover "all services that are covered by Part A and B of Medicare." 42 CFR 422.101(a). And MAOs must comply with all coverage requirements established in statutes, regulations, Medicare manuals and instructions, NCDs and LCDs. *Id.* at § 422.101(b) ("MA organizations must . . . comply with . . . (1) CMS's national coverage decisions; (2) general coverage guidelines included in original Medicare manuals and instructions. . . and (3) written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered. . . .").

72. Under Medicare Advantage, when a healthcare provider furnishes services to a Medicare beneficiary, the provider submits information from the patient encounter directly to the MAO that operates the beneficiary's Medicare Advantage plan. The provider than receives payment from the MAO, instead of directly from CMS.

73. To compensate MAOs for providing coverage for beneficiaries on their plans, CMS makes monthly payments to the MAOs in a capitated (i.e., fixed) amount, per beneficiary enrolled in each Medicare Advantage plan.

3. Medicare Laboratory Testing

74. Clinical laboratory services involve the "examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a

medical condition." Medicare Benefit Policy Manual ("MBPM"), Pub. 100-02, Ch. 15, § 80.1, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

75. Pursuant to Medicare regulations, (i) laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (ii) laboratory test orders must be individualized to patient need, and that need must be documented in the medical record; and (iii) claims for laboratory services that do not meet these requirements are ineligible for payment. *See* 42 C.F.R. § 410.32.

76. All diagnostic laboratory tests "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. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a).

77. A laboratory test order is "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary." MBPM, Ch. 15, § 80.6.1. Medicare requires that an ordering physician "must clearly document, in the medical record, his or her intent that the test be performed." *Id.*

78. A laboratory's claim for a service is ineligible for payment 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).

V. FACTUAL ALLEGATIONS

A. Gastrointestinal Pathology

79. "Staining" is a technique used in the practice of gastroenterology to identify and potentially diagnose various issues, including the presence of Heliobacter pylori (known as "H. pylori") bacteria or cancer.

80. The process of staining involves collecting a biopsy specimen from a patient's gastrointestinal system, preparing a slide using a very thin slice cut from the biopsy specimen, and applying a chemical dye (or "stain") to the slide. A pathologist then examines and interprets the stained specimen slide using a microscope and makes observations and potential diagnoses.

81. The process of preparing and interpreting stains requires a certified laboratory with specialized equipment, trained staff to cut the specimens and stain the slides, and a pathologist to read and interpret the slides.

82. For billing purposes, the staining process is split into two components: a "technical" component and a "professional" component. The technical component encompasses the preparation of the slide and is generally performed by a histology technician (or "histotechnician"). The histotechnician slices the biopsy specimen, places it on the slide and applies the stain. The professional component encompasses the medical review and interpretation of the prepared slide and is performed by a physician with special training in anatomic pathology (or a "pathologist").

83. When submitting a claim for staining services to Medicare or other insurers, a provider can indicate whether he or she is billing for the technical or professional portion of the service, or both (known as "global billing").

84. A hematoxylin and eosin (or "H&E") stain is a routine stain that is considered the cornerstone of gastrointestinal pathology because it provides a detailed view of the biopsied

tissue and allows the pathologist to diagnose a range of ailments, including the presence or absence of H. pylori organisms, with a high degree of confidence and often without the need for further testing.

85. In some cases, a pathologist may review and interpret an H&E stain and determine that additional information is needed to make (or rule out) a diagnosis. In those circumstances, the pathologist may order one or more histochemical stains (known as "special stains") or immunohistochemical stains.

86. Special stains involve the use of dyes that stain particular tissues, structures, or pathogens such as bacteria that may not be visible in a routine H&E stain. These stains are "special" because they are not appropriate for all patients or circumstances. Some of the more common special stains include alcian blue, periodic acid Schiff (together known as "AB-PAS"), Giemsa, and trichrome staining.

87. Under certain circumstances, a pathologist may also order an immunohistochemical stain (or "IHC" stain). Immunohistochemistry is a complex technique that involves the use of antibodies and markers to highlight or identify certain parts of a biopsy tissue sample or organisms. Similar to special stains, an IHC stain can be billed globally or separately using a technical component and a professional component and must be ordered and reviewed by a pathologist. Like special stains, IHC stains are not appropriate or necessary for all patients. IHC stains may be ordered based on the needs of a particular patient and may be used to confirm, rule out, or provide additional information to supplement the pathologist's interpretation of an H&E stain.

88. While histotechnicians may assist with the preparation and staining of slides, it is the sole responsibility of the pathologist to select the stains that are ordered for a patient.

B. APS's Lean Lab Business Model

89. In approximately 2015, APS began promoting a new business model to gastroenterology practices, which APS called its "lean lab" program.

90. Through this business arrangement, APS partnered with gastroenterology practices to construct and operate limited-purpose, in-house pathology laboratories ("lean labs") located in the gastroenterology practices' offices.

91. APS entered into relationships with approximately 50 gastroenterology practices to construct and operate lean labs in the States of Alabama, Arkansas, Arizona, Colorado, Florida, Georgia, South Carolina, Kansas, Louisiana, Michigan, Missouri, Mississippi, North Carolina, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, and Texas.

92. These lean labs were configured to perform only the technical component of gastrointestinal staining services. Specifically, lean labs could prepare slides using patient biopsy specimens and apply H&E and special stains to those slides. However, lean labs could not perform the professional component of the staining services (the microscopic review and interpretation of those slides) because there was no pathologist in the lab to review the slides, nor could they perform immunohistochemical stains due to their complexity. Instead, the gastroenterology practices that hosted APS lean labs needed to send their patients' slides to an outside laboratory so that a pathologist could review the slides and bill for the professional component of the staining services. As part of their arrangement with APS, the practices hosting lean labs agreed to send their patients' slides exclusively to APS for the professional component. In many cases, APS would also perform and bill for additional immunohistochemical stains on the gastroenterology practices' patient specimens once they arrived at APS.

93. The gastroenterology practices hosting APS lean labs would bill Medicare and other insurers for performing the technical component of H&E stains using Current Procedure

Terminology ("CPT") code 88305 with a technical component (or "TC") modifier and would bill for the special stains using CPT codes 88312 and 88313 with a TC modifier. APS would bill for the corresponding professional component of the H&E stains using CPT code 88305 with a professional component modifier (typically a "26" modifier) and bill for the professional component of special stains using CPT codes 88312 and 88313 with a professional component modifier. The modifier codes indicated to the insurer which component of the stain service the provider performed.

94. APS and its owners marketed the lean lab relationship to potential customers as a lucrative opportunity for gastroenterology practices to earn "passive income" by allowing APS to transfer valuable items and services to the practices by paying to set up and manage a lean lab in their office. APS told potential customers that it offered "the most profitable TC/PC split lab model (aka APS Lean Lab) available." When discussing the business with potential customers, APS representatives (including Defendants Hannah, Pledger, and Burkett) would create personalized "pro forma" documents showing providers how they could generate hundreds of thousands—and sometimes millions—of dollars in revenue each year by partnering with APS instead of sending their biopsy specimens to a lab that would perform the staining services globally.

95. For example, APS provided a pro forma document to Atlanta Gastroenterology Associates ("AGA"), a gastroenterology practice group in Atlanta, Georgia, projecting that the practice could make more than $3 million per year by hosting an APS lean lab, with APS contributing to the costs of setting up the lab. In an email later recommending that another practice open an APS lean lab, AGA's Chief Medical Officer wrote that "I think you will be shocked by how much money you are leaving on the table" and that partnering with APS would

provide "rapid results financially to the bottom line," predicting a "50-100% upside in EBIDTA [Earnings Before Interest, Taxes, Depreciation, and Amortization] for your group."

96. APS also emphasized how little responsibility the gastroenterology practices would have in setting up and operating a lean lab. APS told providers that it offered "turn-key" lab setup, that APS would "plan and manage your histology lab setup," and that APS would be "fully responsible for all areas of the lab." As APS told providers, once APS set up a lean lab in a gastroenterology practice's office, the practice wouldn't even know the lean lab was there.

97. In short, APS promoted the lean lab model as an opportunity for gastroenterology practices to tap into a "much greater revenue stream" and earn passive income by letting APS help them convert part of their office space into a "slide factory." The gastroenterology practice simply had to make an upfront investment in lab equipment and place a histotechnician that APS recruited and trained on the practice's payroll.

98. When a gastroenterology practice agreed to partner with APS on a lean lab, the practice and APS would enter into a contractual agreement setting out the terms of their relationship (a "Lean Lab Agreement").

99. Each Lean Lab Agreement would be signed by a representative of the gastroenterology practice. Defendant Hannah, Defendant Burkett, or Defendant Pledger would sign almost every Lean Lab Agreement on behalf of APS.

100. The Lean Lab Agreements identified some, but not all, of the services and benefits that APS actually provided to the gastroenterology practices.

101. APS would work closely with its gastroenterology practice customers to construct the "buildout" of the lean lab in the customer's office. Specifically, APS would help practices apply for necessary Clinical Laboratory Improvement Amendments ("CLIA") certifications;

prepare plans to construct the lean lab; assist with obtaining and installing lean lab equipment (sometimes helping to broker discounts on lab equipment); recruit and train histotechnicians to work in the lean lab; create and provide policies for the lean lab; and provide an electronic data system for the lean lab (also referred to as a "laboratory information system" or "LIS").

102. Once the lean lab was up and running, APS would help the gastroenterology practice staff the lean lab with one or more histotechnicians. APS would recruit and train the histotechnicians. In some instances, APS would pay for travel and lodging for histotechnicians to go to APS's office in North Little Rock for training. The histotechnicians were then employed by the gastroenterology practice hosting the lean lab.

103. APS would assign one of its pathologists to serve as the "medical director" for each lean lab. The APS medical director of each lean lab was responsible for establishing histology protocols for the lean lab, validating equipment, and handling CLIA and routine lab inspections. APS medical directors were also responsible for reviewing daily quality control slides from each lean lab, monitoring the quality of H&E slides and special stains from each lean lab, and following up with histotechnicians to address any quality concerns. Each pathologist at APS would be assigned as medical director for up to five lean labs at a time.

104. When a gastroenterology practice hosting an APS lean lab performed a biopsy on a patient, a histotechnician in the lean lab would use that biopsy specimen to prepare and stain slides (i.e., would perform the technical component of staining services). The histotechnicians (who had been recruited and trained by APS) performed their work pursuant to laboratory protocols designed and implemented by APS. These protocols instructed the histotechnicians which stains and special stains should be ordered based on the part of the gastrointestinal system that a particular biopsy came from. For example, the APS protocol provided that any time a

patient had a biopsy taken from his or her esophagus, the lean lab histotechnician should automatically prepare an AB-PAS special stain slide in addition to the routine H&E slide for that specimen. The lean lab histotechnicians had no ability to determine which stains to order for a particular patient; instead, they were required to simply follow APS's protocol.

105. APS provided ongoing operational assistance and support to its lean labs. Depending on the needs of the particular lean lab, this included maintaining the lab's certifications; overseeing compliance with laboratory policies; supervising and providing coverage for histotechnicians staffing the lean lab; assisting with maintenance, repair, and replacement of lab equipment; providing free or reduced-price laboratory supplies to the lean lab; providing storage of specimen blocks and slides; and maintaining an electronic data system used by the lean lab.

106. In exchange for these services that APS provided in connection with the buildout and management of the lean labs, APS only required the gastroenterology practice to pay APS a one-time "consulting fee" in the amount of $10,000 and a monthly "medical director fee" in the amount of $1,000. As discussed further below, *see* ¶¶ 115-126, the consulting fee and medical director fee did not represent the fair market value of the services APS provided. And in some cases, APS did not even collect the full fees.

107. In reality, the services that APS provided were unlawful remuneration to the gastroenterology practices to refer their pathology patients back to APS. The Lean Lab Agreements expressly required the gastroenterology practices to exclusively refer their pathology patients to APS. This meant that after the biopsy specimen was stained in the lean lab, the gastroenterology practice would ship the stained slides to APS's laboratory in North Little Rock. Once the slides arrived, an APS pathologist would review and interpret the slides, and APS

would bill insurers for the professional component of the stain services. For many patients, APS would also perform additional immunohistochemical stains, and bill insurers for performing those stains globally (i.e., for both the technical and professional components).

108. This arrangement was extremely lucrative for the gastroenterology practices hosting lean labs and for APS.

109. The gastroenterology practices made significant revenue by billing for the technical component of staining services. Meanwhile, they incurred significantly reduced costs in operating the lean lab because APS defrayed those expenses by functionally building and running the lab. The only significant costs incurred by the gastroenterology practice were (i) the initial investment in laboratory equipment (but APS would often help broker discounted equipment); (ii) putting one or more histotechnicians on the practice's payroll (but APS would handle recruitment and training of the histotechnicians); and (iii) paying a $10,000 one-time consulting fee and the $1,000 monthly medical director fee (but as discussed below, those fees did not reflect fair market value and in some cases APS would reduce, waive, or simply not collect them).

110. Through this scheme, APS generated a stream of patient referrals. Rather than sending biopsy samples to a local hospital or other laboratory for staining, APS induced gastroenterology practices around the country to instead ship their samples to APS, so that APS could bill for the professional component of the stains and perform additional immunohistochemical stains.

C. APS Provided Unlawful Kickbacks to Gastroenterology Practices Hosting Lean Labs in Exchange for Patient Referrals

1. APS Provided Gastroenterology Practices With Remuneration

111. A key component of the lean lab arrangement involved APS providing kickbacks to gastroenterology practices to induce the providers to refer their patients, including Medicare beneficiaries, to APS.

112. APS furnished gastroenterology practices with kickbacks at every step of the way. When a gastroenterology practice agreed to host an APS lean lab in its office, APS provided goods and services to support the design, construction, and setup of the lab, as described above in paragraph 102. And once the lean lab was active, APS continued to provide goods and services, including medical director services, as well as operational and management support, as described above in paragraphs 103-106.

113. As Defendant Hannah explained it in a 2022 presentation, "APS will set everything up, assume the role as medical director, and be fully responsible for all areas of the lab . . . . APS will store all of the blocks at no charge. APS will additionally provide vacation coverage, training, EMR [electronic medical record software] integration, and handle all lab inspections."

114. While APS purported to charge lean lab customers a one-time "consulting fee" of $10,000, this fee was a sham. APS conducted no fair market value analysis before setting this fee, and although different customers had different buildout requirements, the fee did not change based on the needs of the particular lab. APS did not adjust the fee based on costs associated with the lean lab's geographic location (although it sometimes would consider simply whether a lab was located within or outside the State of Arkansas), nor did APS adjust the fee over time to

account for inflation. APS never agreed to build a lab for a gastroenterology practice that did not also plan to enter into a Lean Lab Agreement and refer all of its pathology patients to APS.

115. The real reason APS included the consulting fee in its Lean Lab Agreements was to conceal improper kickback relationships between APS and the gastroenterology practices.

116. APS and its owners knew that the services and benefits they provided to their lean lab customers amounted to kickbacks, so they included the consulting fee in the Lean Lab Agreements to make the relationship appear to be an arm's length transaction. When one potential customer questioned the consulting fee, an APS representative explained that the company "[had] to charge something legally or it could be considered a Stark [physician self-referral law] violation." On another occasion, Mr. Hannah wrote that "we must make a profit on the consulting and set up of these[] labs or else we will be seen as giving a kick back or inducement for business."

117. In January 2016, Relator and former APS owner Watkins emailed Defendant Pledger and explained that the consulting fee and medical director fee were "set and non-negotiable." Watkins wrote that these are "fixed fees because APS has to show a reasonable profit on a LeanLab installation in order to comply with the Stark Anti-Kickback Legislation." Watkins went on to say that "APS is not allowed to give away any equipment, supplies or other tangible items which may be interpreted by CMS or the OIG as an incentivization. This is extremely important because we are dealing with government payors on both our side and the physician group side when we install a LeanLab." Watkins asked Pledger to respond "that you understand and will comply with this policy so APS will have a record in the event of a CMS audit." Pledger responded: "I agree."

118. In April 2018, Defendants Hannah, Burkett, and Pledger had an email discussion about reducing the consulting fee charged to a potential lean lab customer. Burkett asked Hannah and Pledger for "direction on what to change the consulting fee to without getting us in trouble for not charging enough."

119. Despite this understanding, APS and its owners would routinely reduce or waive the consulting fee to secure clients. APS and its owners were willing to do so because the consulting fee was meaningless to them; instead, the entire value of the Lean Lab Agreements lay in patient referrals, and APS and its owners were willing to secure those referrals by any means necessary.

120. As Mr. Hannah put it in an email, "I really could care less about the $10,000 fee." Mr. Hannah then directed an employee to keep that customer's consulting fee at $10,000 "on paper" in the contract, but to invoice the provider for only $5,000 "and send them some 'paid in full' paperwork once we get that." "Bottom line, ourselves and [the gastroenterology practice] will make a lot of revenue from this partnership," Hannah explained, "and we don't need to hold it up over a couple thousand dollars." In another instance, an APS employee directed a lean lab customer to cross out the consulting fee listed in the Lean Lab Agreement and write in a fee of only $2,500 instead. Other Lean Lab Agreements simply had the consulting fee paragraph struck in its entirety:

2.2 Payment.

(a.) **Signing Payment; Installation Fee.** As compensation for APS's consulting services, ARKANSAS GASTROENTEROLOGY P.A. shall agree to pay to the non-refundable sum of TEN THOUSAND DOLLARS AND NO CENTS ($10,000.00) via certified check. ARKANSAS GASTROENTEROLOGY P.A. will pay the fee in four (4) monthly installments of TWO THOUSAND FIVE HUNDRED DOLLARS AND NO CENTS ($2,500.00). Immediately upon the execution of this agreement, ARKANSAS GASTROENTEROLOGY P.A. will pay the first monthly installment. Subsequent installments are due upon receipt of invoice.

121. Even when APS collected the full one-time $10,000 consulting fee from a lean lab customer, the fee did not cover the value of the benefits the gastroenterology practices received from APS.

122. Similarly, APS did not conduct any fair market value analysis before setting the monthly medical director fee and did not adjust the fee based on market rates or to account for inflation. When one lean lab customer decided to leave APS and operate its own pathology lab instead, it incurred more than $2,000 per month in medical directorship costs, i.e., more than double the amount (or more than a $12,000 increase annually) compared to what APS had charged.

123. APS often allowed gastroenterology practices to lapse on the monthly medical director fee payments; for example, APS records from September 2021 reflected that at least ten providers had skipped at least one monthly payment of the medical director fee.

124. Like the consulting fee, APS had no interest in making money from the medical director fee. In fact, APS would pass the medical director fees on in full to the pathologist serving as medical director and did not retain any of the fees for itself. Instead, APS furnished the lean labs with medical director services in order to secure a pipeline of patient referrals.

125. Even when APS collected a one-time consulting fee and a monthly medical director fee from a gastroenterology practice customer, APS did not charge or collect any fee for the ongoing operational support it provided to the lean labs in addition to medical director services. This included, for example, lab supplies and equipment, shipping supplies and services, the electronic laboratory information system, and long-term physical storage of specimen slides and blocks.

126. The value of these goods and services was significant. When one lean lab customer considered leaving APS and constructing its own in-house, full-service laboratory, it estimated the capital expenses it would incur just to procure block and slide storage to be $10,000, and that it would cost hundreds of thousands of dollars more to implement its own LIS computer software system.

127. The benefits that APS furnished to the gastroenterology practices were not simply the sum of the cost of each item or service APS provided. To be sure, these goods and services individually and collectively constituted improper kickbacks that APS provided the lean labs to induce patient referrals. But in addition, through these goods and services, APS furnished the gastroenterology practices with the apparatus and infrastructure to be able to bill for the technical component of staining services, which allowed the gastroenterology practices to tap into a new revenue stream and reap significant profits from Medicare and other insurers.

128. The gastroenterology practices were able to bill Medicare and other insurers for the hundreds of thousands of dollars (and in some cases, millions of dollars) using lean labs that APS designed, constructed, certified, recruited and trained staff for, provided medical director services for, supported, and managed.

129. APS provided additional kickbacks to the gastroenterology practices as needed to maintain their relationship and ensure ongoing patient referrals. Aside from the kickbacks described above, the additional kickbacks APS provided to its customers varied depending on the needs of the specific lean lab, but included various forms of goods and services. Many of these benefits were not set out in the written Lean Lab Agreements between the gastroenterology practices and APS.

130. As an illustrative example, when one of APS's lean lab customers told APS it might end their relationship, APS's former Director of Pathology, Dr. Nancy Davis, sent an email on August 31, 2020, summarizing and quantifying some of the perks that APS was providing to the gastroenterology practice, and the benefits that would be lost if the practice left APS. Dr. Davis described these as expenses that the gastroenterology practice "may incur upon leaving the umbrella of APS." These included:

a. Savings on reagents and laboratory supplies estimated at $1,500 per month, plus savings on shipping estimated at $500 per month;

b. Savings on preventative maintenance contracts estimated at $4,000 annually;

c. Pay that APS was providing to a histotechnician working in the lean lab estimated at $800 per month;

d. Storage of the slides and blocks used for the lean lab's pathology testing for 10 years; and

e. A laboratory information system computer service with report delivery.

131. Based on Dr. Davis's estimates, the value of these goods and services provided by APS to the gastroenterology practice exceeded $86,000 annually.

132. Dr. Davis shared her analysis with Defendants Hannah and Pledger and described it as a "[l]ast ditch to keep things as they are."

133. Another example is AGA, a lean lab customer based in Atlanta, Georgia. In addition to the benefits APS provided to all lean lab customers, APS also furnished AGA with thousands of dollars worth of Microsoft Surface tablets, barcode scanners, and label printers for use in its lean lab.

134. Additionally, APS hired the daughter of a physician owner of AGA approximately one month before APS and AGA entered into a lean lab relationship. Defendant Hannah emailed a job agreement to the AGA owner's daughter on April 17, 2017, offering her a

job as a fully-remote marketing manager at APS with an annual salary of $180,000. Hannah wrote that he would be the employee's "direct boss" and explained that her compensation was tied directly to the anticipated volume of referrals APS would receive from her father's practice. Hannah explained: "I did have to adjust the amount slightly because AG [Atlanta Gastroenterology] is going to be able to give us a portion of their work but not all of it." Upon information and belief, $180,000 is above fair market value for a similarly-situated employee performing a marketing manager role in North Little Rock. Less than a month later, on May 15, 2017, AGA executed a Lean Lab Agreement with APS and began referring its patients to APS.

135. APS implemented a standing order to provide a practice in Clermont, Florida, with 200 formalin jars every other week. Upon information and belief, APS provided these jars, which can cost more than $1 each, to the practice at no cost, meaning this benefit amounted to hundreds of dollars in supplies each month.

136. APS, including Defendant Pledger, agreed to pay a histotechnician $500 to perform work at a lean lab in Fort Smith, Arkansas.

137. APS, in communications that included Defendant Pledger, agreed to pay for travel and lodging for newly hired lean lab histotechnicians to travel to North Little Rock, Arkansas, and provided in-person training for those histotechnicians.

138. These are representative examples of the kinds of goods, services, and benefits that APS provided to maintain the flow of patient referrals back to APS.

139. APS provided these goods and services at no cost or below fair market value.

140. These kickbacks constituted "remuneration" as used the term is used in the Anti-Kickback Statute.

2. APS and the Gastroenterology Practices Submitted Claims Resulting From APS's Kickbacks

141. APS furnished these benefits to the gastroenterology practices for the purpose of inducing the providers to refer their patients, including Medicare patients, to APS. APS generally did not have its own patient population and instead depended on gastroenterology practices to refer patients to its lab. The cost of the kickbacks to APS was eclipsed by the profits it made in return; APS made far more from patient referrals than it spent on the goods and services it provided to the gastroenterology practices.

142. But for the kickbacks the gastroenterology practices received from APS, the gastroenterology practices would not have referred their patients to APS for APS to perform the professional component of the staining services and additional immunohistochemical stains. Many of the gastroenterology practices had access to closer labs that could have processed patients' biopsy samples without the need to ship those samples to APS in North Little Rock. The gastroenterology practices sent their patients to APS because of the benefits they received from APS under the Lean Lab Agreements (indeed, they were required to do so by the terms of the contracts) and the significant revenue stream of technical component billing they were able to access because of the apparatus and infrastructure APS provided.

3. APS Falsely Certified AKS Compliance to Medicare

143. When APS enrolled in the Medicare program, and to maintain APS's eligibility to receive payment from Medicare for pathology services, Defendants Hannah and Pledger signed CMS Form 855B as Authorized Officials on behalf of APS.

144. Those Form 855Bs included a certification to abide by Medicare laws, regulations and program instructions applicable to APS.

145. Defendants Hannah and Pledger also certified their understanding that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with the AKS.

146. The requirement that claims and their underlying transactions comply with the AKS is material to CMS's decision to pay a Medicare claim.

147. If Defendants Hannah and Pledger had not certified that they and APS would only seek reimbursement for claims based on transactions compliant with the AKS, APS would not have been permitted to enroll in the Medicare program or receive payment for Medicare claims.

148. Defendants Hannah, Pledger, and Burkett all understood that each time APS submitted a claim for payment to Medicare, APS was impliedly certifying compliance with the AKS.

149. In fact, the claims APS submitted were not compliant with the AKS, as described above.

150. Each time APS submitted a claim for payment to Medicare that was based on an improper referral from an APS lean lab, that claim was false.

151. Likewise, each gastroenterology practice operating an APS lean lab needed to sign a Form 855B and certify compliance with the AKS.

152. Claims submitted by those lean labs for the technical component of H&E and special stains submitted by lean labs were false because the claims and the underlying transactions did not comply with the AKS.

D. APS Caused Gastroenterology Practices to Perform and Bill for Unnecessary Testing

153. To further boost profits, APS also directly submitted, and caused the gastroenterology practices hosting lean labs to submit, claims for pathology testing services that were not medically reasonable or necessary.

154. In most cases, a routine H&E stain is sufficient for the pathologist to review and interpret the slide and make findings and potential diagnoses. A pathologist cannot determine if additional special stains are necessary until he or she has reviewed the H&E stain and made that determination based on the particular circumstances of the individual patient. Nonetheless, APS directed the lean labs to prepare special stains at the same time as the H&E stain and without any individualized determination of medical necessity.

155. To be eligible for reimbursement from Medicare, a claim for laboratory testing services must be reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 424.24(g)(1) (requiring certification of medical necessity).

156. The Medicare Claims Processing Manual: Chapter 16 – Laboratory Services § 120.1 advises that: "Tests 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."

157. The pathologist requesting laboratory testing must also document the medical necessity of the tests he or she orders in the patient record. *See* 42 C.F.R. § 410.32(d)(2)(1).

158. Guidance issued by Medicare Administrative Contractors ("MACs") provides guidance on the circumstances in which ordering special stains is generally medically reasonable and necessary. Local Coverage Determinations ("LCDs") issued by MACs Palmetto, Noridian,

CGS Administrators, and Wisconsin Physician Services Government Health Administrators regarding the appropriate use and billing for special stains all include nearly identical language:

- "Most normal and abnormal conditions of these organs can be detected by the use of routine H&E stain alone."
- "Ordering special stains or [immunohistochemical] stains prior to review of the routine H&E stain is not reasonable or necessary."
- "Only the pathologist may determine the medical necessity of a special stain."
- If additional stains beyond the H&E stain are needed, "specific documentation to justify the medical necessity for the stain is required in the pathology report."

159. A Medicare claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary.

160. Ordering special stains (i) automatically at the same time an H&E stain is ordered, (ii) without a pathologist review of the H&E stain, and (iii) without any determination by a pathologist that a special stain is appropriate for a particular patient's circumstances nor documentation of the reason for additional stains in the medical record fails to establish a justification for why the special stain is reasonable or necessary and will rarely, if ever, be medically necessary. But that's exactly what APS did.

1. APS Implemented a Reflexive Special Stain Protocol Designed to Automatically Order Extra Testing

161. APS and its owners orchestrated the widespread ordering of unnecessary testing through the use of a "special stain protocol" implemented across all of its lean labs. Specifically, at each APS lean lab, the APS pathologist serving as medical director of the lean lab would implement a staining policy created by APS that directed the histotechnicians working in the lean lab to automatically order special stains for patients based only on the part of the body the biopsy specimen came from.

162. The APS special stain protocol was a blanket or reflex order, meaning that it directed histotechnicians to prepare special stains automatically, without pathologist review and without any consideration of the patient's individual circumstances.

163. For example, the special stain protocol provided that all specimens from the esophagus, GE junction, or Z line were to automatically receive an AB-PAS special stain in addition to a routine H&E stain.

164. The special stain protocol provided that all gastric biopsy specimens, including specimens from the antum, body, or GE junction were to automatically receive a Giemsa special stain in addition to a routine H&E stain.

165. The special stain protocol provided that all colonic mucosal biopsies were to be automatically stained with a Trichrome special stain in addition to a routine H&E stain.

166. APS provided lean labs with "cheat sheets" to instruct histotechnicians which special stains should be performed upfront for specimens collected from particular parts of the patient's body.

SLIDE LABELS:

DiffQuick= DQ

ALCIAN BLUE/PAS 2.5= ABPAS

TRICHROME= T or TRI or 3C

H. PYLORI IHC= HP IHC

GI SPECIAL STAINS: ***1 HP IHC per case***

GASTRIC/STOMACH ULCER***	DQ	ABPAS	HP
ANTRUM**	DQ	ABPAS	HP
STOMACH*	DQ	ABPAS	HP
GASTRIC *	DQ	ABPAS	HP
BODY*	DQ	ABPAS	HP
FUNDUS*	DQ	ABPAS	HP
CARDIA*	DQ	ABPAS	HP
GE JUNCTION	DQ	ABPAS	⊘
Z-LINE	DQ	ABPAS	⊘
GASTRIC POLYP	DQ	ABPAS	⊘
GASTRIC MASS/NODULE/ ANASTOMOSIS	DQ	ABPAS	⊘
ESOPHAGUS		ABPAS	
DUODENUM		ABPAS	
SMALL BOWEL		ABPAS	
AMPULLA		ABPAS	

*** Gastric Ulcer #1 pick
**Antrum #2 pick
*Choose first gastric bx

COLON: *ONLY if the following apply*			
R/O Microscopic colitis			TRI
Pre op diarrhea			TRI
Pre of bloody stool			TRI

Ø Do not do a TRI if history of Crohns or ulcerative colitis or polyps

167. The lean labs would prepare the special stain slides at the same time as the routine H&E slides and would send all of the slides to APS together. No pathologist review occurred prior to the ordering and preparation of the special stain slides.

168. The gastroenterology practice hosting the lean lab would then bill insurers for the technical component of the special stain slides that were prepared following the APS protocol, using CPT codes 88305 for H&E stains and 88312 or 88313 for special stains. The gastroenterology practices would include a modifier code in the claims to indicate they were billing for only the technical component.

169. APS caused the lean labs to submit claims for special stains that were prepared concurrently with H&E slides, without pathologist review, and without any determination that a

special stain was reasonable or necessary for a particular patient. As a result, APS engaged in a widespread practice that caused the lean labs to submit claims for services that were not medically reasonable or necessary, were not eligible for coverage or reimbursement by Medicare, and were false.

170. Once the stained slides arrived at APS, an APS pathologist would review the slides, and APS would bill for the corresponding professional component of the stain service. APS submitted claims for special stains that were prepared, reviewed, and interpreted concurrently with H&E slides, without any determination that a special stain was reasonable or necessary for a particular patient, and without documentation justifying the special stains in the medical record. As a result, APS submitted claims for payment for the professional component of services that were not medically reasonable or necessary, were not eligible for coverage or reimbursement by Medicare, and were false.

2. APS Automatically Ordered Additional Immunohistochemical Stains

171. Additionally, once the biopsy specimens from the lean labs arrived at APS's lab, APS would often perform even more stains on the patient biopsy specimens to generate additional revenue.

172. APS had the capacity to perform immunohistochemical stains, a high-complexity stain that lean labs could not perform. APS also had in place a protocol of automatically performing immunohistochemical stains on certain specimens. Like the special stains, APS ordered the immunohistochemical stains on an automatic or reflexive basis, and without an individualized determination by a pathologist that the immunohistochemical stain was reasonable or necessary for an individual patient based on their particular circumstances.

173. APS would bill Medicare and other insurers for immunohistochemical stains using CPT codes 88341 and 88342.

174. Because APS billed for both the technical and professional component of the immunohistochemical stains, these stains constituted a large source of revenue for APS.

175. Upon information and belief, APS would order and perform the immunohistochemical stains prior to pathologist review of the patient's H&E or special stain slides.

3. The Special and Immunohistochemical Stains APS Ordered Were Not Medically Reasonable or Necessary

176. The APS medical reports prepared by the pathologists would not reflect any individual assessment of a patient's circumstances that might justify the special stains. Often, they did not even indicate whether the H&E stain had been reviewed or what the findings were.

177. Because the special stain and immunohistochemical stain services were not reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury, those services were not eligible for coverage or reimbursement by Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 424.24(g)(1) (requiring certification of medical necessity). As a result, APS submitted claims for immunohistochemical stains that were not medically reasonable or necessary, were not eligible for coverage or reimbursement by Medicare, and were false.

178. Because APS ordered the special and immunohistochemical stains prior to review of the patient record or the routine H&E stain, those tests were performed "in the absence of signs, symptoms, complaints, personal history of disease, or injury." As a result, APS submitted claims for immunohistochemical stains that were not medically reasonable or necessary, were not eligible for coverage or reimbursement by Medicare, and were false.

179. Because the APS pathologist ordering the special and immunohistochemical stains did not document the medical necessity of those tests in the patient record, those services

were not eligible for coverage or reimbursement by Medicare. *See* 42 C.F.R. § 410.32(d)(2)(1). As a result, APS submitted claims for immunohistochemical stains that were false.

180. APS pathologists knew that the upfront ordering of special stains was not reasonable or necessary, and that doing so violated Medicare coverage requirements and subjected APS to denials from insurers.

181. On January 24, 2019, APS Director of Pathology Nancy Davis emailed other APS pathologists and told them she was working on an "Evidence Based Black Book" to "combat insurance audits and LCD's." Dr. Davis asked the other pathologists to choose a special stain and "find some chapters or literature or something to justify the stain use . . . . No matter how minimal, just anything that is published somewhere or abstracts or whatever." When another pathologist asked Dr. Davis "What if we decide, upon reviewing the literature, that one or more of the stains is/are not justified?" Dr. Davis responded: "Well this is not really a research project. We are just finding evidence to justify what we do. So don't do that."

182. In other words, Dr. Davis was directing the other APS pathologists to help find after-the-fact justifications for the unnecessary special stains in APS's protocol and would only accept answers that supported APS's desire to automatically order and bill for special stains.

183. Similarly, Dr. Davis and other APS pathologists worked to develop "canned text," which were snippets of text that could be copied and pasted into a pathology report as a purported justification for the stains that had already been ordered. For example, a pathologist could copy and paste canned text stating that "Due to the clinical request to exclude H. pylori, this specimen was evaluated with a Giemsa special stain to to [sic] increase sensitivity for detection of the organism." This canned text misleadingly suggested that the pathologist ordered

a Giemsa special stain based on a clinical assessment of the patient's record. In fact, Giemsa stains were ordered automatically for certain samples based on APS's special stain protocol.

184. The following paragraphs describe several examples of Medicare Part B beneficiaries who received unnecessary special stains and/or immunohistochemical stains performed by APS and lean labs following APS's special stain protocol.[2]

185. **Patient A.** Patient A had two biopsy samples prepared by an APS lean lab in Atlanta, Georgia, on November 19, 2019. One biopsy sample was from the duodenum and one was from the gastric antrum. Following the APS special stain protocol, the lean lab prepared and billed for the technical component of an H&E stain and an AB-PAS special stain for the duodenum biopsy sample, and prepared and billed for the technical component of an H&E stain, an AB-PAS stain, and a Giemsa stain for the gastric antrum biopsy sample. The gastroenterology practice submitted claims to Medicare for these services on December 3, 2019, and received a total payment of $201.82.

186. Once APS received the samples, it performed and billed for the corresponding professional component of the H&E and special stains. APS also performed and billed for an additional immunohistochemical stain for the gastric antrum sample. APS submitted claims to Medicare for these services on November 25, 2019, and received a total payment of $175.39.

187. The APS pathologist who reviewed the specimens wrote that the duodenum biopsy revealed mucosa with no diagnostic abnormality and normal villous architecture with no evidence of Celiac sprue. The APS pathologist then wrote "Alcian blue/PAS stain to identify gastric foveolar metaplasia and Whipple's disease is negative; no parasites are seen."

---

[2] To protect the privacy of patient health information, the Complaint refers to these patients pseudonymously. The United States has separately provided the names of the patients to Defendants.

188. Patient A's pathology report offers no discussion of the H&E stains and no indication that the pathologist reviewed those stains and then determined that the AB-PAS stains were appropriate for Patient A. While the report references that the AB-PAS stain of the gastric antrum was used to rule out Whipple's disease, there is nothing in the report suggesting that the pathologist thought that Patient A might have Whipple's disease, an extremely rare condition affecting approximately nine in one million people. Nor does the pathology report explain why an additional immunohistochemical stain was necessary to confirm the negative H. pylori result from the Giemsa stain. These special and immunohistochemical stains were not medically reasonable or necessary.

189. **Patient B.** Patient B had six biopsy samples collected in Shawnee, Kansas, on February 20, 2018, from the duodenum, gastric antrum, gastric body, distal esophagus, gastric fundus polyp, and mid esophagus. An APS lean lab following APS's special stain protocol performed and billed for the technical component for an H&E stain for each of the six biopsies, an additional AB-PAS special stain for each of the six biopsies, and an additional Giemsa special stain for three of the six biopsies. The gastroenterology practice submitted claims to Medicare for these services on March 14, 2018, and received a total payment of $509.19.

190. When APS received the specimens, it performed and billed for the corresponding professional component of the H&E and special stains. APS also performed and billed for an additional immunohistochemical stain on the gastric antrum biopsy. APS submitted claims to Medicare for these services on February 23, 2018, and received a total payment of $377.35.

191. A total of six H&E stains, nine special stains, and one immunohistochemical stain were performed on Patient B's biopsy specimens. The nine special stains were prepared by the lean lab before an APS pathologist reviewed a single H&E slide for Patient B.

192. The pathology report for Patient B offers no indication that the APS pathologist reviewed the H&E stains or determined that the AB-PAS special stains, Giemsa special stains, or immunohistochemical stain were necessary for Patient B. The pathology report notes normal and negative findings for all of the routine, special, and immunohistochemical stains. The report does not offer an explanation, for example, as to why APS needed to order an H&E stain, Giemsa special stain, and immunohistochemical stain on Patient B's gastric antrum biopsy sample when there is no indication that any of those stains identified H. pylori organisms. These special and immunohistochemical stains were not medically reasonable or necessary.

193. **Patient C.** Patient C had a biopsy sample from the gastric antrum collected in Atlanta, Georgia, on November 19, 2019. An APS lean lab following APS's special stain protocol performed and billed for the technical component for an H&E stain, an additional AB-PAS special stain, and an additional Giemsa special stain for Patient C's biopsy. The gastroenterology practice submitted claims to Medicare for these services on December 3, 2019, and received a total payment of $129.95.

194. When APS received the specimen, it performed and billed for the corresponding professional component of the H&E and special stains. APS performed and billed for an additional immunohistochemical stain on Patient C's biopsy. APS submitted claims to Medicare for these services on November 25, 2019, and received a total payment of $136.33.

195. A total of one H&E stain, two special stains, and one immunohistochemical stain were performed on Patient C's biopsy specimens. The two special stains were prepared by the lean lab before an APS pathologist reviewed a single H&E slide for Patient C.

196. The pathology report for Patient C offers no indication that the APS pathologist reviewed the H&E stain or determined that the Alcian Blue special stain, Giemsa special stain, or

immunohistochemical stain were necessary for Patient C. The pathology report notes normal and negative findings for all of the routine, special, and immunohistochemical stains. The report does not offer any explanation as to why APS needed to order an AB-PAS stain, a Giemsa special stain, or an immunohistochemical stain on Patient C's biopsy sample when there was no indication that any of those stains identified a cause for concern or need for further testing. These special and immunohistochemical stains were not medically reasonable or necessary.

197. **Patient D.** Patient D had biopsy samples from the mid esophagus, distal esophagus, gastric antrum, and duodenum collected in Lafayette, Louisiana, on February 20, 2018. An APS lean lab following APS's special stain protocol performed and billed for the technical component for an H&E stain for each biopsy, an additional AB-PAS special stain for each biopsy, and an additional Giemsa special stain for the gastric antrum biopsy. The gastroenterology practice submitted claims to Medicare for these services on February 26, 2018, and received a total payment of $299.70.

198. When APS received the specimens, it performed and billed for the corresponding professional component of the H&E and special stains. APS also performed and billed for an additional immunohistochemical stain on Patient D's gastric antrum biopsy. APS submitted claims to Medicare for these services on February 26, 2018, and received a total payment of $256.70.

199. A total of four H&E stains, five special stains, and one immunohistochemical stain were performed on Patient D's biopsies. The five special stains were prepared by the lean lab before an APS pathologist reviewed a single H&E slide for Patient D.

200. The pathology report for Patient D offers no indication that the APS pathologist reviewed the H&E stain or determined that the AB-PAS special stain or Giemsa special stain

were necessary for Patient D. The pathology report notes normal and negative findings for all of the routine and special stains, except for the stains associated with the gastric antrum biopsy. The report does not offer an explanation as to why APS needed to order both an H&E stain and an AB-PAS stain for each of Patient D's biopsy samples, nor why APS needed to order a Giemsa special stain on Patient D's gastric antrum biopsy. The pathology report for the gastric antrum biopsy notes that the Giemsa stain identified chronic and active gastritis with H. pylori organisms. But the pathology report does not indicate whether the H. pylori organisms could be observed on the H&E slide, nor does it explain why an additional immunohistochemical stain needed to be performed to confirm the findings on the Giemsa stain. These special stains and immunohistochemical stain were not medically reasonable or necessary.

201. **Patient E.** Patient E had biopsy samples from the gastric body, distal esophagus, and proximal esophagus collected in Saint Louis, Missouri, on July 23, 2021. An APS lean lab following APS's special stain protocol performed and billed for the technical component for an H&E stain for each biopsy, an additional AB-PAS special stain for each biopsy, and an additional Giemsa special stain for the gastric body biopsy. The gastroenterology practice submitted claims to Medicare for these services on August 23, 2021, and received a total payment of $309.05.

202. When APS received the specimens, it performed and billed for the corresponding professional component of the H&E and special stains. APS also performed and billed for an additional immunohistochemical stain on Patient E's gastric body biopsy. A total of three H&E stains, four special stains, and one immunohistochemical stain were performed on Patient E's biopsy specimens. The four special stains were prepared by the lean lab before an APS

pathologist reviewed a single H&E slide for Patient E. APS submitted claims to Medicare for these services on July 28, 2021, and received a total payment of $208.55.

203. The pathology report for Patient E offers no indication that the APS pathologist reviewed the H&E stains or determined that the AB-PAS special stains, Giemsa special stain, or immunohistochemical stain were necessary for Patient E. The pathology report notes normal and negative findings for all of the routine, special, and immunohistochemical stains. The report does not offer any explanation why APS needed to order an H&E stain, an AB-PAS stain, a Giemsa special stain, and an immunohistochemical stain on Patient E's gastric body biopsy sample when there is no indication that any of those stains identified a cause for concern or need for further testing. These special and immunohistochemical stains were not medically reasonable or necessary.

204. APS also submitted and caused lean labs to submit claims for beneficiaries of Medicare Advantage. For example, on or about June 27, 2019, an APS lean lab following APS's special stain protocol performed and billed for the technical component two H&E stains and two special stains on biopsies taken from Patient F. The gastroenterology practice submitted claims to Patient F's UnitedHealth Medicare Advantage plan for these services on or around August 1, 2019. When APS received the specimens, it performed and billed for the corresponding professional component of the H&E and special stains. APS also performed and billed for an additional immunohistochemical stain. A total of two H&E stains, two special stains, and one immunohistochemical stain were performed on Patient F's biopsy specimens. The two special stains were prepared by the lean lab before an APS pathologist reviewed a single H&E slide for Patient F. APS submitted claims to Patient F's Medicare Advantage plan for these services on or around July 24, 2019.

205. These special and immunohistochemical stains were not medically reasonable or necessary.

206. In addition to being false because they were not medically reasonable or necessary, the claims APS submitted for Patients A-F were also false for the independent reason that they were referrals from APS lean labs resulting from the kickback relationship between APS and the gastroenterology practice. Thus, these claims were also false because they arose from violations of the AKS and because APS falsely certified to CMS that the claims and the underlying transactions complied with the AKS.

4. APS Financially Incentivized Its Pathologists and Its Lean Lab Customers to Order Large Numbers of Medically Unnecessary Stains

207. APS heavily incentivized its pathologists to review and bill for as many slides as possible by paying pathologists lucrative "slide bonuses" based on the number of slides they reviewed.

208. For example, Director of Pathology Nancy Davis received a per-slide bonus of $8 for every slide she reviewed in a month over a base number of 4,000 slides. Dr. Davis reviewed as many as 700 slides a day and spent as little as two seconds reviewing each slide. APS paid Dr. Davis approximately $1 million annually, approximately 60% of which (i.e., $600,000) was based on slide reading (or "production").

209. Other APS pathologists received similar per-slide bonuses and were also compensated at or around $1 million annually.

210. Only "billable slides" were eligible for determining the pathologists' compensation. A "billable slide" was a slide that was associated with a particular CPT code and billing entry. Thus, APS ensured that its pathologists had a personal financial incentive not to

discard slides or review H&E slides and make a determination that special stain slides were medically unnecessary.

211. The special stain protocol, and the unnecessary special stains that resulted from the protocol, was also a key component of APS's lean lab kickback scheme. Because APS enabled the gastroenterology practices hosting lean labs to bill for the technical component of the special stain procedures, the inflated number of stains that APS lean labs ordered meant that the gastroenterology practices hosting those lean labs would profit by billing for the technical component of the medically unnecessary special stains, while APS would profit by billing for the corresponding professional component of the unnecessary stains.

212. This meant that APS was able to entice gastroenterology practices to sign up for Lean Lab Agreements by offering them inflated profit projections based on the unnecessary stains the lean lab would perform using the APS special stain protocol.

213. APS and its owners knew this. When APS and its owners approached a potential lean lab customer, they used projections assuming that the gastroenterology practice would significantly increase the volume of special stains it ordered if it switched to APS and used its special stain protocol.

214. There is no legitimate reason why a gastroenterology practice that switched from, for example, sending its biopsy specimens out to a lab at a local hospital for staining to partnering with APS and hosting a lean lab should see a significant increase in the volume of stains performed. But that's exactly what would happen when a gastroenterology practice agreed to work with APS.

215. For example, when an APS pathologist made a marketing pitch to a gastroenterology practice located in Oklahoma City, Oklahoma, about the prospect of opening a

lean lab, the pathologist included two projections in the meeting: one in which the gastroenterology practice could increase its revenue by $1 million annually using its current biopsy metrics, and another where the practice would increase its revenue by $3 million if it changed its special stain protocols to match APS's other customers.

216. After APS presented to the practice group, one of the group's physicians sent around a link to CMS guidance regarding special stains and wrote: "I share the similar concern about unnecessary use of special stains in the normal biopsy specimen to improve the bottom line." Another physician asked: "Are we leaving money on the table or are they [APS] expecting us to upcharge path services for no clinical gain?" This feedback was later shared with pathologists at APS.

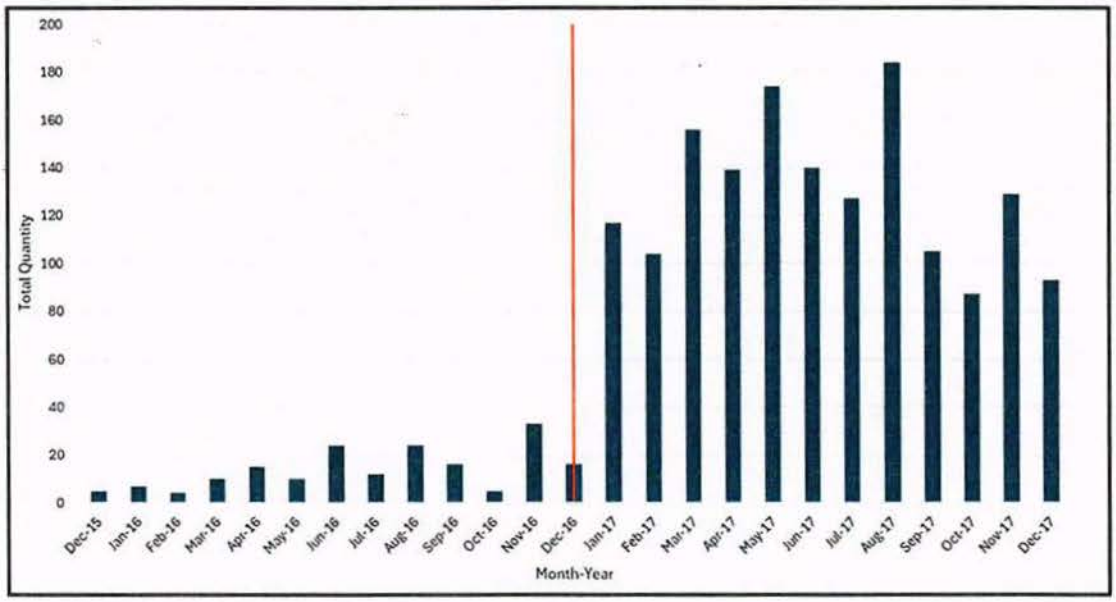
217. On another occasion in January 2019, APS pathologists discussed presenting to a gastroenterology practice about "best practice recommendations," a presentation that "usually also directly leads to increased specimen counts as the drs start trying to follow the recommendations." More specimens meant more stains, which meant more revenue for both the gastroenterology practice and APS.

218. Later that month, an APS pathologist told Relator Denise Aucoin that the pathologist and Dr. Davis were "trying to roll out some useful marketing material for current clients aimed at increasing their biopsy numbers." The pathologist explained that Defendant Pledger "mentioned to me yesterday that you first want to increase productivity from our current customers as 'the best customers are the ones you already have.'"

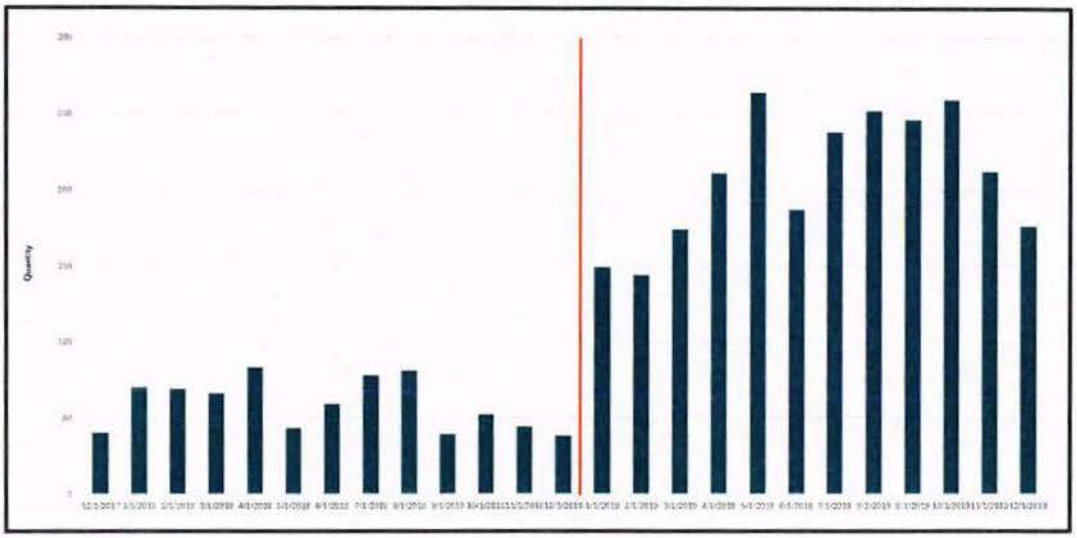
219. On another occasion, an APS employee discussing a potential lean lab customer sent an email, including to Defendant Hannah, saying that the provider "will have to move to our biopsy protocol because those numbers are too low for a Lean Lab."

220. APS's efforts were successful. There was a direct, causal connection between a gastroenterology practice entering into a Lean Lab Agreement with APS and an increase (often a dramatic increase) in the volume of special stains that the gastroenterology practice ordered.

221. The following charts show the claims volume for special stains associated with patients who visited two gastroenterology practices over time, based on claims submitted to Medicare Part B. The vertical axis (y-axis) represents the volume of special stains (CPT codes 88312 and 88313) ordered for patients of the gastroenterology practice within 14 days of a visit to that gastroenterology practice, and the horizontal axis (x-axis) represents time. The vertical line represents the approximate date the gastroenterology practice entered into a Lean Lab Agreement with APS.



Gastroenterology Practice A (Shawnee, KS)



Gastroenterology Practice B (Fayetteville, AR)

222. But for the kickbacks APS provided to the gastroenterology practices, and the outsized revenue APS projected for those practices because of the unnecessary procedures included in its special stain protocol, the gastroenterology practices would not have referred their patients to APS.

223. But for APS directing the gastroenterology practices to perform unnecessary special stains, the gastroenterology practices would not have billed Medicare for the technical component of those unnecessary stains.

224. And but for the APS Lean Lab Agreements, which required the gastroenterology practices to exclusively refer their patients to APS in exchange for the kickbacks provided under the agreement, APS would not have billed for the professional component of the special stain services, nor performed and billed for additional immunohistochemical stains on the lean lab patients' biopsy samples.

225. In this way, APS was also able to stifle competition from other pathology service providers who were unwilling to perform unnecessary special stains just for the sake of increasing revenue.

226. In one instance, APS reached out to a gastroenterology practice in Little Rock, Arkansas, that had been using a competitor pathology laboratory and tried to solicit their business. Although the gastroenterology practice had been ordering special stains in approximately 8.4% of cases with its current laboratory provider, APS sent the gastroenterology practice financial models estimating that the practice could make approximately $1 million more annually if it switched to APS, based on an assumption that its special stain rate would increase from 8.4% to 53%.

227. Pathology laboratories that were only willing to order special stains that are reasonable and necessary could not fairly compete with the financial projections offered by APS, which were based on special stain rates unsupported by medical necessity.

E. APS Lean Labs Suffered Quality Control Issues

228. One challenge the APS lean labs suffered as a result of being managed by medical directors who were not on-site, were responsible for running up to five lean labs at once, and were reading up to 700 slides per day, was frequent quality control issues.

229. For example, an APS lab manager raised three quality control issues that arose at the AGA lean lab in Atlanta, Georgia, after two blocks of patient biopsy specimens went missing. The APS lab manager wrote that this "seems to be a pattern lately" and that she had had to discuss similar issues "multiple times."

230. On February 8, 2019, an APS pathologist emailed an APS lab manager and Dr. Davis about "bugs" in an APS lean lab. The pathologist wrote that there is "some sort of organism growing" in the lab and that she could "see it all over the slides for all the stains." She speculated it was caused by a "contaminated water bath."

231. On September 10, 2019, an individual associated with a lean lab wrote to Defendants Pledger, Hannah, and Burkett, saying that they were "losing a lot of tissue" in the

lab. "Potential cancer is being cut through and used up before we even see the H&E." The employee said she was "really concerned about patient care going forward with this . . . I'm afraid we're going to miss a lot of diagnoses, and be unable to work up malignancies as necessary."

232. On December 23, 2022, an APS pathologist shared an email thread with other APS pathologists about a lean lab that was having repeated issues with specimen mix-ups and could not keep up with the volume of samples. The pathologist wrote: "This lab has been a huge cluster F."

233. As these and other incidents demonstrate, gastroenterology practices were not choosing APS because it provided the highest level of service. Rather, the gastroenterology practices partnered with APS because of the financial benefits APS offered and because of the profitability of the lean lab model that APS designed, which was driven by kickbacks and unnecessary testing.

F. APS and Its Owners Knew and Repeatedly Ignored Complaints That Its Business Practices Were Illegal

234. Since at least October 2017, APS and its owners knew that its lean lab business model and special stain protocol were unlawful.

235. Time and again, APS and its owners received questions, warnings, and complaints about its special stain protocol, which they downplayed or disregarded.

236. On October 11, 2017, an employee at a gastroenterology practice located in Lafayette, Louisiana, emailed Defendant Pledger with a message saying "we can talk about this in detail today." Attached to the email was a document titled "Pathology Concerns," which said that "Several MACs have issued LCDs for pathology claims. Listed below is a sample of the policy." The remainder of the document outlined relevant language from the LCDs, including

statements that "[o]rdering special stains or IHC [immunohistochemical] stains prior to review of the routine H&E stain is not reasonable or necessary," "it is not usually reasonable and necessary to perform special stains or IHC to determine the presence of H. pylori organisms," and "[i]f special stains or IHC are needed in addition to the routine H&E for gastric specimens, specific documentation to justify the medical necessity for the stain is required in the pathology report."

237. In March 2018, Relator Brian Watkins approached Defendants Pledger and Burkett and relayed concerns from a lean lab customer that APS was overutilizing special stains. Upon information and belief, attorneys representing the lean lab customer sent a letter to APS shortly thereafter expressing similar concerns about APS's billing practices.

238. On April 25, 2019, an APS pathologist emailed another APS pathologist about a lean lab customer in Alabama and noted that "Alabama is in the Palmetto Medicare LCD which is the totally nuts one that says special stains should be used on no more than 20% of GI biopsies."

239. On May 2, 2019, the same APS pathologist emailed the other APS pathologists, as well as Defendants Pledger and Burkett, and told them that the Alabama practice would "not be following our normal staining protocol." She explained that the practice would no longer be doing upfront special staining or automatic immunohistochemical stains and told the other pathologists that if they were reviewing slides from that practice, the pathologists should be sure to note a specific justification for any special stains ordered. The pathologist chalked this change up to "internal politics" and a "contentious relationship" instead of acknowledging the conflict between APS's staining protocol and Medicare coverage requirements.

240. On September 3, 2019, APS's Revenue Cycle Management Managing Director sent an email to Defendant Hannah attaching the Palmetto LCD related to special stains and

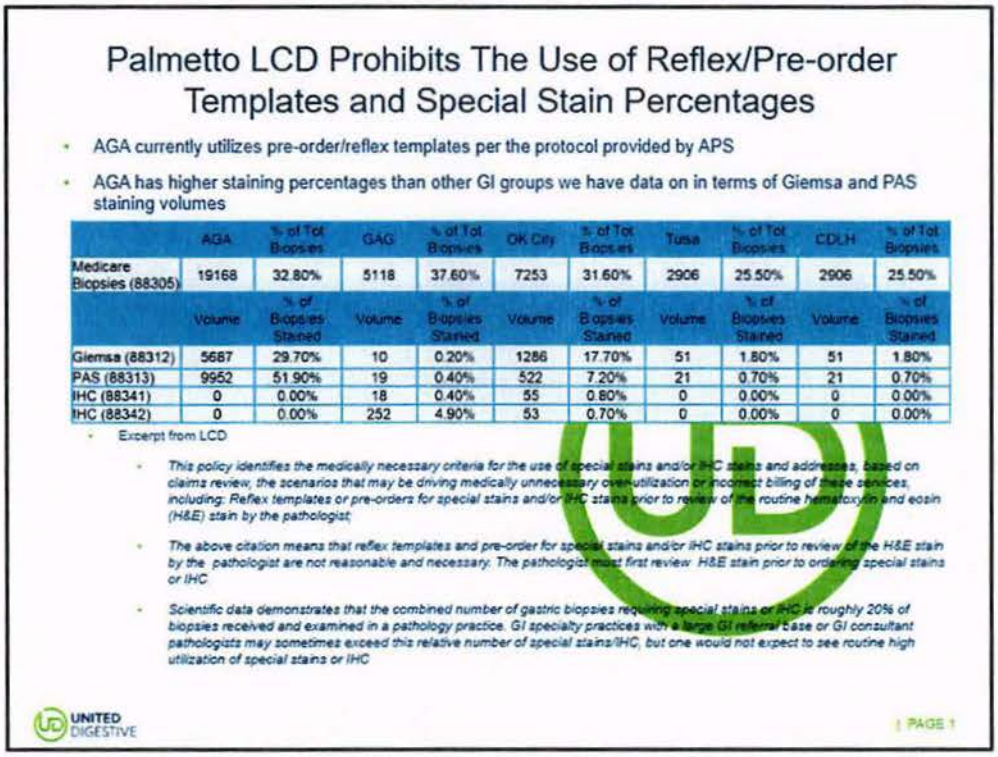
highlighting the section discussing special stains and immunohistochemical stains for gastrointestinal pathology.

241. On September 16, 2019, Relator Denise Aucoin forwarded an email to Defendants Pledger and Burkett from an attorney who had reviewed a Lean Lab Agreement sent to a potential customer. The attorney raised "important questions and issues regarding the arrangement's compliance with the federal anti-kickback statute."

242. Also on September 16, 2019, Defendants Hannah and Burkett, along with other APS employees, met with management from AGA, one of APS's largest lean lab customers. The purpose of the meeting was to address concerns AGA had raised regarding APS's special stain protocol. At the meeting, Defendants Hannah and Burkett agreed to provide AGA with a formal legal opinion supporting the use of reflexive orders and its high utilization of special stains; a letter of indemnification; and results from an audit of a gastrointestinal pathology lab with a similar protocol. Upon information and belief, APS never provided those documents.

243. Defendant Burkett and other APS employees had a follow-up meeting with AGA on October 4, 2019, to further discuss AGA's concerns.

244. On October 9, 2019, Defendants Hannah, Pledger, and Burkett received copies of a PowerPoint presentation made by AGA. The presentation explained how the "Palmetto LCD Prohibits The Use of Reflex/Pre-order Templates and Special Stain Percentages."



Palmetto LCD Prohibits The Use of Reflex/Pre-order Templates and Special Stain Percentages

- AGA currently utilizes pre-order/reflex templates per the protocol provided by APS
- AGA has higher staining percentages than other GI groups we have data on in terms of Giemsa and PAS staining volumes

	AGA	% of Tot Biopsies	GAG	% of Tot Biopsies	OK City	% of Tot Biopsies	Tulsa	% of Tot Biopsies	CDLH	% of Tot Biopsies
Medicare Biopsies (88305)	19168	32.80%	5118	37.60%	7253	31.60%	2906	25.50%	2906	25.50%
	Volume	% of Biopsies Stained	Volume	% of Biopsies Stained	Volume	% of Biopsies Stained	Volume	% of Biopsies Stained	Volume	% of Biopsies Stained
Giemsa (88312)	5687	29.70%	10	0.20%	1286	17.70%	51	1.80%	51	1.80%
PAS (88313)	9952	51.90%	19	0.40%	522	7.20%	21	0.70%	21	0.70%
IHC (88341)	0	0.00%	18	0.40%	55	0.80%	0	0.00%	0	0.00%
IHC (88342)	0	0.00%	252	4.90%	53	0.70%	0	0.00%	0	0.00%

- Excerpt from LCD
  - *This policy identifies the medically necessary criteria for the use of special stains and/or IHC stains and addresses, based on claims review, the scenarios that may be driving medically unnecessary over-utilization or incorrect billing of these services, including: Reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist;*
  - *The above citation means that reflex templates and pre-order for special stains and/or IHC stains prior to review of the H&E stain by the pathologist are not reasonable and necessary. The pathologist must first review H&E stain prior to ordering special stains or IHC*
  - *Scientific data demonstrates that the combined number of gastric biopsies requiring special stains or IHC is roughly 20% of biopsies received and examined in a pathology practice. GI specialty practices with a large GI referral base or GI consultant pathologists may sometimes exceed this relative number of special stains/IHC, but one would not expect to see routine high utilization of special stains or IHC*

UNITED DIGESTIVE

PAGE 1

245. The AGA presentation included data about the rates at which the APS lean lab at AGA ordered special stains compared to other gastroenterology practices. The data presented by AGA showed that, in some instances, by following APS's special stain protocol, AGA's lean lab was ordering special stains over 100 times more frequently than other providers.

246. In October 2019 at a conference in San Antonio, Texas, Relator Denise Aucoin had a conversation with an AGA executive in which the executive told Ms. Aucoin that APS's special stain protocol was illegal. After the discussion between Ms. Aucoin and the executive, Relator Brent Aucoin witnessed a heated discussion between the executive and Defendant Burkett.

247. In December 2019, an APS lean lab customer in Little Rock, Arkansas, emailed a gastroenterology practice located in Yuma, Arizona about their arrangement with APS. The administrator of the Yuma gastroenterology practice asked if the lean labs "follow Medicare rules for all non-Medicare patients for H. Pylori? (pathologist must call medical necessity)" and

asked "do you stain all your gastric cases with H. Pylori but only bill for the medical necessity ones?" The Little Rock gastroenterology practice forwarded the questions to Defendant Pledger, who said that there "is no 'rule' just guidelines that CMS recommends that labs follow in regards to stains."

248. On February 10, 2022, the president of a gastroenterology practice located in Clarkston, Michigan, emailed an APS pathologist and wrote that it was "inappropriate to do special stains on every single upper endoscopy . . . . I strongly request that no special stains would be performed unless request it or absolutely necessary." The APS pathologist forwarded the email to Defendants Pledger and Burkett and asked if they "want[ed] to bother replying."

249. In April 2022, the president of the Clarkston gastroenterology practice had further email correspondence with the APS pathologist concerning the ordering of upfront special stains. The APS pathologist told the president of the practice that the practice could determine "what upfront stains are performed in your lab and when." In fact, the practice was following the APS special stain protocol implemented by the APS medical director and APS had ignored the practice's previous request for APS to stop performing upfront special stains. The pathologist forwarded her email correspondence to Defendant Pledger, who then forwarded the email to Defendant Burkett.

250. On May 31, 2022, an attorney representing the same gastroenterology practice sent a letter to Defendant Hannah terminating the practice's relationship with APS. The attorney wrote that despite the provider's request "that it did not want additional staining performed on specimens unless absolutely needed," APS performed special stains "almost universally on the specimens. . . . APS instructed [the provider's] histotechnician to prep all the slides for special staining and ignored [the provider's] request and CMS guidelines. Eventually during a phone

call, Mr. Donell Burkett, one of the owners of the company, indicated that APS pathologists were not comfortable with [the provider's] request. [The provider] is not comfortable with unnecessary and unethical practices of staining slides and billing insurance companies and patients for the services which are not absolutely indicated."

251. In December 2022, the same gastroenterology practice entered into a settlement agreement with APS. As part of the settlement agreement, APS agreed to pay $18,356 to the gastroenterology practice.

252. On October 23, 2024, APS executed a settlement agreement with a gastroenterology practice lean lab customer located in Shreveport, Louisiana. The gastroenterology practice had been audited by Blue Cross Blue Shield regarding the justification for special stain claims submitted through the provider's lean lab pursuant to APS's special stain protocol. The gastroenterology practice settled with the insurer and sought indemnification from APS. Under the terms of the settlement agreement, APS agreed to pay the gastroenterology practice $147,298.21.

253. In a letter to APS's counsel sent on July 3, 2025, counsel for a gastroenterology practice lean lab customer located in Lafayette, Louisiana, wrote that Blue Cross had also audited his client and issued refund requests related to special stains ordered in the provider's APS lean lab using the APS special stain protocol. As the attorney explained, the "primary basis for the refund requests is the fact that the procedures and protocols used by [the provider] and APS did not include the prior review and evaluation by APS pathologists of the initial H&E slides prior to APS pathologists ordering and/or having [the provider] prepare and ship special stain slides to APS." The attorney went on to explain that the gastroenterology practice "prepared and shipped the special stain slides to APS according to the specific protocols

established, implemented and monitored by APS. But for those APS procedures and protocols, [the provider] would not be in this predicament."

254. On August 6, 2025, APS executed a settlement agreement with the gastroenterology practice. Defendant Hannah signed the settlement agreement on behalf of APS. Under the terms of the settlement agreement, APS agreed to pay the practice $289,154.54.

G. APS's Owners Knew About, Orchestrated, and Perpetrated, the Lean Lab Scheme

255. As owners and executives of APS, Defendants Hannah, Burkett, and Pledger were actively involved in the day-to-day operations of the company, including with respect to conduct discussed in this Complaint.

256. As discussed above in paragraphs 51-55, Defendants Hannah and Pledger personally signed the Medicare enrollment paperwork on behalf of APS and certified that claims would comply with applicable regulations, including the AKS.

257. Defendants Hannah, Burkett, and Pledger were each personally involved in each phase of the lean lab business model, including marketing and promoting the business model to prospective customers and assisting with the operation and administration of the lean labs. Defendants Hannah, Burkett, and Pledger all personally received complaints or warnings regarding the legality of APS's conduct and downplayed or disregarded them.

258. Defendant Pledger was responsible for compliance at APS.

259. Defendant Burkett was responsible for billing at APS.

260. Defendant Hannah was responsible for overseeing APS's sales and marketing efforts at a corporate level, including business strategy and marketing and promotion of the lean lab business model.

261. But each of APS's owners were personally and actively involved in marketing and promoting the lean lab business model and recruiting potential customers. These efforts included selling potential customers on using APS's special stain protocol.

262. For example, in November 2016, Defendant Hannah emailed with the CEO of a gastroenterology practice located in Shawnee, Kansas, about setting up a lean lab in their office. Defendant Hannah explained the steps that would need to be completed, including hiring a histotechnician, integrating with the practice's IT system, assigning a medical director, and setting up the "new staining protocols." Hannah noted that Defendant Pledger "has also identified a great candidate for the histology tech position." Defendant Hannah forwarded the email to Defendant Pledger who asked him to tell the doctor that he would "make another visit in early December to go over the lab." Defendant Pledger also mentioned that he had spoken with another doctor "and relayed the information to Donell [Defendant Pledger]", who would be working on a proposal for another gastroenterology practice.

263. In February 2017, Dr. Davis, the former Director of Pathology at APS, emailed Defendants Hannah and Burkett about a potential lean lab customer located in Covington, Louisiana. Dr. Davis included that the current staining rates for the practice and observed that the numbers "will be different with APS protocol." Dr. Davis asked Defendants Hannah and Burkett to visit the practice with her to "pitch" the doctors. Defendant Burkett responded with a draft projection estimating how many stains the practice would order "using our model." Burkett predicted dramatic increases in the practice's stain rates: even though he projected that the rate of H&E stains would stay the same, he predicted that special stains billed using code 88312 would increase from 12 to 175 orders per month, and special stains billed using code 88313 would

increase from 158 to 482 orders per month. Defendant Burkett asked Defendant Hannah if this looked "right to you."

264. In April 2017, Defendant Burkett emailed with a potential lean lab customer about some changes the gastroenterology practice had requested to the contract. Specifically, the gastroenterology practice proposed that the APS medical director be required to submit timesheets describing the number of hours and type of work performed by the pathologist during the prior month. Defendant Burkett rejected the change and explained that the "workload distribution" for the medical director "has a high standard deviation" and that the medical director "is required to charge you a medical director fee to avoid conflicts with Stark Law."

265. In June 2017, Defendant Hannah emailed with the practice manager for a potential lean lab customer in Lafayette, Louisiana. Defendant Hannah had previously visited the practice's office and provided them with assistance completing and filing their CLIA certification paperwork. Defendant Hannah told the practice manager to contact Defendant Pledger if they needed any help with the CLIA paperwork since Defendant Pledger was the "CLIA expert around here."

266. Defendant Hannah and Defendant Burkett were involved in creating and developing financial projections for potential lean lab customers, which showed gastroenterology practices how much money they would make if they switched to APS's special staining protocol and opened an APS lean lab in their practice. In many instances, it was Defendants Hannah and Burkett, and not APS pathologists, estimating how many stains a gastroenterology practice would order with an APS lean lab.

267. In April 2019, an APS Territory Manager emailed Defendants Hannah, Burkett, and Pledger about an upcoming dinner meeting with a potential lean lab customer in Shreveport,

Louisiana. The email included a list of bullet points the practice requested APS and its owners to discuss at dinner. The list included a discussion of the "value proposition/benefits" when APS "integrates into an existing operation." It also included a discussion of what having a lean lab would mean to the practice, including an "increase in 88313 & 88312" (i.e., the billing codes for special stains). The list also included a discussion of "what APS offers as part of the terms of the transaction," and included "provid[ing] [the practice] with access to lower equipment pricing, ongoing maintenance agreement, and supplies," and asked whether it would be an option to provide a "[p]er diem" for histotechnicians "when on PTO, sick day, other."

268. In January 2019, an APS employee emailed Defendants Burkett and Pledger about his efforts to sign up a gastroenterology practice in Wichita Falls, Texas. The employee said he provided the potential customer with Defendant Burkett's contact info and noted that the physician "pushed me on the consulting fee a bit" and that the employee "pushed back softly about the Stark law & the value added services / protocols that we provide" but noted the doctor would "likely want to discuss further."

269. As discussed above in paragraph 135, Defendant Hannah personally facilitated hiring the daughter of the owner of AGA. Defendant Hannah sent the job offer to the employee and stated that her compensation was based on the anticipated volume of referrals APS would receive from AGA.

270. Once a gastroenterology practice agreed to host an APS lean lab, Defendant Hannah, Defendant Burkett, or Defendant Pledger would sign and execute the Lean Lab Agreement with the gastroenterology practice on behalf of APS.

271. Upon information and belief, either Defendant Hannah or Defendant Burkett would prepare each Lean Lab Agreement and would be responsible for deciding the amount of

the one-time consulting fee that would be charged to a gastroenterology practice, including whether that agreement would be reduced or waived. As discussed above in paragraphs 115-121, Defendant Hannah was personally involved in reducing or waiving the consulting fee on multiple occasions, sometimes in discussion with Defendant Burkett.

272. Defendant Pledger was actively involved in the setup and buildout phase for new lean labs. In particular, Defendant Pledger would often visit the site of a new lean lab, help draw up plans for the lean lab, assist the gastroenterology practice with identifying and ordering equipment for the lab (including sometimes brokering deals or discounts on that equipment), assisting the gastroenterology practices apply for and obtain CLIA certification for their lean lab, and recruiting and training histotechnicians to work in the lean lab.

273. Defendant Burkett was responsible for facilitating the installation and use of the LIS software that APS provided to the lean labs. For example, in November 2019, Defendant Burkett visited the AGA lean lab in Atlanta, Georgia after the practice complained to APS about its special stain protocol. Defendant Burkett modified how the LIS handled the automatic ordering of special stains in an effort to alleviate AGA's complaints. Defendant Pledger also participated in discussions with AGA about how to modify their protocols to comply with applicable regulations. However, APS and its owners limited this change to the AGA lean lab, despite knowledge that APS's special stain protocol did not comply with applicable legal obligations and remained in effect at all other APS lean labs.

274. As discussed above in paragraphs 235-255, Defendants Hannah, Pledger, and Burkett each personally received complaints or concerns about the legality of APS's business model and downplayed or disregarded those complaints or concerns.

VI. CAUSES OF ACTION

COUNT I

Violation of the False Claims Act:
Presentation, or Causing Presentation, of False or Fraudulent Claims for Payment
(31 U.S.C. § 3729(a)(1)(A))

Claims Resulting from a Violation of the Anti-Kickback Statute

All Defendants

275. The United States realleges and incorporates by reference all paragraphs of this Complaint set out above as if fully set forth in this paragraph.

276. By virtue of the acts described above, the Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A). That is, the Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment that resulted from violations of the Anti-Kickback Statute.

277. Specifically, the Defendants caused each of the gastroenterology practices hosting APS lean labs to submit claims for payment for the technical component of H&E and special stain services performed in the lean lab. Those claims were false because they resulted from violations of the Anti-Kickback Statute.

278. Additionally, the claims APS submitted for payment for pathology services for patients referred by the gastroenterology practices hosting lean labs, including claims for the professional component of H&E and special stains and claims for immunohistochemical stains, were false because they resulted from violations of the Anti-Kickback Statute.

279. The United States, unaware of the falsity of the claims made or caused to be made by the Defendants, paid claims that it would not have paid had it known of the Defendants' illegal conduct.

280. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the Defendants' conduct.

281. By reason of the foregoing and because of the Defendants' wrongful conduct, the United States has suffered actual damages in an amount to be determined at trial, and therefore is entitled under the False Claims Act to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

COUNT II

False Claims Act:
Presentation, or Causing Presentation, of False or Fraudulent Claims for Payment
(31 U.S.C. § 3729(a)(1)(A))

Implied Certification

All Defendants

282. The United States realleges and incorporates by reference all paragraphs of this Complaint set out above as if fully set forth in this paragraph.

283. By virtue of the acts described above, the Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A). That is, the Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment that falsely represented compliance with material statutory, regulatory, or contractual requirements.

284. As part of their provider agreements with CMS, APS and the gastroenterology practices hosting APS lean labs represented they would comply with applicable statutory, regulatory, and contractual requirements and certified their understanding that payment for any

claim was conditioned on, among other requirements, the claim and the underlying transaction complying with the Anti-Kickback Statute.

285. Because the Defendants caused APS and the gastroenterology practices to submit claims for payment based on transactions that were not compliant with these certifications, specifically because of the improper remuneration APS provided to the gastroenterology practices, the following claims were false: (i) the technical component of the H&E and special stain services performed by lean labs; (ii) the corresponding professional component of the H&E and special stains performed by APS on patients referred by lean lab customers; and (iii) the immunohistochemical stains performed by APS for patients referred by lean lab customers.

286. The United States, unaware of the falsity of the claims made or caused to be made by the Defendants, paid claims that it would not have paid had it known of the Defendants' illegal conduct.

287. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the Defendants' conduct.

288. By reason of the foregoing and because of the Defendants' wrongful conduct, the United States has suffered actual damages in an amount to be determined at trial, and therefore is entitled under the False Claims Act to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

COUNT III

False Claims Act:
Presentation, or Causing Presentation, of False or Fraudulent Claims for Payment
(31 U.S.C. § 3729(a)(1)(A))

Medically Unnecessary Services
All Defendants

289. The United States realleges and incorporates by reference all paragraphs of this Complaint set out above as if fully set forth in this paragraph.

290. By virtue of the acts described above, the Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A). That is, the Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment that falsely represented compliance with material statutory, regulatory, or contractual requirements.

291. Each time APS, or a gastroenterology practice with an APS lean lab, submitted a claim for payment, the ordering provider impliedly certified that the service provided was medically reasonable and necessary for the patient and that the claim was accurate, complete, and truthful.

292. Defendants caused APS and the gastroenterology practices to submit claims for payment for services including: (i) the technical component of the special stain services performed by lean labs prior to a pathologist's review of the H&E stain and without a determination that special stains were needed for the particular patient; (ii) the corresponding professional component of those special stains performed by APS; and (iii) immunohistochemical stains performed by APS prior to a pathologist's review of the H&E stain

or any previously ordered special stains and without a determination that an immunohistochemical stain was needed for the particular patient. As a result, APS submitted or caused the submission of claims for services that were not medically reasonable or necessary and therefore not covered or payable, and were false.

293. The United States, unaware of the falsity of the claims made or caused to be made by the Defendants, paid claims that it would not have paid had it known of the Defendants' illegal conduct.

294. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the Defendants' conduct.

295. By reason of the foregoing and because of the Defendants' wrongful conduct, the United States has suffered actual damages in an amount to be determined at trial, and therefore is entitled under the False Claims Act to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

COUNT IV

False Claims Act:
Presentation, or Causing Presentation, of False or Fraudulent Claims for Payment
(31 U.S.C. § 3729(a)(1)(B))

Making or Using False Records or Statements
Defendants Advanced Pathology Solutions LLC, Advanced Pathology Solutions PLLC, Defendant Hannah and Defendant Pledger

296. The United States realleges and incorporates by reference all paragraphs of this Complaint set out above as if fully set forth in this paragraph.

297. Defendants Advanced Pathology Solutions LLC, Advanced Pathology Solutions PLLC, Kevin Hannah, and Daniel Hunter Pledger knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United

States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of those defendants' statements and actions.

298. These false records and statements included false certifications on provider enrollment forms that APS's claims to Medicare for laboratory testing complied with the AKS, when in fact those claims violated the AKS.

299. Defendants Advanced Pathology Solutions LLC, Advanced Pathology Solutions PLLC, Kevin Hannah, and Daniel Hunter Pledger 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 or not they were false.

300. By virtue of these fraudulent claims, the United States suffered damages and therefore is entitled to treble damages under the FCA, to be determined at trial, plus civil penalties for each violation.

COUNT V

Unjust Enrichment

All Defendants

301. The United States realleges and incorporates by reference all paragraphs of this Complaint set out above as if fully set forth in this paragraph.

302. The United States is entitled, under federal common law, to the recovery of monies by which Defendants have been unjustly enriched due to their actions as described in this Complaint.

303. Through the conduct and acts described above, the Defendants were unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, and as dictated by the needs of justice and

fairness, should be returned to the United States or would be unconscionable for the Defendants to retain.

304. Through the conduct and acts described above, the Defendants have received payments from the Government to which they were not entitled, which unjustly enriched the Defendants, and for which they must make restitution. The Defendants received such payments based on the submission of false claims and based on causing the submission of false claims. In equity and good conscience, such money belongs to the United States and to the Medicare program and should not be retained by the Defendants.

305. By obtaining payments as a result of their violation of Federal law, the Defendants were unjustly enriched, and they are liable to account and pay such amounts, which are to be determined at trial, to the United States.

COUNT VI

Payment By Mistake

All Defendants

306. The United States realleges and incorporates by reference all paragraphs of this Complaint set out above as if fully set forth in this paragraph.

307. The United States is entitled, under federal common law, to the recovery of monies the United States paid under a misapprehension of fact.

308. As described in this Complaint, the United States paid monies to APS and the gastroenterology practices hosting APS lean labs based on the mistaken understanding that the claims APS and the gastroenterology practice (i) complied with the AKS and (ii) were medically reasonable and necessary.

309. The Defendants benefitted from these mistaken payments: in the case of monies paid directly to APS, APS and its owners benefitted financially by directly receiving those funds. In the case of payments made to the gastroenterology practices for the technical component of the staining services, APS and its owners benefitted by receiving valuable patient referrals, which allowed them to generate more revenue.

310. Equity requires that the Defendants make restitution to the United States, in an amount to be determined at trial, and return the monies that were paid by mistake, particularly where the United States' mistake was based on misrepresentations made or caused by the Defendants.

VII. PRAYER FOR RELIEF

Wherefore, the United States demands and prays that judgment be entered in its favor on Counts I through VI as follows:

1) On the First, Second, and Third Counts against all Defendants, under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, as well as its costs pursuing this action, together with all such further relief as may be just and proper.

2) On the Fourth Count against Defendants Advanced Pathology Solutions LLC, Advanced Pathology Solutions PLLC, Defendant Hannah and Defendant Pledger, under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, as well as its costs pursuing this action, together with all such further relief as may be just and proper.

3) On the Fifth Count, against all Defendants, for unjust enrichment, for the amounts by which the Defendants were unjustly enriched, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

4) On the Sixth Count, against all Defendants, for payment by mistake, for the amounts paid to APS or to the gastroenterology practices hosting APS lean labs by mistake, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

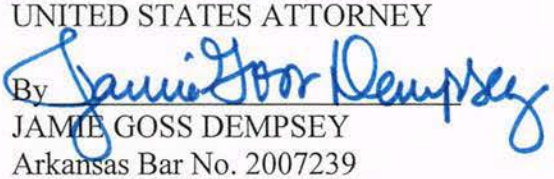
VIII. JURY DEMAND

311. Pursuant to Federal Rule of Civil Procedure 38, the United States requests a trial by jury.

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General
U.S. Department of Justice, Civil Division

JONATHAN D. ROSS
UNITED STATES ATTORNEY

By 
JAMIE GOSS DEMPSEY
Arkansas Bar No. 2007239
Assistant United States Attorney
425 West Capitol Ave., Suite 500
Little Rock, AR 72201
Telephone: (501) 340-2600
jamie.dempsey@usdoj.gov

JAMIE ANN YAVELBERG
EDWARD CROOKE
EVAN J. BALLAN
JEFFREY A. MCSORLEY
Attorneys, Civil Division
U.S. Department of Justice
P.O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Telephone: (202) 305-2335
evan.j.ballan@usdoj.gov