

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Defense Health Agency (DHA), acting on behalf of the TRICARE Program; and the United States Department of Veterans Affairs (VA) (collectively, the “United States”), Defendant AGA, LLC d/b/a Atlanta Gastroenterology Associates (“Atlanta Gastroenterology Associates”), [REDACTED] [REDACTED] (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Atlanta Gastroenterology Associates is a gastroenterology physician practice headquartered in Atlanta with more than 60 locations throughout Georgia.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. The United States contends that Atlanta Gastroenterology Associates submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17 (hereinafter the “federal healthcare programs”).

D. The United States contends that it has certain civil claims against Atlanta Gastroenterology Associates arising from the submission of claims for gastrointestinal pathology staining services from May 15, 2017, through May 28, 2020, including claims submitted by Atlanta Gastroenterology Associates for the technical component of the staining procedures using CPT codes 88305, 88312, and 88313 with a technical component modifier, and claims for the corresponding professional component of the staining procedures submitted by Advanced Pathology Solutions (APS) using CPT codes 88305, 88312, and 88313 with a professional component modifier. Specifically, the United States contends that Atlanta Gastroenterology Associates engaged in the following conduct:

i. Beginning on or about May 15, 2017, Atlanta Gastroenterology Associates entered into an agreement with APS, an anatomic pathology lab located in Little Rock, Arkansas.

ii. Under the agreement, APS assisted Atlanta Gastroenterology Associates with developing, constructing, and setting up a limited-capacity pathology laboratory located in Atlanta Gastroenterology Associates' office (which APS called a "lean lab"). In that lean lab, histology technicians trained by APS and working under the direction and supervision of a medical director pathologist employed by APS would prepare slides containing patients' biopsy specimens using chemicals or dyes called "stains." Atlanta Gastroenterology Associates would bill the patient's insurer for performing this "technical component" of the various clinical laboratory services, referred to herein as "stain procedures." Atlanta Gastroenterology Associates would then mail the prepared specimen slides from their offices in Georgia to APS's lab in Arkansas, where a pathologist employed by APS would review and interpret them. APS would bill the patient's insurer for performing this corresponding "professional component" of the stain procedures.

iii. APS provided remuneration to Atlanta Gastroenterology Associates in connection with its lean lab in the form of: (a) below fair market rates for ongoing supervision and operational support of the lean lab; (b) below market rates for medical director services; and (c) free supplies unrelated to the collection, transport, processing or storage of lab specimens for APS. Both the technical and professional components of clinical laboratory services are designated health services for purposes of the physician self-referral law, 42 U.S.C. § 1395nn (commonly referred to as the "Stark Law"). The financial relationships between APS and the physicians who stand in the shoes of Atlanta Gastroenterology Associates for purposes of the Stark Law did not satisfy the requirements of any applicable exception to the Stark Law. Atlanta

Gastroenterology Associates physicians' referrals to APS for designated health services were, therefore, prohibited, and the submission of claims for the improperly referred services violated the Stark Law.

iv. APS provided additional remuneration to Atlanta Gastroenterology Associates in connection with its lean lab, including, but not limited to, (a) the buildout and setup of the lean lab; for example, APS provided Atlanta Gastroenterology Associates with laboratory information systems, Microsoft Surface tablets, barcode scanners, and label printers used to operate the lean lab; (b) specimen storage services; (c) supplies for use in the lab; (d) shipping; and (e) enabling Atlanta Gastroenterology Associates to bill for the technical component of the stain procedures. Atlanta Gastroenterology Associates did not compensate APS for the fair market value of this remuneration.

v. The agreement between Atlanta Gastroenterology Associates and APS required Atlanta Gastroenterology Associates to exclusively refer its patients (including beneficiaries of federal healthcare programs) to APS to perform the professional component for stains created in the lean lab hosted at Atlanta Gastroenterology Associates' office.

vi. As a further inducement to enter into the lean lab agreement, approximately one month before APS and Atlanta Gastroenterology Associates entered into the lean lab agreement, APS offered to hire the daughter of a physician owner and officer of Atlanta Gastroenterology Associates. She was made a fully-remote marketing manager at a salary of \$180,000 per year and APS indicated that the daughter's salary was tied to the volume of pathology referrals that Atlanta Gastroenterology Associates would be making to APS.

vii. APS provided the remuneration described above to induce Atlanta Gastroenterology Associates to refer patients (including beneficiaries of federal healthcare programs) to APS for the performance of the professional component of the pathology services. Atlanta Gastroenterology Associates' knowing and willful receipt of the remuneration described above, in return for referrals, was in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and Atlanta Gastroenterology Associates thus caused the submission of false claims to Medicare, TRICARE, and the VA.

viii. Additionally, Atlanta Gastroenterology Associates ordered certain clinical laboratory services that were not reasonable and necessary for the diagnosis or treatment of illness or injury and billed Medicare, TRICARE, and the VA for those procedures using CPT codes 88312 and 88313.

ix. In the field of gastrointestinal pathology, preparing a specimen using hematoxylin and eosin dyes (known as an "H&E" stain) is a routine practice that allows the pathologist to identify and diagnose a variety of conditions. In some cases, however, a pathologist will review an H&E stain and determine that additional information is needed, so the pathologist may order additional "special stains" to confirm or rule out certain diagnoses. Special stains are called "special" because they are not necessary or appropriate for all patients.

x. Following a special stain protocol implemented by the pathologists at APS who were overseeing the lean lab, Atlanta Gastroenterology Associates prepared and ordered special stains automatically (or reflexively) based on the source of the specimen biopsy (i.e., the location in the patient’s gastrointestinal system from which the specimen was taken) rather than the particular patient’s need. For example, Atlanta Gastroenterology Associates automatically prepared an Alcian Blue special stain (in addition to an H&E stain) for all esophageal specimens. The effect of these reflexive special stain orders was to drive up the volume of procedures (and corresponding revenue) for Atlanta Gastroenterology Associates and APS.

xi. In approximately mid-2019, Atlanta Gastroenterology Associates met with APS to address concerns that Atlanta Gastroenterology Associates was performing and billing for special stain services that were not medically reasonable or necessary. Atlanta Gastroenterology Associates provided data to APS showing that it had been ordering certain special stains over 100 times more often than other gastroenterology practices. Additionally, the special stain protocol was inconsistent with a Local Coverage Determination (L35922) issued by the Medicare Administrative Contractor for Atlanta Gastroenterology Associates’ jurisdiction. Among other things, the Local Coverage Determination explained that reflex special stain orders or special stain orders made prior to pathologist review of a routine H&E stain were not reasonable or necessary. According to the Local Coverage Determination, a pathologist must review the routine H&E stain before ordering any special stain.

xii. Atlanta Gastroenterology Associates terminated its relationship with APS effective May 28, 2020.

This conduct is referred to below as the “Covered Conduct.”

■ [REDACTED]

[REDACTED]

F. This Settlement Agreement is neither an admission of liability by Atlanta Gastroenterology Associates nor a concession by the United States that its claims are not well founded. Atlanta Gastroenterology Associates denies the United States’ allegations in Paragraph D.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Atlanta Gastroenterology Associates shall pay to the United States four million, seven-hundred and fifty thousand dollars (\$4,750,000) (the “Settlement Amount”) and interest on the Settlement Amount at a rate of 4.125% per annum from February 9, 2026, through the date of payment, of which two million, three-hundred and seventy-five thousand dollars (\$2,375,000) is restitution, no later than ten (10) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Eastern District of Arkansas.

█ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases Atlanta Gastroenterology Associates together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; United Digestive; and the corporate successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the civil monetary provisions of the Stark Law at 42 U.S.C. §§ 1395nn(g)(3) and (g)(4) or the common law theories of payment by mistake, unjust enrichment, and fraud. These entities are collectively referred to as the “Released Entities.”

[REDACTED]

5. Notwithstanding the releases given in Paragraphs 3 and 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due;

- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

8. Atlanta Gastroenterology Associates waives and shall not assert any defenses Atlanta Gastroenterology Associates may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. Atlanta Gastroenterology Associates fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Atlanta Gastroenterology Associates has asserted, could have asserted, or may assert in the future against the United

States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

[REDACTED]

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE, or any state payer, related to the Covered Conduct; and Atlanta Gastroenterology Associates agrees not to resubmit to any Medicare contractor, TRICARE, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

12. Atlanta Gastroenterology Associates agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Atlanta Gastroenterology Associates, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

- (3) Atlanta Gastroenterology Associates' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Atlanta Gastroenterology Associates makes to the United States pursuant to this Agreement [REDACTED]

[REDACTED]

[REDACTED]

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Atlanta Gastroenterology Associates, and Atlanta Gastroenterology Associates shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Atlanta Gastroenterology Associates or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Atlanta Gastroenterology Associates further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any

State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Atlanta Gastroenterology Associates or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Atlanta Gastroenterology Associates agrees that the United States, at a minimum, shall be entitled to recoup from Atlanta Gastroenterology Associates any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Atlanta Gastroenterology Associates or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Atlanta Gastroenterology Associates or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Atlanta Gastroenterology Associates' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. Atlanta Gastroenterology Associates agrees to reasonably cooperate with the United States' investigation of individuals and entities not released in this Agreement. Specifically, and upon reasonable notice, Atlanta Gastroenterology Associates shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors,

Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on Atlanta Gastroenterology Associates' successors, transferees, heirs, and assigns.


■ [REDACTED]

25. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 2/27/2026

BY: 
Evan J. Ballan
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: JAMIE DEMPSEY Digitally signed by JAMIE DEMPSEY
Date: 2026.02.26 14:13:10 -06'00'
Jamie Goss Dempsey
Assistant United States Attorney
U.S. Attorney's Office for the Eastern District of Arkansas

DATED: _____

BY: _____
Susan E. Gillin
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____
Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Evan J. Ballan
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____

Jamie Goss Dempsey
Assistant United States Attorney
U.S. Attorney's Office for the Eastern District of Arkansas

DATED: _____

BY: _____

**KENNETH
KRAFT**  Digitally signed by KENNETH
KRAFT
Date: 2026.02.26 19:04:53 -05'00'

Susan E. Gillin
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____

Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Evan J. Ballan
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____

Jamie Goss Dempsey
Assistant United States Attorney
U.S. Attorney's Office for the Eastern District of Arkansas

DATED: _____

BY: _____

Susan E. Gillin
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 2/25/2026

BY: _____

BORKENHAGE N.WESTON.EAR L.1138755149
Digitally signed by BORKENHAGEN.WESTON. EARL.1138755149
Date: 2026.02.25 08:05:04 -05'00'

For

Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

ATLANTA GASTROENTEROLOGY ASSOCIATES - DEFENDANT

DATED: _____

BY: Annaliese Impink
Annaliese Impink
General Counsel and Compliance Officer
Atlanta Gastroenterology Associates

DATED: _____

BY: _____
Dan Barnowski
Counsel for Atlanta Gastroenterology Associates

ATLANTA GASTROENTEROLOGY ASSOCIATES - DEFENDANT

DATED: _____

BY: _____

Annaliese Impink
General Counsel and Compliance Officer
Atlanta Gastroenterology Associates

DATED: 2/25/2026

BY: Dan Bo

Dan Barnowski
Counsel for Atlanta Gastroenterology Associates

