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FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA and
THE STATE OF CALIFORNIA, *ex. rel.*
AMERICAN INTEGRA LLC
Plaintiffs,

v.

ELITE MEDICAL BILLING
CORPORATION;
STERLING PATHOLOGY MEDICAL
CORPORATION, doing business as
STERLING PATHOLOGY NATIONAL
LABORATORIES, (also known as
STERLING PATHOLOGY MEDICAL
GROUP);
CHANGGAO YANG, M.D. (also known as
CHANG GAO YANG, and CHENGGAO
YANG);
MICHAEL OKUNIEWSKI;
ELLIE LEKOV, M.D. (also known as ELLIE
SUVOUZ LEKOV, and ELI LEKOV);
JENNY CHANG, a.k.a JENNY AU;
and DOES 1-10,
Defendants.

Case No. _____

**COMPLAINT FOR TREBLE DAMAGES
AND CIVIL PENALTIES FOR
VIOLATION OF**

1. **THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3279**
2. **THE CALIFORNIA FALSE CLAIMS ACT, CAL. GOV. CODE §12650-12652**
3. **ANTI-KICKBACK STATUTE, 42 U.S.C. § 1320A-7B (B)**
4. **MAKING OR USING FALSE RECORD OR STATEMENT TO CAUSE FALSE CLAIMS TO BE PAID**
5. **CONSPIRACY TO VIOLATE THE FEDERAL FALSE CLAIMS ACT**
6. **IMPROPERLY AVOIDING AN OBLIGATION TO PAY OR TRANSMIT MONEY TO THE GOVERNMENT**
7. **UNJUST ENRICHMENT**

DEMAND FOR JURY TRIAL

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1 **COMPLAINT FOR DAMAGES**

2 Plaintiffs the United States of America (United States) and the State of California
3 (the “State”), by and through Relator American Integra LLC (Relator) and the
4 undersigned counsel, allege as follows:

5 **I. SUMMARY**

6 1. This action is brought against Defendants Sterling Pathology Medical
7 Corporation (Sterling) and Elite Medical Billing Corporation (Elite), who knowingly
8 engaged in unlawful laboratory billing practices and illicit marketing. These actions are in
9 violation of the False Claims Act (31 U.S.C. § 3729, et seq.) (FCA), the California False
10 Claims Act (Cal. Gov. Code §12652) (CFCA), and the Anti-Kickback Statute (42 U.S.C. §
11 1320a-7b(b)) (AKS). The suit is filed under seal on behalf the United States and the State of
12 California, pursuant to 31 U.S.C. § 3730.

13 2. Defendants submitted false claims to Medicare, Medicaid, and the government
14 for unnecessary, unbundled, and upcoded Pathology special stains. They also engaged in
15 illicit COVID-19 test billing using unlawful contracted cappers, runners, and kickbacks to
16 obtain patients' insurance information and driver's licenses for unearned payments under
17 the COVID-19 CARES Act and the “HRSA COVID-19 Uninsured Program.”

18 3. These unlawful and false healthcare claims submitted by Defendants have led
19 to tens of millions of dollars in undeserved overpayments from the government,
20 undermining the integrity of our healthcare system and misappropriating taxpayer funds.

21 4. Under Title XVIII of the Social Security Act, Section 1862(a)(1)(A), and Federal
22 Regulation 42 CFR § 410.32(a), Medicare, Medicaid, and TRICARE patients are entitled to
23 receive care necessary for their clinical needs, not for the financial gains of their healthcare
24 providers. These provisions, along with the FCA, CFCA, and AKS, hold healthcare providers
25 accountable if they bill for unnecessary services or treatment, manipulate billing through
26 unbundling and upcoding, or engage in illicit marketing practices.

27 5. Defendants systematically exploited a well-known self-referral loophole in the
28 billing process for Pathology special stains for Medicare, Medicaid, and TRICARE

1 beneficiaries, in violation of the FCA and CFCA. They falsified physician names on final
2 pathology reports and used unlicensed staff or medical providers not authorized to practice
3 medicine in California. This manipulation allowed Defendants to generate millions in
4 unearned revenues.

5 6. Defendants further exploited the COVID-19 pandemic by mass billing for
6 COVID-19 testing, using illicit marketing and kickbacks. They leveraged lucrative loopholes
7 and reimbursements in laboratory test payments under the CARES Act and HRSA COVID-
8 19 Uninsured Program, accruing tens of millions of dollars in improper revenues through
9 emergency government relief programs, in violation of the AKS.

10 7. Since at least 2012, Sterling and Elite have reaped profits from their false and
11 predatory laboratory billing practices. They submitted countless false claims to the
12 government for medically unnecessary "special stain" Pathology services and COVID-19
13 testing procured through unlawful use of cappers and runners, in violation of the FCA,
14 CFCA, and AKS. Sterling's billing patterns and high frequency of certain codes reveal a
15 reliable indication of fraud.

16 8. This case, under the FCA, CFCA, and AKS, seeks to hold Defendants
17 accountable for their widespread laboratory testing fraud. Supported by exemplar Medicare
18 patient records, Sterling-generated special stain reports, and Elite billing documents, the
19 complaint demonstrates a pervasive and long-running scheme to defraud the government.

20 9. Defendants' deceitful practices, which included cloned test requisitions and
21 reports, fabricated reports, pass-through billing, and kickbacks, targeted predominantly
22 Medicare and Medicaid beneficiaries. Their recent COVID-19 testing schemes deliberately
23 focused on certain immigrant communities — whom Defendants believed were culturally
24 more cooperative and less likely to raise concerns about false claims.

25 10. Defendants' institutional "upcoding" and "unbundling" schemes violated the
26 FCA and CFCA, targeted government beneficiaries, while providing kickbacks to third-
27 party providers in exchange for large-scale milling and access to beneficiaries' driver's
28 licenses and insurance information in violation of the AKS. The scheme resulted in

1 unearned COVID-19 CARES Act and HRSA COVID-19 Uninsured Program payments for
2 testing which was never performed.

3 11. Through their fraudulent business model, Sterling and Elite amassed
4 astonishing revenues, undermining the trust and financial stability of government
5 healthcare programs. Their actions not only violated multiple federal and state statutes, but
6 also deprived vulnerable patients of much-needed healthcare resources.

7 12. This case seeks to hold Defendants accountable for their unlawful actions and
8 recover damages for the United States and the State of California. With the evidence
9 gathered, including contracts between Sterling and its illicit marketing cappers, Plaintiffs
10 aim to demonstrate the extent of Defendants' fraudulent practices and secure justice for the
11 government and taxpayers.

12 13. Damages in this case are estimated to be \$35-40 million on an excess of 420,000
13 false claims. Additionally, Plaintiffs seek a civil penalty of \$13,508 to \$27,018 per federal
14 false claim under the FCA, a civil penalty of \$5,500 to \$11,000 per state false claim under
15 the CFCA, and treble (triple) damages as authorized by 31 U.S.C. § 3279.

16
17 **II. JURISDICTION AND VENUE**

18 14. This Court has original *subject matter jurisdiction* pursuant to 28 U.S.C. § 1331
19 and 31 U.S.C. § 3732, because this action is brought for violations of the False Claims Act
20 pursuant to 31 U.S.C. § 3279, *a federal statute*. This Court also has supplemental
21 jurisdiction pursuant to 28 U.S.C. § 1367 over the claims of the State.

22 15. This Court also has *personal jurisdiction* over Defendants and venue is proper
23 in this District pursuant to 31 U.S.C. § 3732(a), because Defendants can be found in, reside,
24 and/or transact business in this District, and because fraudulent acts proscribed by 31
25 U.S.C. § 3729 occurred in this District.

26 16. *Venue* is also proper pursuant to 28 U.S.C. § 1391(b) because one or more
27 Defendants reside in this District, and because a substantial part of the events or omissions
28 giving rise to the claims alleged occurred in this District. Specifically, *Defendants Elite*

1 *Medical Billing Corporation and Jenny Chang a.k.a. Jenny Au*, physically house and
2 operate all the billing files for Defendants in Hanford, California which is located in **Kings**
3 County, within the jurisdiction of the United States District Court for the **Eastern** District
4 of California.

5 17. This action is timely because it has been filed within the period prescribed by
6 31 U.S.C. §§ 3731(b) and 3730(h)(3), and California False Claims Act, Cal. Gov. Code §12652.

7 18. Relator concurrently served upon the Attorney General of the United States,
8 the United States Attorney for the **Eastern** District of California, the Attorney General of
9 the State of California, and the District Attorney's Office the original Complaint and a
10 written disclosure summarizing the known material evidence and information in the
11 possession of Relator, in accordance with the provisions of 31 U.S.C. § 3730(b)(2). The
12 disclosure statement is supported by material evidence, and documentary evidence has been
13 produced with the disclosure. Relator shall similarly serve a copy of any subsequent
14 amended complaints to the government.

15
16 **Relator's Direct and Independent Knowledge**

17 19. Under 31 U.S.C. § 3730(e)(4)(A), there has been no statutorily relevant public
18 disclosure of "substantially the same allegations or transactions" alleged in this Complaint.
19 Relator makes the allegations in this Complaint based on its own knowledge, experience,
20 and observations. Relator is the original source of the information on which the allegations
21 herein are based, has direct and independent knowledge of such information, and has
22 voluntarily disclosed such information to the United States and the State *before* filing this
23 action.

24 20. To the extent there has been any such public disclosure, Relator meets the
25 definition of an "original source," as that term is defined under 31 U.S.C. § 3730(e)(4)(B).
26 Specifically, Relator voluntarily disclosed to the Government the information upon which
27 allegations or transactions at issue in this complaint are based prior to any purported public
28 disclosure under 31 U.S.C. § 3730(e)(4)(A).

1 21. Alternatively, Relator has knowledge that is independent of and materially
2 adds to any purported publicly disclosed allegations or transactions, and Relator voluntarily
3 provided to the Government before filing this complaint. Relator therefore qualifies as an
4 “original source” of the allegations in this Complaint such that the so-called public disclosure
5 bar set forth at 31 U.S.C. § 3730(e)(4) even if invoked, would be inapplicable.
6

7 **III. PARTIES**

8 **A. Plaintiffs**

9 22. Plaintiff the UNITED STATES brings this action pursuant to 31 U.S.C. § 3279
10 by and through Relator. At all times relevant to this Complaint, the United States, acting
11 through the Centers for Medicare & Medicaid Services ("CMS"), has reimbursed Defendants
12 for the provision of various medical services and treatments for eligible individuals through
13 the Medicare program. Thus, the United States brings this action on behalf of its agencies,
14 CMS, Health and Human Services (“HHS”), and on behalf of the Medicare program.

15 23. Plaintiff the STATE OF CALIFORNIA brings this action through the Relator
16 pursuant to the California False Claims Act, Cal. Gov. Code §12652 which allows a relator
17 to bring a civil lawsuit for violations of this code on behalf of the State. The State has
18 reimbursed Defendants for the provision of various medical services and treatments for
19 eligible individuals through the Medicaid (Medi-Cal) program.

20 **B. Defendants**

21 24. Defendant STERLING PATHOLOGY MEDICAL CORPORATION, doing
22 business as STERLING PATHOLOGY NATIONAL LABORATORY and also known as
23 STERLING PATHOLOGY MEDICAL GROUP (collectively “Sterling”), is a for profit
24 professional corporation organized and existing under the laws of the State of California,
25 having its principal place of business in Seal Beach, California.

26 25. Sterling provides “clinical medical laboratory” services *nationwide*, as
27 credentialed in California, Florida, Maryland, New York, Rhode Island, and Pennsylvania.
28 Sterling bills the government for healthcare services under a number of aliases and

1 identifications including National Provider Identifier (NPI) **1174518302**, NPI 1467444893,
2 NPI 1255324018, and Medicare No. HW16573, and MediCal No. A627810.

3 26. Defendant CHANG GAO YANG, M.D., a.k.a CHANGGAO YANG AND
4 CHENGGAO YANG (Yang) is an individual domiciled in California. Yang is the “Chief
5 Executive Officer, Secretary, and Chief Financial Officer” of Sterling, and otherwise the
6 corporate parent of, owns, or otherwise controls Sterling. Yang is licensed as a California
7 physician License No. AG2281 and bills under **NPI 1366435638**.

8 27. Defendant MICHAEL OKUNIEWSKI (Okuniewski) is an individual domiciled
9 in California, who has been the managing Vice President of Operations and Sales, and the
10 Chief Marketing Officer at Sterling since September 2011.

11 28. Defendant ELLIE LEKOV, M.D. (Lekov) is an individual domiciled in
12 California, and a managing agent and pathologist having her principal place of business at
13 Sterling. She bills under **NPI 1033266788**.

14 29. Defendant ELITE MEDICAL BILLING CORPORATION (Elite), a California
15 Corporation Entity No. C3247563 located in Hanford, California, and JENNY CHANG
16 (Chang), an individual (President and founder of Elite) are the principal and sole medical
17 billers for Defendants and receive a sizable percentage of Sterling’s earnings.

18 30. At all times mentioned herein, each defendant was the agent for each other
19 defendant, was acting in the course and scope of such agency and was engaged in a
20 conspiracy to do the things herein alleged.

21 31. Plaintiffs are informed and believe and, on that basis, allege that at all times
22 relevant herein, Defendants, and each of them, were and remain the alter-egos of each other,
23 that they did and still do dominate, influence and control each other, that there existed and
24 still exists a unity of ownership between them, that the individuality and separateness of
25 each entity was and remains non-existent, that each such entity was and remains a mere
26 shell, conduit and/or naked framework which the other defendants used and still use to
27 conduct their business affairs, and that each such entity was and remains inadequately
28 capitalized, and that an injustice and fraud upon Plaintiffs will result if the theoretical

1 separateness of the defendant entities is not disregarded and each such defendant held
2 liable for all relief being sought herein. Plaintiffs are informed and believe and on that basis
3 alleges that at all times herein, Defendants, and each of them, knowingly and willfully
4 conspired, joined and participated with each other in the conduct alleged in furtherance of
5 a conspiracy between and among Defendants to enrich themselves at Plaintiffs' expense, and
6 that each such defendant is therefore liable with each other defendant for the conduct herein
7 alleged, for the damages suffered by Plaintiffs and for the relief being sought herein.

8 32. Plaintiffs are ignorant of the true names and capacities of the defendants sued
9 herein under the fictitious names DOES 1 through 10. Each of the fictitiously named
10 defendants is responsible in some manner for the acts and violations herein alleged.
11 Plaintiffs will seek leave to amend this complaint to allege said defendants' true names and
12 capacities as soon as Plaintiffs ascertain them.

13 **C. Relator**

14 33. Relator AMERICAN INTEGRA LLC is a limited liability company registered
15 and operating under the laws of New Mexico, bringing this action on behalf of itself, the
16 United States, and the State as authorized by 31 U.S.C. § 3279 and Cal. Gov. Code § 12652.

17 34. Relator's original source knowledge of the matters giving rise to this action
18 stems from Relator's business transactions with Defendants beginning in 2019 to 2023.

19 35. Relator's principal has engaged in business with Defendants Sterling,
20 Okuniewski, Lekov, and Yang, and engaged in business and referral discussions with
21 Defendants Elite and Chang. Relator has no current relationship with Defendants.

22
23 **IV. COMMON FACTUAL ALLEGATIONS: BACKGROUND**

24 **A. Medicare and Medi-Cal**

25 36. Medicare, a federally funded health insurance program, is administered by the
26 U.S. Department of Health and Human Services (HHS) through its Center for Medicare and
27 Medicaid Services (CMS). *See* 42 U.S.C. § 1395, *et seq.*

1 37. Medicaid is a joint federal-state initiative that provides healthcare to low-
2 income individuals. *See* 42 U.S.C. §§ 1396a(a)-(b). States develop and implement plans
3 approved by HHS and CMS and pay providers according to established rates. The federal
4 government then reimburses states based on a predetermined share of the total amount
5 expended under the state plan. *See* 42 U.S.C. § 1396b(a)(1).

6 **B. Government Claims**

7 38. Providers must obtain a provider number¹ to file claims for government
8 reimbursement of services. By becoming a participating provider in Medicare, enrolled
9 providers agree to abide by the rules, regulations, policies, and procedures governing
10 reimbursement, and to keep and allow access to records and information as required by
11 Medicare.

12 39. The Medicare Enrollment Application form for Institutional Providers, CMS-
13 855A, requires that an authorized official such as the chief executive officer execute a
14 “Certification Statement” that “legally and financially binds this provider to the laws,
15 regulations, and program instructions of the Medicare program.” Through its authorized
16 official, the Institutional Provider must also certify that:

- 17 • I have read and understand the Penalties for Falsifying Information
18 I understand that any deliberate omission, misrepresentation,
19 or falsification of any information . . . contained in any
20 communication supplying information to Medicare . . . may be
21 punished by criminal, civil or administrative penalties, including but
22 not limited to the denial or revocation of Medicare billing privileges,
23 and/or imposition of fines, civil damages, and/or imprisonment.
- 24 • I agree to abide by the Medicare laws, regulations and program
25 instructions that apply to this provider. The Medicare laws,
26 regulations, and program instructions are available through the
27 Medicare contractor. I understand that payment of a claim by
28 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 and the Stark law), and on the provider’s compliance with all
applicable conditions of participation in Medicare.

¹ Medicare maintains a unique National Provider Identifier (NPI) system, which assigns a unique, 10-digit numeric identifier to each institution, physician, non-physician practitioner, or medical group practice requesting or receiving payment for services provided to beneficiaries. NPI’s are assigned to institutions as well as individual health care providers.

- 1 • I agree that any existing or future overpayment made to the provider
2 by the Medicare program may be recouped by Medicare through the
3 withholding of future payments.
- 4 • I will not knowingly present or cause to be presented a false or
5 fraudulent claim for payment by Medicare, and I will not submit
6 claims with deliberate ignorance or reckless disregard of their truth
7 or falsity.

8 40. To bill Medicare for services provided to beneficiaries in California, providers
9 submit a claim electronically (837P) or on Form CMS-1500 to Noridian, containing certain
10 required information pertaining to the Medicare beneficiary.

11 41. Claims must include essential information such as beneficiary's details, service
12 description, billing CPT codes, date of service, the rendering provider's National Provider
13 Identifier (NPI), the referring physician's NPI, and a certification that the services were
14 personally rendered by the provider and certifying that the contents of the form were true,
15 correct, complete, that the form was prepared in compliance with all Medicare laws and
16 regulations.

17 **C. Laboratory Testing**

18 42. 42 CFR §410.32 outlines billing regulations for "...diagnostic laboratory tests,
19 and other diagnostic tests."

20 43. Section 410.32(a) provides, "...laboratory tests must be ordered by the
21 physician who is treating the beneficiary, that is, the physician who furnishes a consultation
22 or treats a beneficiary for a specific medical problem and who uses the results in the
23 management of the beneficiary's specific medical problem." "Tests not ordered by the
24 physician who is treating the beneficiary are not reasonable and necessary." *Id.*

25 44. If diagnostic testing is necessary for the diagnosis or treatment of illness or
26 injury, or to improve the functioning of a malformed body member, Medicare imposes
27 additional requirements before covering the testing.

28 45. Medicare only pays for medically necessary services that were provided as
represented and prohibits claims procured through kickbacks or bribes. Medicare does not
cover diagnostic testing, *including Pathology special stain testing*, that is not reasonable and
necessary for diagnosis or treatment of illness or injury.

D. Local Carrier Determination

1 46. CMS² outlines coverage for special stains under Local Coverage Determination
2 (LCD) L36353³. LCD deems special stain testing medically necessary only in specific
3 circumstances, namely, explained below, thereby imposing strict requirements for self-
4 referral by the laboratory (Pathology doctor).

5 47. This LCD allows for very limited special stains and imposes three express
6 requirements if such a “self-referral” is made resulting in additional codes and charges by
7 the lab “...there may be additional tests, such as special stains, that the pathologist may
8 need to perform, even though they have not been specifically requested by the treating
9 physician/practitioner. The pathologist may perform such additional tests under the
10 following circumstances:

- 11 a) Services are medically necessary so that a complete and accurate diagnosis can
12 be reported to the treating physician/practitioner;
13 b) Results of the tests are communicated to and are used by the treating
14 physician/practitioner in the treatment of the beneficiary; and
15 c) Pathologist documents in his/her report why additional testing was done.”
16

17 48. CMS expressly mandates that “The above citation means that reflex templates
18 or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin
19 and eosin (H&E) stain by the pathologist are not reasonable and necessary. A pathologist
20 must first review the H&E stain prior to ordering special stains or IHC.”

21 49. Medicare’s LCD incorporates by reference “Title XVIII of the Social Security
22 Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or
23 services which are not reasonable and necessary for the diagnosis or treatment of illness or
24 injury.”
25

26
27 ² The Medicare Administrative Contractor (MAC) (MAC) for Jurisdiction E has granted
limited coverage for special stain services under 42 U.S.C. 1395ff(f)(2)(B).

28 ³ LCD accessed on 4/11/2023 at <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36353&ver=34>.

E. Pathology Billing Codes

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50. Pathology services use a set of codes called Current Procedural Terminology (CPT) for billing purposes. These codes, ranging from 80002 to 89399, specify the procedures conducted, with surgical pathology services represented by codes 88300 to 88399.

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51. The complexity of the surgical pathology service is reflected in the codes used. For instance, simpler services use the CPT 88302 code, while highly complex ones use CPT 88307. However, pathologists most frequently use CPT codes 88304 or 88305.

52. Routine Hematoxylin and Eosin (H&E) staining, a standard part of pathology services, is included in the billing codes from CPT 88300 to 88309. Therefore, additional charges for routine H&E staining are inappropriate and unwarranted.

53. When cases are complex or results are unclear, pathologists may order additional special stains, represented by CPT codes 88312-88313 and 88341-88344. These special stains incur higher charges than standard pathology services.

54. The Pathology section of the CPT codebook is quite straightforward, consisting of only four pages and listing 44 items. However, despite its brevity, every word and sentence in the procedure descriptors holds significant meaning.

55. In this context, a "specimen" refers to tissue that requires individual examination and diagnosis. Multiple specimens from the same patient, such as separately identified endoscopic biopsies or skin lesions, each receive their own codes based on the level of service provided.

56. The terms "unit of service" and "specimen" are fundamental to understanding CPT coding for surgical pathology. Each separately identified and diagnosed specimen corresponds to a unit of charge.

57. A specimen is typically considered "submitted for individual and separate attention" when it arrives in the lab in a separately labeled container. However, this is not always the case — sometimes, tissues in separate containers must be combined as a single charge, based on specific rules from the American Medical Association (AMA) or the payer.

1 For a tissue sample to justify a charge, it must be individually diagnosed in the final
2 diagnosis section of the medical report.

3 **F. Pathology Limitations**

4 58. According to Title XVIII of the Social Security Act §1833(e), Medicare
5 payments are not allowed for claims lacking the necessary documentation or for services
6 deemed unreasonable or unnecessary. Furthermore, Medicare Local Coverage
7 Determinations (LCDs) prohibit healthcare payments for inappropriate or automatic/reflex
8 ordering of special stains self-referred by pathologists.

9 59. The typical billing practice in pathology is a "1 jar, 1 specimen, 1 CPT code"
10 rule. However, some unethical laboratories may exploit a known loophole by reflexively
11 billing or excessively using special stain codes to inflate revenue, thereby shifting to a "1 jar,
12 1 specimen, multiple CPT codes" approach, which can double or triple earnings per
13 specimen.

14 60. Special stains (coded as CPT 88312-88313, or 88341-88344) should only be used
15 when standard H&E staining cannot provide all the necessary information, and the ordered
16 special stain has a reasonable likelihood of contributing to or being relevant for the final
17 diagnosis.

18 61. Medicare payments for pathology are divided into technical (TC) and
19 professional components (PC). Each component is billed separately, or the laboratory may
20 bill globally for both the TC and PC if it performs both components.

21 **G. Pathology Payments Slashed Nationally**

22 62. In 2009, CMS introduced a single payment for multiple prostate saturation
23 biopsy pathology services to address overpayment patterns, which effectively reduced
24 earnings for reading prostate biopsies.

25 63. In 2013, CMS further reduced all pathology reimbursements to tackle ongoing
26 overbilling issues. This measure approximately halved reimbursement for the technical
27 component (TC), leading to a 30% overall reduction in payment for a global pathology claim.

28

1 64. CMS reduced reimbursement for immunohistochemistry special stains by over
2 30% in 2014 (following consistent increases the previous year). Despite these systematic
3 reductions in pathology reimbursements, starting in 2016, claims and payments for
4 immunohistochemistry submitted to Medicare began to rise again, necessitating further
5 measures to ensure appropriate use and to combat overuse and abuse.

6 65. Around 2011, reimbursements for surgical pathology CPT codes 88300-88399
7 were significantly reduced, by an average of one-third. This led to substantial revenue losses
8 for pathology labs. For example, reimbursements for pathology code CPT 88305 fell from an
9 average of roughly \$200 to \$78.65 per specimen by 2019 (source:
10 https://www.palmettogba.com/palmetto/fees_front.nsf/fee_main?OpenForm).

11 66. Shortly thereafter, both self-referred and non-self-referred special stain usage
12 saw rapid increases, with self-referred special stains growing over 400% between 2004 and
13 2010. Self-referred special stains (from owner-operator laboratories) increased at a higher
14 rate than non-self-referred special stains. Specifically, the number of self-referred special
15 stains rose from about 60,000 in 2004 to about 340,000 in 2010—an increase of more than
16 400 percent.

17 **H. Pathology Fraud And Abuse⁴**

18 67. When pathology codes 88304-88309 are billed routinely with special stain
19 codes (CPT codes 88312-88313 and 88341-88344), they trigger a Medically Unlikely Edit
20 (MUE), indicating potential billing fraud.

23 ⁴ The Government Accountability Office (GAO) published a general consensus report
24 highlighting the increased use of anatomic pathology services by providers who self-refer,
25 resulting in substantial additional healthcare and Medicare spending. See
<https://www.gao.gov/assets/660/655442.pdf> The GAO report found that referrals for pathology
26 services significantly increased after owner-operator labs began self-referring.

27 Medicare paid approximately \$1.28 billion in 2010 under the physician fee schedule
28 for pathology services across all settings, with nearly 80% (\$945 million) performed in
physician offices and independent laboratories, like Sterling. The GAO report also found that
special stains, used with pathology services, accounted for about 66% of the \$1.94 billion
spent on these services in 2010, mainly for examining biopsy tissue samples.

1 75. Sterling routinely upcoded by improperly self-ordering, and habitually adding
2 "special stain" CPT codes to routine Pathology CPT codes without meeting any of the
3 requirements for government laboratory testing as outlined in Title 42, CFR 410.32(a).

4 76. In many instances, including for beneficiaries outlined in Section VII below,
5 the special stain "Tests [were] not ordered by the physician who is treating the beneficiary,"
6 the reading pathologist, and were therefore "not reasonable and necessary." *Id.*

7 77. Special stains are required in uncommon instances and must be reviewed by a
8 pathologist before being ordered. Reflex or pre-ordering special stains, as done by
9 Defendants, indicates premeditated and deliberate medical billing fraud.

10 78. Defendants directed and required staff including administrative and clerical
11 workers to pre-order and self-refer special stains for each specimen, resulting in double to
12 triple revenues per specimen and circumventing the typical one specimen-one code rule in
13 Pathology.

14 79. Defendants' annual revenues were substantially enhanced by their control
15 over the number of inappropriate and self-ordered special stains at Sterling, instituting an
16 unlawful business model of phantom requisitions, false Pathology reports, and duplicitous
17 pre-ordering, among other schemes.

18 80. Reflex or pre-ordering special stains and/or ordering them for nearly every
19 Pathology specimen (as done by *Sterling*), is all but a guarantee of premediated and
20 deliberate medical billing fraud.

21 81. These institutional wide upcoding policies, knowingly devised by defendants,
22 earned them sizable wealth while billing for Pathology slides, special stains, and other tests
23 that were either not created or examined but billed, or not ordered by a treating physician
24 and billed to the government..

25 82. The reading pathologist in most instances reads out the slide and report based
26 on the H&E stain, but Sterling, Lekov and/or Yang then scrubbed the report and signed it
27 themselves, always with an added-on special stain. As Such, Sterling in many cases as
28

1 shown in Section VII below, has no legitimate physician order for performing special stain
2 tests, no signatory, and no records conforming with CFR §410.32.

3 83. The rules require that the rendering pathologist must first review each routine
4 H&E stain specimen before any special stain is ordered or billed. When performed in this
5 manner, special stains are billed separately and additionally. The use of special stains before
6 the analysis of the routine H&E-stained specimen is medically unnecessary and therefore
7 not reimbursable.

8 84. For every legitimate or actual surgical tissue specimen which Sterling received
9 for routine Pathology, Sterling directed and required that the administrative staff or one of
10 the pathologists pre-ordered and self-referred one or more special stains per tissue. Each
11 improper special stain code then resulted in double to sometimes triple revenues per
12 specimen in favor of Sterling. These unlawful billing practices are ongoing.

13 85. Sterling's fraudulent billing practices and special stain schemes have persisted
14 for over a decade, and are continuing- allowing Defendants including Sterling executives,
15 pathologists, and billing managers to accumulate significant wealth.

16 86. Defendants' disregard for medical necessity, correct billing, and
17 reasonableness requirements contributed to a culture focused on maximizing revenues at
18 the expense of lawful billing practices.

19 87. The improper self-referrals, upcoding, and ordering of special stains, along
20 with the lack of compliance with regulations, indicate a deliberate and systematic effort by
21 Sterling and its co-conspirators to defraud the healthcare system for financial gain.

22 88. The False Claims Act claim highlights Defendants' unlawful practices,
23 emphasizing the need for accountability and proper oversight in the Pathology lab industry
24 to prevent such fraudulent schemes from causing undue financial strain on the healthcare
25 system.

26 89. By exposing Sterling's fraudulent billing practices, the FCA claim seeks to put
27 an end to Defendants' systematic abuse of the system and ensure that other Pathology labs
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1 adhere to ethical and lawful practices for the benefit of patients, healthcare providers, and
2 taxpayers.

3 90. Even worse, at least 15-25% of Sterling's COVID-19 testing revenues in 2021
4 and 2022 were procured through billing the government for *phantom testing*- testing which
5 was never done nor results ever made available or reported to beneficiaries.

6 91. Sterling directly solicited Medicare and Medicaid beneficiaries to undergo its
7 laboratory tests and agreed to not bill the beneficiaries for deductibles or co-pays in
8 exchange for them undergoing any tests which Sterling ordered or billed. Sterling promised
9 beneficiaries that the tests were fully covered and "free." Defendants also paid cash
10 kickbacks to cappers and runners, including foreign nationals and immigrants contracted
11 by a California *fabric company* and others to induce referrals to federal healthcare programs
12 for laboratory testing.

13 92. Sterling mandates that its administrative staff reflex order special stains on
14 all Pathology specimens for all beneficiaries, and that if any specimen is submitted for H&E
15 Pathology, that a standing order for at least one special stain (and in some cases multiples)
16 must be ordered per specimen received. In other instances, Sterling's administrative staff
17 and transcriptionists are instructed to auto populate its reports with special stain verbiage,
18 and cause charges to be billed to the government for special stains.

19 93. If a physician orders or a patient submits to one H&E stain service at Sterling,
20 Sterling institutionally mandates that it must self-order and bill Medicare, Medicaid, and
21 carriers for at least one corresponding special stain code for each H&E code, thereby
22 doubling and often tripling Sterling's earnings per specimen.

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VI. DEFENDANTS' FRAUDULENT ACTS

A. Sterling Pathology

94. Defendant Changgao Yang, M.D. serves as Sterling’s President, Chief Executive Officer (CEO), and “billing compliance officer” oversees contractor and employed pathologists⁵.

95. Sterling pathologists and Defendants Yang and Lekov rank in the 95th-100th percentile in three categories for total payment per pathologist, highest number of patients, and highest payments per patient statewide compared to the other approximately 1083 California pathologists.

96. Defendant Yang holds NPI 1366435638. Yang's excessive special stain order rates far exceed national standards of 5-10%. Specifically and by way of example, in CY 2017, YANG’s total Medicare production was as follows: 5798 units of CPT 88305, and total 12,756 units of “special stains”. Accordingly, YANG’s “special stain” order and bill rate in CY 2017 was approximately 220%.

97. On analysis for 2017 CY, Defendant Yang billed Medicare approximately \$8,724,888 in that year alone, an average from 1.3 to 9.6 “special stains” per beneficiary as set forth below and in the table-

- a) Yang billed 2776 units of special stain CPT 88312 on 1573 patients, thus an average order rate of 1.8 stains per patient;
- b) An additional 6736 units of special stain CPT 88313 on 2248 patients, thus an average order rate of 2.99 stains per patient.
- c) An additional 1098 units of special stain CPT 88341 on 271 patients, thus an average order rate of 4.1 stains per patient; and
- d) A further 2146 units of special stain CPT 88344 on 224 patients, thus an average order rate of 9.6 stains per patient for this code.

CPT Codes	Number of Services	Number of Medicare Beneficiaries	Average Medicare Payment	Payments	Special Stain Payments

⁵ At relevant times, Sterling represented it employed six pathologists “Changgao Yang, M.D., PhD, Ellie Lekov, M.D., Kimberly Woodward, M.D., Paul F. Kirshman, M.D., William Ngoc Nguyen, M.D., and [Doctor 1] M.D.”

88305	5,798	2,385	\$124.50	\$296,933	
88312	2,776	1,573	\$148.20	\$233,120	\$233,120
88313	6,736	2,248	\$185.96	\$418,032	\$418,032
88341	1,098	271	\$334.56	\$90,667	\$90,667
88342	528	416	\$119.24	\$49,603	\$49,603
88344	2,146	224	\$1531.60	\$343,078	\$343,078
Total CMS Payments					\$1,134,500

98. Defendant Lekov holds NPI 1033266788. Lekov's excessive special stain order rates far exceed national standards of 5-10%. In CY 2017, Lekov's Medicare production was as follows: 2550 units of CPT 88305 for total specimens billed, and 4482 units of "special stains"⁶. Accordingly, Dr. Lekov's "special stain" order and bill rate in CY 2017 was 172%, well above the national benchmark.

99. Sterling pathologists Yang and Lekov received more than 50% and 62% of their total Medicare revenues from special stains, respectively, compared to a non-Sterling pathologist's 2.1%⁷.

Pathologist	NPI	% of total Medicare revenues from special stain CPTs
Doctor 1	1932145133	2.1%
Defendant LEKOV	1033266788	62%
Defendant YANG	1366435638	50%

100. Sterling pathologists Yang and Lekov processed *fewer* specimens in 2013, but increased revenues through special stain upcoding, earning significantly more per patient and per-specimen than non-Sterling pathologists.

⁶ "Special Stains" CPT include codes 88312- 88313, and 88341- 88344.

⁷ In comparison, in CY 2017 Dr. P.S. (a non-Sterling pathologist) with NPI 1932145133 (practicing in the same geographic area as Defendants) received 2.1% of his total Medicare revenues from "special stains".

1 101. Despite CMS's national reduction of Pathology reimbursement by 30%
2 effective January 1, 2013, Yang's upcoding scheme resulted in \$716 payment per patient in
3 2013, up from \$537 in 2012, and an additional \$308,000 in Medicare revenues, despite also
4 having *fewer* specimens.

5 102. In contrast to non-Sterling pathologists operating within CMS's reduced
6 Pathology allowances amounts, Sterling (Yang) billed and received on average 300%-500%
7 more per patient from CMS during the same period.

8 103. In comparison to Yang's earnings of \$537-\$716 per patient as a result of
9 upcoding with inappropriate special stain codes, an average non-Sterling pathologist in the
10 same region earned only \$75-105 per patient during the same time period.

11 **B. Elite Medical Billing Corporation**

12 104. Defendants Elite Medical Billing Corporation and Jenny Chang perform all of
13 Sterling's coding, billing, collections, and appeals, in an ongoing relationship that facilitates
14 Sterling's illicit practices. Elite and Chang processed Sterling's unlawful claims, securing a
15 portion of the profits from fraudulent special stain upcoding and COVID-19 testing.

16 105. Granted direct access to Sterling's electronic medical records and billing data,
17 Elite and Chang were able to review, audit, correct, appeal, and generate detailed reports
18 on Sterling's billing practices. This included systematic upcoding, unbundling, and excessive
19 use of special stain codes.

20 106. In 2022, Elite and Chang created and submitted approximately 200,000 new
21 government claims for COVID-19 testing on behalf of Sterling, thereby securing payments
22 from the CARES Act and HRSA COVID-19 Uninsured Program. To manage the surge in
23 volume, Chang expanded Elite's operations by recruiting overseas billers.

24 107. Elite and Chang profited from Sterling's gross earnings based on an agreement
25 that allotted them a portion of the gross collections. They supplied Sterling with the
26 necessary coding, billing infrastructure, logistics, and staff, thus enabling Sterling's
27 fraudulent billing practices.

28

1 108. Upon information and belief, communications, and directives between
2 Sterling, Okuniewski, Yang, Lekov and Elite's ownership management under Chang
3 required that all Pathology claims be scrubbed by Elite and Chang to add-on billing for at
4 least one special stain code for each H&E code billed per specimen. This ensured no
5 pathology claim was submitted without unbundling and upcoding.

6 109. Communications and directives between Sterling, Okuniewski, Yang, Lekov,
7 and Elite's management under Chang indicated that all pathology claims should include at
8 least one special stain code for each H&E code billed per specimen.

9 110. Despite their awareness of Sterling's fraudulent practices, Elite and Chang
10 willingly participated in the fraud, processing false claims and upcoded entries, and
11 transmitting fraudulent codes and claims for government payment. In return, they retained
12 5-6% of the gross collections from Sterling's unlawful billing.

13 111. Elite and Chang's close collaboration with Sterling enabled fraudulent billing,
14 with both parties profiting from the increased revenues. From 2020 to 2023, they conspired
15 to process false and fraudulent COVID-19 testing claims to the government, which did not
16 meet the regulations for those services. Sterling, remaining Elite's primary and most
17 profitable client, led to a substantial volume and earnings surge due to the CARES Act.

18 112. As Chang explained it on or about April 4, 2023, Sterling remains her and
19 Elite's "number 1" (and most profitable) client: "we were part of the CARES Act" so "our
20 [2021 and 2022] volumes were through the roof."

21 113. For their pivotal role in facilitating Sterling's fraudulent billing, Elite and
22 Chang received remuneration exceeding the scope of their "billing services". By merging
23 their systems with Sterling's, they cemented their complicity in Sterling's fraudulent billing
24 practices, receiving a percentage of the gross revenues and disproportionate "perks".

25 114. Elite and Chang's deep involvement in Sterling's operations allowed them a
26 comprehensive insight into Sterling's patient database, pathology records, and medical
27 requisitions. Their unrestricted, remote access into Sterling's complete data facilitated the
28 perpetuation of fraudulent billing practices.

1 115. Despite being a medical billing company with an obligation to uphold lawful
2 practices, Elite and Chang were complacent about Sterling's fraudulent addition of a special
3 stain code to every H&E stain. Their remuneration was not in line with the standard "billing
4 services" they purported to provide, indicating their complicity in Sterling's fraudulent
5 practices.

6 116. By turning a blind eye to the fraudulent practices and facilitating the
7 submission of false claims, Elite and Chang became key enablers in Sterling's unlawful
8 operations. Their direct involvement and profiteering from Sterling's illicit gains underscore
9 their active participation in the fraud.

10 117. All the fraudulent actions of Elite and Chang were carried out under the
11 knowledge and directives of Sterling, Okuniewski, Yang, and Lekov. This high-level
12 conspiracy was critical in maintaining Sterling's unlawful operations and resulted in
13 significant financial damage to the government's Medicare, Medicaid, and Tricare
14 programs.

15 118. In summary, Elite and Chang were instrumental in facilitating and
16 perpetuating Sterling's fraudulent practices. Their direct involvement, extensive access to
17 Sterling's data, active participation in submitting false claims, and disproportionate
18 remuneration highlight their complicity in Sterling's systematic defrauding of government
19 healthcare programs.

20 119. The relationship between Elite, Chang, and Sterling was not just a service
21 provider-client relationship; it was a partnership in unlawful activities. The considerable
22 access Elite and Chang had to Sterling's data, their willingness to turn a blind eye to
23 fraudulent practices, and their direct involvement in the fraudulent scheme.

24 120. Elite and Chang were not mere bystanders in Sterling's fraud against the
25 government. They were active participants who benefited financially from their
26 involvement. By processing, billing, and posting deposits for Sterling's unlawful claims, they
27 directly profited from the fraud, collecting a percentage of the illicit gains.

28

1 121. Elite and Chang's involvement in this long running billing scheme was not
2 incidental and went beyond mere negligence or ignorance; it was intentional and calculated
3 to maximize their own financial gain at the expense of the government.

4 **C. Defendants Executed A Widely Known Special Stain Over-Billing**
5 **Scheme**

6 122. Defendants' excessive profits originated from a carefully devised and
7 intentional fraudulent course of action, encompassing unlawful upcoding and unbundling
8 practices, as well as the employment of runners and cappers.

9 123. Sterling's lead executives, including CEO Yang and VP Okuniewski, devised,
10 implemented, and enforced aggressive and illicit upcoding which focused on unlawful special
11 stain codes, and they overlooked compliance issues and cultivated a profit-centric
12 environment within the organization.

13 124. Sterling's illicit billing practices can be traced back to at least 2012, aligning
14 with the arrival of VP and "marketing director" Okuniewski, who was instrumental in
15 implementing Defendants' scheme to increase earnings despite decreasing patient numbers.

16 125. Sterling's fraudulent conduct was partially a reaction to CMS's significant
17 reductions in standard Pathology CPT code payments in 2009 and 2013, prompting Sterling
18 to inappropriately upcode and take advantage of add-on special stain codes to manipulate
19 its earnings.

20 **D. Defendants Blatantly Violated Medicare Regulations.**

21 126. Sterling, reliant on referring physicians and healthcare providers for
22 submitting specimens for testing, encountered obstacles due to significant reductions in the
23 CMS Pathology fee schedule. To counterbalance these financial challenges, Sterling
24 employed self-referral schemes, characterized by a substantial overutilization of special
25 stains.

26 127. Defendants systematically engaged in reflexive and pre-ordering of numerous
27 special stain codes for virtually every patient specimen submitted for Pathology services.
28 They executed this without fulfilling the criteria of medical necessity, treating doctor's
orders, and Medicare LCDs. Furthermore, Defendants reflex ordered special stains before

1 pathologists had the opportunity to examine the H&E slide and neglected to accurately
2 document the need for these deceptively ordered special stains.

3 **E. Defendants' Knowingly Submitted False Claims.**

4 128. Defendant Okuniewski represented to Relator's principal that Sterling always
5 has two pathologists review and read each slide but represented that they only bill the
6 government or carriers for one doctor, not two.

7 129. Okuniewski admitted to Relator's principal and concurred that special stains
8 should be ordered less than 10% of the time at sterling. On or about February 10, 2020
9 Okuniewski then misrepresented to Relator's principal that Sterling's special stain rate did
10 not exceed 10%, which it did- in order to retain Relator's principal's account.

11 130. When confronted with Sterling's overutilization of special stains and billing for
12 Patients 1 ,2, 3, and 4 in Section VII below, Okuniewski misrepresented that Sterling only
13 ordered special stains in 10% of cases, and that special stains were not billed for each of
14 these patients (which they were.)

15 131. Defendants' employees and staff were instructed to bill the government for
16 unlawful special stains. Defendants' mandates included expressly using "generic" physician
17 names (whom had no direct role with the services rendered) in on the Pathology report and
18 outside Pathology consult requisition forms.

19 132. Defendants thus caused the submission of false claims to the government for
20 special stains for each patient, and they knew that their practice of billing for special stains
21 on every specimen or nearly every specimen was fraudulent.

22 133. Defendants told their employees to electronically transmit or mail false
23 claims to the government for payment on countless Pathology and laboratory claims which
24 Defendants knew violated the FCA and CFCA.

25 **F. Defendants Obtained Payment for Tests by Falsely Certifying the**
26 **Rendering Doctor's Name and/or Signature, and Medical Necessity.**

27 134. The Social Security Act (SSA) provides: "no payment may be made under Part
28 A or Part B [of Medicare] for any expenses incurred for items or services which ... are not
reasonable and necessary " 42 U.S.C. 1395(a)(I)(A). The SSA defines "certificate of medical

1 necessity" as a form or other document containing information required by the carrier to
2 be submitted to show that an item is reasonable and necessary" (42 U.S.C. 1395(2)(B).)

3 135. The SSA prohibits payments for items or services that are not reasonable and
4 necessary. Medical necessity certificates must contain information required by the carrier
5 to show that an item is reasonable and necessary.

6 136. Defendants submitted claims for payment relying on fraudulent medical
7 necessity certificates, generic physician names, and fictitious ordering physicians. This
8 large-scale fraud resulted in the defendants retaining millions of dollars in unearned
9 payments.

10 137. Defendants directed managing agents and administrative staff to pre-sign
11 blank medical necessity certificates, using these templates to create fraudulent certificates
12 without the reading pathologist or treating physician's actual approval. In some instances,
13 the medical transcription service was instructed to create false report templates, which
14 automatically added a negative special stain result to all Sterling reports.

15 138. Defendants ordered and conducted tests without physicians' orders or medical
16 necessity, defrauding Medicare and the State on a massive scale and retaining tens of
17 millions of dollars in unearned payments.

18 139. Defendants also received denials and record requests on some of their improper
19 and duplicate claims. They presented false records for government payments and deflected
20 billing inquiries and complaints from confused beneficiaries questioning double Pathology
21 charges.

22 140. To procure their fraud, Defendants instructed managing agents, including
23 Lekov and administrative staff, to reflexively pre-sign blank certificates of medical
24 necessity. Defendants used these "templates" to create fraudulent certificates of medical
25 necessity for their claims, without the treating physician or reading pathologist actually
26 signing off on the specific special stain test underlying the claim.

27 141. Sterling, Yang, and Lekov's known practice of assigning "generic" doctor's
28 names on Pathology reports and requisitions reflects a failure to comply with Medicare and

1 Medicaid rules which require accurate identification of the rendering provider by name and
2 NPI.

3 142. Furthermore, Defendants ordered and conducted tests for which there were no
4 physicians' orders or medical necessity. Defendants have perpetrated this fraud on a
5 massive scale and have received many tens of millions of dollars in undeserved payments
6 from both Medicare and the State.

7 **Doctor 1**

8 143. In Section VII below, Doctor 1 the reading pathologist, did not order the special
9 stains added by Sterling for the Medicare beneficiaries. Sterling had no authority to order
10 the special stains, as that authority belonged to Doctor 1.

11 144. Doctor 1 is an independent contractor who explains he reads on average 2-3
12 slides for Sterling per month. As a non-employed pathologist, Doctor 1 has not been to
13 Sterling's premises since 2008 or 2009, when he visited once when he began his relationship
14 with Sterling. Sterling ships out slides monthly to Doctor 1 who reads (interprets) Sterling's
15 slides at his own company premises in another city and issues a formal Pathology report.

16 145. Sterling pays Doctor 1 per slide on an end-of-month invoicing. Sterling
17 suppresses Doctor 1's Pathology report, issues its own report, and adds and bills a special
18 stain code and service which was neither ordered by Doctor 1 nor performed or read out by
19 him.

20 146. Sterling does not disclose that it bills for special stains on the slides read by
21 Doctor 1 which neither required a special stain for the final diagnosis, nor did Doctor 1 order
22 a special stain.

23 147. Sterling's practice of suppressing Doctor 1's Pathology report, issuing its own
24 report, and adding special stain codes and services without Doctor 1's authorization or
25 medical necessity constitutes fraud against Medicare and Medicaid.

26 148. Doctor 1 neither requested the special stain services which were billed by
27 Sterling, Yang, and Lekov, nor authorized the special stains, nor billed the government for
28 reading these special stains. Doctor 1's Medicare records reflect his annual special stain

1 order and bill rate year-over-year is approximately 2.1%, a hundredfold less than Defendant
2 Yang's special stain order rate.

3 149. Doctor 1, the reading pathologist on Sterling's reports, never ordered the
4 special stains, and Sterling added the special stain code after Doctor 1 read the slides and
5 had rendered his final diagnosis. Not only was there no medical necessity for the special
6 stain Sterling billed, but there was also an absence of a treating physician order for it.
7 Sterling did not have any authority to even order the special stains because Doctor 1 held
8 that authority as the reading pathologist.

9 **Doctor 2**

10 150. Similarly, Doctor 2, the reading pathologist, did not authorize the special
11 stains added by Sterling for patients, including Patient 5 discussed in Section VII below.
12 Sterling had no authority to order the FIVE special stains for Patient 5; that authority lay
13 exclusively with Doctor 2, the rendering and reading pathologist. Medicare does not
14 reimburse for tests unless they are ordered by the treating physician or the rendering
15 provider. As neither the patient's treating doctor nor Doctor 2 ordered these special stains,
16 and given that these were reflexive and cloned special stain orders directed by business
17 imperatives from Defendants Sterling, Yang, Lekov, Okuniewski., Elite, and Chang, each of
18 these FIVE special stains constitutes a separate false claim.

19 **G. Defendants Habitually Upcoded and Unbundled Special Stain Test**
20 **Claims for Unjust Enrichment**

21 151. Sterling upcoded, unbundled, billed, and received and retained payments from
22 the government for test claims which did not conform to NCCI, violated the LCDs for special
23 stains, were not ordered by the treating physician, were medically unnecessary, were in
24 some instances incompatible special stain code and diagnosis combinations, and failed to
25 adhere to CMS mandates for countless beneficiaries including Patients 1,2, 3, 4, and 5 as
26 outlined in Section VII below.

27 152. Defendants conspired to violate the FCA and the CFCA by causing the
28 submission of false or fraudulent claims; conspired to make and use, or cause to be made or

1 used, false records material to false or fraudulent claims; and once put on notice of the
2 unlawful billing, conspired to not disclose, or return the resulting overpayments to the
3 government.

4 153. By consistently and knowingly adding special stains without medical necessity
5 or physician orders, Defendants Sterling, Yang, and Lekov have defrauded Medicare and
6 the State, collecting tens of millions of dollars in undeserved payments.

7 154. Defendants' fraudulent practices have not only caused financial harm to the
8 government but have also jeopardized the health and wellbeing of patients by providing
9 them with potentially unnecessary and misleading diagnostic information.

10 155. The fraudulent actions of Defendants Sterling, Yang, Lekov, and their
11 managing agents, including Okuniewski, have violated the FCA, CFCA, and AK and caused
12 substantial harm to the United States government and the State, as well as to the Medicare
13 and Medicaid programs, and their beneficiaries.

14 156. In light of the substantial fraud perpetrated by Defendants and the harm
15 caused to the government and its beneficiaries, Defendants must be held fully accountable
16 for their unlawful actions and to recover the ill-gotten gains obtained through their
17 fraudulent practices.

18 157. The practices complained of herein are continuing, resulting in the submission
19 of additional false or fraudulent claims.

20 **H. Defendants Affirmatively Modified Their Upcoding And Unbundling**
21 **Practices To Evade Government Detection.**

22 158. On or about January 1, 2020, Defendants Sterling, Yang, Lekov, Okuniewski,
23 and Does 1-10 modified their companywide upcoding and unbundling mandates and policies
24 to add certain verbiage to their Pathology reports as follows “Initial H&E reviewed. Special
25 stains are performed and reviewed when indicated, with appropriate negative and positive
26 controls.” Although sterling did not change its company mandate to unlawfully upcode each
27 specimen with a minimum of one special stain, it added the language intended to evade
28 repayment demands.

1 159. Sterling's described policy change is evident when analyzing Sterling's 2017
2 Pathology reports compared to its 2020 reports. However, regardless of Sterling's amended
3 documentation, every patient's specimen was reflexively required to be pre-ordered and
4 billed for a special stain, regardless of lack of medical necessity or the lack of an authorized
5 physician order for the special stain. Hence, Sterling continues to unlawfully and with
6 knowing intent upcode and bundle Pathology specimens with at least one special stain code
7 per specimen.

8 **I. Defendants Billed For COVID-19 Testing Which Was Never Performed.**

9 160. Sterling claimed a capacity for performing "33,000" COVID tests per week, all
10 compensated by Medicare, Medicaid, or the government through the CARES Act and the
11 HRSA COVID-19 Uninsured Program. The government requires that for the laboratory
12 service to be deemed reimbursable, testing results must be made available to the treating
13 provider, or in some cases directly to the patient.

14 161. During 2021 and 2022, Sterling collected more COVID-19 samples than they
15 could test due to their illicit marketing and recruitment practices. Despite lacking the
16 resources required to timely or adequately process these specimens, Sterling failed to halt
17 sample collection. Consequently, Sterling was unable to process numerous specimens and
18 failed to provide results, despite billing the government for all collected samples, regardless
19 of whether they were tested.

20 **J. Defendants Engaged In Pass-Through Billing.**

21 162. Sterling utilized pass-through billing, contracting with external laboratories
22 and pathology corporations to perform medical testing services, yet billed Medicare and
23 Medicaid as if the tests were conducted in-house. This misleading practice allowed Sterling
24 to charge inflated prices for the tests, thereby profiting from the unwarranted markup.

25 163. Defendants unethically billed the government globally for services performed
26 by external labs, including *Neogenomics Laboratories Inc.*, at marked-up prices, in violation
27 of regulations.

1 164. Medicare mandates that any service attached to a line-item CPT 90 modifier
2 must disclose the provider's information. Defendants neglected to adhere to government
3 regulations in their billing practices, including failing to correctly identify the reading
4 pathologist's NPI and neglecting to attach a modifier 90 on healthcare lab claims.
5 Defendants inappropriately used external labs and pathologists without appropriate
6 disclosure or billing adjustments.

7 165. From at least 2008, Defendants systematically contracted with independent
8 pathologists (such as Doctor 1 and Doctor 2), physically sending glass slides to pathologists
9 located away from Sterling's premises for pathology report generation.

10 166. Despite the fact that contractors did not read the slides at Sterling's premises
11 in Seal Beach, Sterling failed to accurately reflect the place of service on its claims to the
12 government. Sterling misrepresented the services rendered by omitting correct modifiers
13 and other claims information.

14 167. Sterling also neglected to comply with Correct Coding Initiatives (CCI), which
15 mandate the addition of a -90 modifier to identify services performed by a party other than
16 the reporting physician.

17 168. Further, Sterling concealed the external pathologists' report from the medical
18 record but used the external pathologist's name on Sterling's final Pathology report, falsely
19 implying that Sterling provided the services.

20 169. Sterling subsequently billed the government under their own doctors' names
21 for services they did not provide. Sterling's alleged "ordering doctor" for most of its special
22 stains was illusory, as the "generic" named pathologist on some reports never read the
23 Pathology slide upon which Sterling billed for its special stain.

24 170. By misrepresenting the true provider of the services and neglecting to properly
25 apply required billing modifiers, Sterling violated applicable laws and regulations, including
26 the Stark Law and the Anti-Kickback Statute, which aim to prevent fraud and abuse in the
27 healthcare system.

28

1 **VII. DEFENDANTS' EXEMPLAR FALSE HEALTHCARE CLAIMS**

2 171. Defendants submitted o false claims and received and retained payments for
3 upcoded and unbundled special stain codes for Medicare and Medicaid beneficiaries. The
4 following examples detail Defendants' fraudulent billing practices for five patients,
5 involving unnecessary special stains, upcoding, and unbundling charges:

6 **A. Patient 1 (E.M., age 76)**

7 172. Defendants Sterling, Elite, Chang, and Dr. Lekov billed unnecessary special
8 stain services for Patient 1, which were read by an outside contracted dermatopathologist,
9 Doctor 1. No medical necessity or treating physician's request was present for the special
10 stain. The special stain was marked as negative "(ct/mw)." The claim was submitted on
11 February 6, 2020, and payment was obtained from the government, hence a false claim.

12 173. Sterling's report reflects the actual service was performed (read out) by an
13 outside (contracted) pathologist Doctor 1, however Dr. Lekov signed and issued the final
14 Pathology report which ADDED a special stain service, which resulted in improper
15 unbundling and upcoding, including CPT code 88305 for a standard H&E stain and an
16 additional CPT code 88312 for a special stain.

17 174. There was no medical necessity for the special stain as Doctor 1 made his final
18 diagnosis based on the routine H&E stain. There was also no order or request by Doctor 1
19 for a special stain or any comment requiring further testing.

20 175. Patient 1's treating physician did not request or order the unnecessary special
21 stain service and charge, which Sterling and Lekov reflex added solely pursuant to
22 Defendants' billing mandates.

23 **A. Patient 2 (J.J., age 68)**

24 176. Similarly, Defendants and Dr. Lekov billed unnecessary special stain services
25 for Patient 2, which were read by dermatopathologist Doctor 1. No medical necessity or
26 treating physician's request was present for the special stain. The special stain was marked
27 as negative "(ct/mw)." The Pathology report shows that the additional service was
28

1 unnecessary and not medically justified. The special stain claim was submitted on February
2 6, 2020, and payment was obtained from the government, hence a false claim.

3 **B. Patient 3 (W.M., age 89)**

4 177. Likewise, Defendants and Dr. Lekov upcoded and billed unnecessary special
5 stain services for Patient 3, which were read by dermatopathologist Doctor 1. No medical
6 necessity or treating physician's request was present for the special stain. The Pathology
7 report reflects the special stain was negative and marked as "(ct/mw)." The claim was
8 submitted on February 6, 2020, and payment was obtained from the government, hence a
9 false claim.

10 **C. Patient 4 (M.B., age 73)**

11 178. Defendants and Dr. Lekov upcoded and billed unnecessary special stains for
12 Patient 4, which were read by Doctor 1. They submitted two false claims for special stains.
13 Both special stains were marked as negative, with no medical necessity or treating
14 physician's request for either stain. The special stain claims were submitted in 2020, and
15 payments were obtained from the government, hence two false claims.

16 **D. Patient 5 (S.B., age 61)**

17 179. Defendants and Dr. Yang upcoded and billed five false and unnecessary
18 special stain services for Patient 5, which were read by Doctor 2. All five special stains were
19 marked as negative "(nh/es)" with no medical necessity or treating physician's request.
20 Sterling could not produce any special stain slides for this patient, as they likely never
21 existed. Five special stain claims were submitted for payment on April 6, 2017, and payment
22 was obtained for this claim- hence five false claims.

23 180. There was no indication of medical necessity for the reflex special stains
24 because Doctor 2 made her final diagnosis on the routine H&E stain.

25 181. There was also no order or request by the reading pathologist Doctor 2 for a
26 special stain on either of these FIVE specimens, or any comment in her reading which
27 required a special stain on any of the FIVE specimens. Further, there was no clinical
28

1 information or request by Patient 5's treating provider that either expressly requested or
2 ordered the special stains.

3 182. Neither Sterling nor its representatives could produce any of the "special stain"
4 slides for Patient 5 despite multiple demands for them to produce the slides, raising
5 questions about their existence. This lack of evidence suggests that the slides might have
6 never existed in the first place, further implicating Sterling and its representatives in
7 fraudulent billing practices.

8
9 **VIII. LEGAL FRAMEWORK**

10 **A. Violations of the Federal False Claims Act (FCA)**

11 183. This claim for violations of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, is
12 brought by the Relator in the name of the United States, pursuant to 31 U.S.C. § 3730(b).
13 Relator is an "original source" of the information on which this claim is based, as that term
14 is defined in 31 U.S.C. § 3730(e)(4)(B).

15 184. 31 U.S.C. § 3729(a)(1)(A) provides that any person who:

16 knowingly presents, or causes to be presented, a false or
17 fraudulent claim for payment or approval . . . is liable to the
18 United States Government for a civil penalty of not less than
19 \$5,000 and not more than \$10,000, as adjusted by the Federal
20 Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times
21 the amount of damages which the Government sustains because
22 of the act of that person.

23 185. 31 U.S.C. § 3729(b)(1) defines "knowingly" to "mean that a person, with respect
24 to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance
25 of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or
26 falsity of the information; and (B) require[s] no proof of specific intent to defraud."

27 186. In relevant part, 31 U.S.C. § 3729(b)(2) defines "claim" as:

28 any request or demand, whether under a contract or otherwise,
for money or property and whether or not the United States has
title to the money or property, that—

(i) is presented to an officer, employee, or agent of the
United States; or

1 (ii) is made to a contractor, grantee, or other recipient, if
2 the money or property is to be spent or used on the
3 Government's behalf or to advance a Government program
4 or interest, and if the United States Government—

5 (I) provides or has provided any portion of the
6 money or property requested or demanded; or

7 (II) will reimburse such contractor, grantee, or
8 other recipient for any portion of the money or
9 property which is requested or demanded

10 187. The Medicare claims submitted by Defendants to CMS and/or its Medicare
11 Administrative Contractors are “claims” within the meaning of the FCA.

12 188. By virtue of the acts described above, Defendants knowingly presented, or
13 caused to be presented, false or fraudulent claims for payment or approval by regularly and
14 freely unbundling and separately charging for **Pathology special stains** and procedures
15 that were part of a global fee schedule, and thus not eligible for separate billing, in violation
16 of 31 U.S.C. § 3729(a)(1)(A).

17 189. By virtue of the acts described above, Defendants knowingly presented, or
18 caused to be presented, false or fraudulent claims for payment or approval for innumerable
19 **special stain codes** which were not performed as such, in violation of 31 U.S.C. §
20 3729(a)(1)(A).

21 190. 31 U.S.C. § 3729(a)(1)(B) provides that any person who:

22 knowingly makes, uses, or causes to be made or used, a false
23 record or statement material to a false or fraudulent claim is
24 liable to the United States Government for a civil penalty of not
25 less than \$5,000 and not more than \$10,000, as adjusted by the
26 Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus
27 3 times the amount of damages which the Government sustains
28 because of the act of that person.

191. 31 U.S.C. § 3729(b)(4) defines “material” as “having a natural tendency to
influence, or be capable of influencing, the payment or receipt of money or property.”

192. By virtue of the acts described above, Defendants knowingly made, used, or
caused to be made or used, false records and statements material to the foregoing false or
fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B). Specifically, Defendants

1 knowingly submitted false or fraudulent claims using false CPT billing codes, which not
2 only influenced, but determined, the amount they were paid.

3 193. The United States, unaware of the falsity or fraudulence of the claims
4 presented by Defendants, or the falsity of the records and/or statements which the
5 Defendants made, used, or caused doctors and other health care providers to make, and in
6 reliance on the accuracy thereof, paid Defendants, doctors, and other health care providers
7 for claims that would otherwise not have been allowed, suffering damages.

8 194. 31 U.S.C. § 3729(a)(1)(G) provides that any person who

9 knowingly makes, uses, or causes to be made or used, a false
10 record or statement material to an obligation to pay or transmit
11 money or property to the Government, or knowingly conceals or
12 knowingly and improperly avoids or decreases an obligation to
13 pay or transmit money to the Government . . . is liable to the
14 United States Government for a civil penalty of not less than
\$5,000 and not more than \$10,000, as adjusted by the Federal
Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times
the amount of damages which the Government sustains because
of the act of that person.

15 195. 31 U.S.C. § 3729(b)(4) defines “obligation” to include “an established duty,
16 whether or not fixed, arising from an express or implied contractual . . . relationship, from
17 a fee-based or similar relationship, from statute or regulation, or from the retention of any
18 overpayment[.]”

19 196. By virtue of the acts described above, Defendants knowingly concealed and/or
20 knowingly and improperly avoided an obligation to pay or transmit money to the
21 Government resulting from Defendants’ retention of the foregoing overpayments, in
22 violation of 31 U.S.C. § 3729(a)(1)(G).

23 197. As a result of the above-described conduct, the United States is entitled to civil
24 penalties and treble damages as provided by 31 U.S.C. § 3729(a)(1).

25 198. 31 U.S.C. § 3729(a)(1)(C) provides that any person who “conspires to commit”
26 any of the foregoing violations is liable for the same civil penalties and treble damages.
27 Defendants conspired to commit each the violations alleged, for which they are jointly and
28 severally liable.

B. Violations of the California False Claims Act (CFCA)

199. This claim for violations of the California False Claims Act, Cal. Gov't Code § 12650, *et seq.*, is brought by Relator in the name of the State of California, pursuant to Gov't Code § 12652(c). Relator is an "original source" of the information on which this claim is based, as that term is defined in Gov't Code § 12652(d)(3)(C).

200. Gov't Code § 12651(a) provides that:

"Any person who commits any of the following enumerated acts in this subdivision shall have violated this article and shall be liable to the state or to the political subdivision for three times the amount of damages that the state or political subdivision sustains because of the act of that person. A person who commits any of the following enumerated acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than five thousand five hundred dollars (\$5,500) and not more than eleven thousand dollars (\$11,000) for each violation, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990"

201. Gov't Code § 12651(a)(1) provides that any person who "knowingly presents or causes to be presented a false or fraudulent claim for payment or approval" is so liable.

202. Gov't Code § 12650(b)(2) defines "knowingly" to "mean that a person, with respect to information, does any of the following:

(A) Has actual knowledge of the information.

(B) Acts in deliberate ignorance of the truth or falsity of the information.

(C) Acts in reckless disregard of the truth or falsity of the information.

Proof of specific intent to defraud is not required.

203. In relevant part, Gov't Code § 12650(b)(1) defines "claim" as:

any request or demand, whether under a contract or otherwise, for money, property, or services, and whether or not the state or a political subdivision has title to the money, property, or services that meets either of the following conditions:

(A) Is presented to an officer, employee, or agent of the state or of a political subdivision.

1 (B) Is made to a contractor, grantee, or other recipient, if
2 the money, property, or service is to be spent or used on a
3 state or any political subdivision's behalf or to advance a
4 state or political subdivision's program or interest, and if
5 the state or political subdivision meets either of the
6 following conditions:

7 (i) Provides or has provided any portion of the
8 money, property, or service requested or
9 demanded; or

10 (ii) Reimburses the contractor, grantee, or other
11 recipient for any portion of the money, property, or
12 service that is requested or demanded.

13 204. The Medicaid claims submitted by Defendants to the California MMIS Fiscal
14 Intermediary are “claims” within the meaning of the CFCA.

15 205. By virtue of the acts described above, Defendants knowingly presented, or
16 caused to be presented, false or fraudulent claims for payment or approval by regularly and
17 freely upcoding and bundling for genetic panels in violation of Gov’t Code § 12651(a)(1).

18 206. By virtue of the acts described above, Defendants knowingly presented, or
19 caused to be presented, false or fraudulent claims for payment or approval for I tests which
20 were not performed as such, in violation of Gov’t Code § 12651(a)(1).

21 207. Gov’t Code § 12651(a)(2) provides that any person who “knowingly makes,
22 uses, or causes to be made or used a false record or statement material to a false or
23 fraudulent claim” is liable for the same treble damages and civil penalties.

24 208. Gov’t Code § 12650(b)(4) defines “material” as “having a natural tendency to
25 influence, or be capable of influencing, the payment or receipt of money, property, or
26 services.”

27 209. By virtue of the acts described above, Defendants knowingly made, used, or
28 caused to be made or used, false records and statements material to the foregoing false or
fraudulent claims, in violation of Gov’t Code § 12651(a)(2). Specifically, Defendants
knowingly submitted false or fraudulent claims using false CPT billing codes, which not
only influenced, but determined, the amount they were paid.

204. The State, unaware of the falsity or fraudulence of the claims presented by
Defendants, or the falsity of the records and/or statements which the Defendants made,

1 used, or caused doctors and other health care providers to make, and in reliance on the
2 accuracy thereof, paid Defendants, doctors, and other health care providers for claims that
3 would otherwise not have been allowed, suffering damages.

4 211. Gov't Code § 12651(a)(7) imposes liability for the same treble damages and civil
5 penalties on any person who

6 Knowingly makes, uses, or causes to be made or used a false
7 record or statement material to an obligation to pay or transmit
8 money or property to the state or to any political subdivision, or
9 knowingly conceals or knowingly and improperly avoids, or
decreases an obligation to pay or transmit money or property to
the state or to any political subdivision.

10 212. Gov't Code § 12650(b)(5) defines "obligation" to include "an established duty,
11 whether or not fixed, arising from an express or implied contractual . . . relationship, from
12 a fee-based or similar relationship, from statute or regulation, or from the retention of any
13 overpayment."

14 213. By virtue of the acts described above, Defendants knowingly concealed and/or
15 knowingly and improperly avoided an obligation to pay or transmit money to the State
16 resulting from Defendants' retention of the foregoing overpayments, in violation of Gov't
17 Code § 12651(a)(7).

18 214. Gov't Code § 12651(a)(8) imposes liability for the same treble damages and civil
19 penalties on any person who is a beneficiary of an inadvertent submission of a false claim,
20 subsequently discovers the falsity of the claim, and fails to disclose the false claim to the
21 state or the political subdivision within a reasonable time after discovery of the false claim.

22 215. By virtue of the acts described above, Defendants, to the extent they were
23 beneficiaries of the inadvertent submission of false claims, were alerted by Relator to the
24 falsity of the claims but failed to disclose the false claims to the State within a reasonable
25 time thereafter, in violation of Gov't Code § 12651(a)(8). As a result of the above-described
26 conduct, the State is entitled to civil penalties and treble damages as provided by Gov't Code
27 § 12651(a).

1 216. Gov't Code § 12651(a)(3) provides that any person who “conspires to commit”
2 any of the foregoing violations is liable for the same civil penalties and treble damages.
3 Defendants conspired to commit each the violations alleged, for which they are jointly and
4 severally liable pursuant to Gov't Code § 12651(a)(c).

5 **C. Violation of the Federal Anti-Kick Back Statute**

6 217. The Federal Anti-Kickback Statute (AKS) is a part of the Social Security Act,
7 codified at 42 U.S.C. § 1320a-7b(b). The statute states:

8 “(b) Illegal remunerations

9 (1)Whoever knowingly and willfully solicits or receives any remuneration
10 (including any kickback, bribe, or rebate) directly or indirectly, overtly or
 covertly, in cash or in kind—

11 (A)in return for referring an individual to a person for the furnishing or
12 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

13 (B)in return for purchasing, leasing, ordering, or arranging for or
14 recommending purchasing, leasing, or ordering any good, facility, service, or
15 item for which payment may be made in whole or in part under a Federal
16 health care program, shall be guilty of a felony and upon conviction thereof,
17 shall be fined not more than \$100,000 or imprisoned for not more than 10
 years, or both.

18 (2) Whoever knowingly and willfully offers or pays any remuneration
19 (including any kickback, bribe, or rebate) directly or indirectly, overtly or
20 covertly, in cash or in kind to any person to induce such person—

21 (A)to refer an individual to a person for the furnishing or arranging for the
22 furnishing of any item or service for which payment may be made in whole or
 in part under a Federal health care program, or

23 (B)to purchase, lease, order, or arrange for or recommend purchasing,
24 leasing, or ordering any good, facility, service, or item for which payment may
25 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 10 years, or both.”

26 218. The AKS is specifically designed to address fraud and abuse in federal
27 healthcare programs. Besides the AKS, the beneficiary inducement statute (42 U.S.C. §
28

1 1320a-7a(a)(5)) also may impose civil monetary penalties on physicians who offer
2 remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.

3 219. Under 42 U.S.C. § 1320a-7a, providers who pay or accept kickbacks also face
4 Civil Monetary Penalties (CMPL) of up to \$50,000 per kickback plus three times the amount
5 of the remuneration.

6
7 **IX. CLAIMS FOR RELIEF**

8 **A. FIRST CLAIM: Violation Of The Federal False Claims Act, 31 U.S.C. §**
9 **3279**

10 By Plaintiff United States Against All Defendants and Does 1-10

11 220. Plaintiff repeats and re-alleges all the preceding paragraphs of the Complaint
12 inclusive, as if fully set forth herein.

13 221. By falsely certifying the accuracy, completeness, and compliance of their
14 reimbursement claims with Medicare laws, regulations, and instructions for payment,
15 Defendants knowingly submitted false or fraudulent claims. This action is in violation of 31
16 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A).

17 222. Due to Defendants' false claims, CMS disbursed funds that would not have
18 been paid if the falsity were known. Each false claim constitutes a separate violation of the
19 FCA.

20 223. During the statutory period, Defendants violated the FCA in several ways.
21 They submitted claims to CMS and its contractors for tests that did not meet Medicare
22 coverage requirements and misrepresented them as meeting such requirements. They
23 claimed tests were medically necessary when they were not and claimed that tests were not
24 illegally induced through offers of remuneration, violating the AKS

25 224. Defendants knowingly submitted upcoded and unbundled claims for Pathology
26 special stains under CPT codes 88312-88313, 88341-88344, among other codes, for
27 numerous Medicare beneficiaries. This includes false special stain claims for Patient 1, 2, 3,
28

1 4 and 5 as outlined in Section VII. Defendants knew these tests were not covered by
2 Medicare, yet they upcoded and unbundled claims for unjust enrichment.

3 225. Under the FCA, "knowingly" is defined as having actual knowledge of the
4 information or acting in deliberate ignorance or reckless disregard of the truth or falsity of
5 the information. Defendants acted "knowingly" under 31 U.S.C. § 3729(b)(1) in the
6 following ways:

7 (i) Defendants had actual knowledge of their billing practices. They were directly
8 involved in using external labs and pathologists without proper disclosure and billing
9 adjustments, and they deliberately and improperly billed the government globally
10 for services performed by external labs at marked-up prices (pass-through billing.)
11

12 (ii) They acted in deliberate ignorance of the truth by claiming that two pathologists
13 read each slide while billing for only one reading. They contracted with independent
14 pathologists, sent slides offsite for reading, and failed to correctly reflect the true
15 rendering provider on claims.
16

17 (iii) Defendants acted in reckless disregard of the truth when they named a generic
18 purported "ordering doctor" for most special stains, knowing that some of these
19 named pathologists never read the slides for which they were billed.
20

21 (iv) Defendant Okuniewski represented to the Relator's principal that Sterling
22 *always has two pathologists review and read each slide "at no extra charge,"* despite
23 evidence demonstrating otherwise. He also misrepresented that Sterling's special
24 stain rate was "under 10%", and conformed to national standards, despite mountains
25 of evidence showing Sterling's special stain order rate far exceeded 10% (was 100%-
26 220%.) These misrepresentations demonstrate actual knowledge of the information
27 related to Defendants' fraudulent billing practices.
28

1 (v) Sterling routinely added a special stain result and bill to each report read by
2 outside pathologists who never used or ordered such stains, further demonstrating
3 deliberate ignorance of the truth or falsity of the information when billing the
4 government for these services.

5 (vi) The government required that outside services not be marked up when the
6 referring lab bills for technical services performed by the reference lab. Yet,
7 Defendants knowingly disregarded this requirement by billing the government
8 globally for lab services at marked-up prices.

9 (vii) Defendants failed to comply with government regulations that require them to
10 correctly identify and bill using the reading pathologist's NPI and attach modifier 90
11 on their healthcare lab claims performed by reference laboratories. This shows a
12 reckless disregard for the truth or falsity of the information in their billing practices.

13 (viii) Elite Medical Billing Corporation managed by Jenny Chang, knowingly and
14 actively participated in the fraudulent billing practices by submitting false claims to
15 Medicare and Medicaid, Tricare, the CARES Act, and the HRSA COVID-19
16 Uninsured Program on behalf of Sterling. Elite's involvement in submitting these
17 false claims shows actual knowledge of the fraudulent information.

18 (ix) Chang, as the manager of Elite, was responsible for overseeing the billing
19 practices and ensuring compliance with government regulations. Her position within
20 the company indicates that she either had actual knowledge of the false information
21 or acted in deliberate ignorance of the truth or falsity of the information related to
22 the fraudulent billing practices.

23 (x) Elite and Chang facilitated the submission of false claims for unnecessary
24 laboratory tests, including special stain Pathology tissue services and COVID-19
25 testing, by engaging in upcoding, unbundling, and using contracted cappers, runners,
26
27
28

1 and kickbacks to obtain patients' insurance information for unearned COVID-19
2 CARES Act payments. This demonstrates a reckless disregard for the truth or falsity
3 of the information in their billing practices.

4 226. Defendants' actions satisfy the definition of "knowingly" under 31 U.S.C. §
5 3729(b)(1). There is no need to prove specific intent to defraud.

6 227. As a result of the false claims knowingly submitted by Defendants, the United
7 States suffered substantial damages in excess of \$35 million, the final amount to be
8 determined at trial.

9 228. In summary, Defendants knowingly submitted false claims to CMS, acted in
10 deliberate ignorance and reckless disregard of the truth, and misrepresented their
11 compliance with Medicare laws, regulations, and instructions for payment. These actions
12 led to disbursements that would not have been made had the falsity been known, causing
13 significant damages. Each of these actions violates the False Claims Act.

14 229. Defendants knowingly engaged in improper billing practices as defined under
15 31 U.S.C. § 3729(b)(1), without needing to prove specific intent to defraud.

16 230. Due to the false claims knowingly submitted by Defendants, the United States
17 suffered substantial damages in excess of \$35 million, the final amount to be determined at
18 trial.

19
20 **B. SECOND CLAIM : Violation Of The California False Claims Act, Cal.**
21 **Govt Code. §12650-12652**

22 By Plaintiff State of California Against All Defendants and Does 1-10

23 231. Plaintiff repeats and re-alleges all preceding paragraphs of the Complaint
24 inclusive, as if fully set forth herein.

25 232. Defendants violated the California False Claims Act (CFCA) for Medi-Cal (Cal.
26 Gov't Code §§ 12650-12656).

1 233. Defendants submitted non-compliant claims to the State, misrepresented tests
2 as medically necessary, and unlawfully induced tests through offers of remuneration,
3 violating the AKS.

4 234. Medi-Cal and Medicaid, funded by federal and state sources, were defrauded
5 by Defendants' actions.

6 235. The State seeks treble damages, penalties, and costs under CFCA. Cal. Govt.
7 Code §12651 subd. (a)(1).

8 236. Defendants knowingly submitted or caused to be presented to Medicaid false
9 or fraudulent claims for payment or approval for payment, including but not limited to the
10 exemplar false claims identified in Section VII of this Complaint. Defendants' conduct was
11 a substantial factor in causing the false claims to be presented. Defendants provided their
12 knowing misrepresentations for the purpose of obtaining government payments to which
13 they knew or should have known they were not entitled under proper payment rules for
14 laboratory and special stain claims. This knowledge was demonstrated as follows:

15 (i) Defendants had actual knowledge of their billing practices, as they were
16 directly involved in using external labs and pathologists without proper
17 disclosure and billing adjustments. They also deliberately and improperly
18 billed the government globally for services performed by external labs at
19 marked-up prices (pass-through billing).

20
21 (ii) Defendants acted in deliberate ignorance of the truth or falsity of the
22 information by claiming that two pathologists read each slide while billing
23 for only one reading. They contracted with independent pathologists, sent
24 slides offsite for reading, and failed to correctly reflect the true rendering
25 provider on claims, as was otherwise required.

26
27 (iii) Defendants acted in reckless disregard of the truth or falsity of the
28 information when they named a generic purported "ordering doctor" for most

1 special stains, knowing that some of these named pathologists never rendered
2 services or read the slides they billed for.

3
4 (iv) Defendants failed to comply with government regulations that require
5 them to correctly identify and bill using the reading pathologist's NPI and
6 attach modifier 90 on their healthcare lab claims performed by reference
7 laboratories. This shows a reckless disregard for the truth or falsity of the
8 information in their billing practices.

9 237. Defendants' misrepresentations had a natural tendency to influence or were
10 capable of influencing the State's decisions to remit payments on the false claims at issue in
11 this action, and to make remittances to Defendants on claims which violated the CFCA,
12 including but not limited to the claims identified in Section VII.

13 238. By the same acts, Defendants knowingly made false records or statements to
14 get fraudulent claims paid by the State. Cal. Govt. Code §12651 subd. (a)(2).

15 239. Defendants' misleading records or statements influenced the State's payment
16 decisions for false claims.

17 240. Defendants submitted non-compliant and medically unnecessary tests to Medi-
18 Cal and Medicaid, using false documents to present them as compliant.

19 241. For each claim, including those for patients in Section VII of this Complaint,
20 Defendants knowingly assisted in or conspired to present false or misleading information in
21 support of a claim for payment, violating CFCA.

22 242. As a result of Defendants' actions, the State suffered damages in excess of \$4.8
23 million, the specific amount to be determined at trial. The State has been substantially
24 damaged by Defendants' false statements.

25
26 **C. THIRD CLAIM : Violation Of The Anti-Kickback Statute, 42 U.S.C. §**
27 **1320A-7B(B)**

28 By Plaintiff United States Against All Defendants and Does 1-10

1 243. Plaintiff repeats and re-alleges all preceding paragraphs of the Complaint
2 inclusive, as if fully set forth herein.

3 244. Defendants knowingly and willfully violated the Anti-Kickback Statute (AKS)
4 codified by 42 U.S.C. § 1320A-7B(B) by offering and paying remuneration, including
5 kickbacks, to induce referrals for laboratory testing from federal healthcare programs.

6 245. The AKS states: "Whoever knowingly and willfully offers or pays any
7 remuneration...to any person to induce such person to purchase...any good, facility, service,
8 or item for which payment may be made in whole or in part under a Federal health care
9 program, shall be guilty of a felony....42 U.S.C. § 1320a-7b(b)(2)(8)."

10 246. In 2020, Sterling initiated a fraudulent scheme involving COVID-19 test
11 overbilling. This scheme resulted in illicitly obtained revenues exceeding tens of millions of
12 dollars, primarily from government funds, including the CARES Act and HRSA COVID-19
13 Uninsured Program allocations.

14 247. Defendants Sterling, Elite, and Chang capitalized on the COVID-19 pandemic,
15 generating significant revenue through illegal marketing practices, including the payment
16 of over \$1.2 million in kickbacks to patient recruiters conditioned on steering patients and
17 securing "clean claims" paid under the CARES Act.

18 248. From mid-2020 through February 2023, Sterling contracted with a large
19 number of third-party independent runners, cappers, and agents to solicit, procure, and
20 refer specimens for Sterling's COVID-19 scheme, including Company 1, a *fabric company* to
21 act as Sterling's "Agent" to "provide nasal specimen collection services for COVID testing."
22 Sterling paid these unqualified agents for performance and expressly conditioned its
23 payments on the contractual obligation that "*the specimens were properly documented by*
24 *Agent, Sterling submitted billing to insurance payers and to the HRSA COVID-19*
25 *Uninsured Program and the Coronavirus Aid, Relief, and Economic Security Act (CARES*
26 *Act) for specimen services."*

27 249. Defendants entered into numerous illicit referral agreements, several labeled
28 as "Lab Services Agreements" (LSA). These agreements, both written and verbal, involved

1 third-party patient recruiters who agreed to steer patients to Sterling and provide patient
2 demographic information, including copies of insurance cards and driver's licenses, in
3 exchange for payments ranging from \$18 to \$39 for each referral leading to a "clean claim"
4 submitted to the government. Notably, Defendants misrepresented the fair market value
5 for specimen collection services in their contracts, stating a range of \$18-\$21, which aligns
6 more closely with industry standards. However, in practice, they incurred or paid \$35- \$39
7 per specimen, a sum significantly above fair market value, thus indicating their intent to
8 incentivize referrals rather than simply pay for services rendered. This discrepancy further
9 substantiates the allegation that these payments were indeed kickbacks intended to induce
10 referrals, rather than legitimate compensation for services.

11 250. Defendants knowingly and willfully paid more than fair market value for
12 COVID-19 specimen collection. They actually incurred and paid \$35-\$39 per specimen, but
13 concealed this amount by writing in their LSA contracts **(Exhibits A and B)** that they
14 would pay \$18-\$21 per specimen. Further, Defendants conspired with individual 1 and
15 Company 1 and Individual 2 and Company 2 to conceal the kickback fees they paid. This is
16 a violation of the False Claims Act, which prohibits knowingly and willfully submitting false
17 claims to the government.

18 251. These illicit practices induced even healthy individuals to undergo
19 unnecessary tests. The costs of these unnecessary tests were then fraudulently passed on to
20 Medicare and other government-funded healthcare programs, including the CARES Act and
21 HRSA COVID-19 Uninsured Program.

22 252. Defendants' actions constitute a violation of the AKS, 42 U.S.C. § 1320A-7B(B),
23 as they offered, solicited, and paid kickbacks to induce referrals for laboratory testing from
24 federal healthcare programs, leading to an increase in unnecessary tests and false claims,
25 thereby causing substantial financial damage to the United States.

26 253. On information and belief, Defendants further exploited the patient
27 information obtained through these illicit practices by fraudulently billing for additional
28 tests and procedures not supported by diagnosis codes or eligible for reimbursement, as well

1 as multiple and repeat claims for the same services on the same patients- tests which were
2 not performed.

3 **Discounts and “Perks”**

4 254. Defendants engaged in unlawful practices by offering and providing prohibited
5 forms of remuneration in the form of discounts and "perks." Specifically, the Defendants
6 routinely reduced or waived coinsurance and deductible amounts for patients, a practice
7 explicitly excluded from the discount safe harbor under 42 C.F.R. § 1001.952(h)(5)(iii) and
8 (iv).

9 255. Defendants did not report these reductions or waivers to Medicare, Medicaid,
10 or other Federal health care programs, and continued to bill the government at the full rate
11 for tests, in violation of 42 C.F.R. § 414.21.

12 256. In order to induce patients to submit to their tests, Defendants, including Elite
13 and Chang, routinely offered to reduce or waive government beneficiaries' co-pays and
14 deductibles.

15 257. Defendants used these reductions and waivers to encourage patients to
16 undergo tests and to discourage them from filing complaints or reporting Sterling's upcoding
17 to the government.

18 258. Furthermore, Defendants routinely offered "perks" to community physicians
19 and providers, such as free meals, sponsorships, uncompensated services, and other
20 remuneration, in exchange for access and to promote overutilization of Sterling's lab
21 services and self-ordering of special stains tests for their patients.

22 259. As a direct result of these unlawful schemes, Defendants induced providers to
23 order tests and patients to undergo tests that they would not have otherwise ordered or
24 submitted to, and further discouraged them from reporting Defendants to the government.

25 **Company 1**

26 260. On or around September 16, 2021, Defendants Sterling, Yang, and Okuniewski
27 conspired with Company 1, pursuant to a "Laboratory Services Agreement" (LSA), to
28 unlawfully collect and exploit insurance and identification details for fraudulent

1 government billing, largely targeting immigrant communities in Los Angeles and
2 surrounding areas, as evidenced in **Exhibit "A."**

3 261. Defendants directed Company 1 to obtain as many insurance cards and drivers'
4 licenses as possible, with the aim of maximizing Sterling's fraudulent billings, irrespective
5 of whether the billed tests were performed.

6 262. Sterling and Okuniewski, intending to defraud the government, instructed
7 Company 1 to collect insurance and identification details for fraudulent billing under the
8 CARES Act and the HRSA COVID-19 Uninsured Program, compensating Company 1 on a
9 per claim basis, ranging from \$18 to \$39.

10 263. The LSA obligated Company 1 to provide Sterling with personal demographic
11 information and copies of primary insurance details, as required for "clean claim" billing.

12 264. For each patient recruited by Company 1, Sterling incurred fees ranging from
13 \$18 to \$21. Despite the explicit terms of the written LSA, Sterling verbally agreed to
14 reimburse Company 1 at a higher rate, while simultaneously professing a desire to avoid
15 violations of Stark Law and the federal Medicare/Medicaid Anti-Kickback Law.

16 265. On or around May 18, 2022, Company 1 and Sterling executed a "Services
17 Payment Agreement," in which Sterling committed to an additional payment of \$171,752.00
18 for Company 1's services, as per **Exhibit "B."**

19 **Company 2**

20 266. Similarly, on or around January 15, 2021, Defendants Sterling, Yang, and
21 Okuniewski conspired with Individual 2 and Company 2, to unlawfully collect and exploit
22 identification and insurance details for fraudulent government billing, predominantly
23 targeting immigrant communities in California.

24 267. Between January and December 2021, Company 2 collected over 13,000
25 patient demographics and billing information for Sterling's fraudulent testing scheme. Each
26 fraudulent "clean claim" incurred fees of \$39 to Company 2, with no written agreement due
27 to the Defendants' concerns about violating the Anti-Kickback Statute (AKS).
28

1 268. Sterling remunerated Individual 2 or Company 2 with \$276,235.71 for their
2 services in recruiting patients and facilitating fraudulent laboratory billing, thus inducing
3 referrals to federal and state healthcare programs.

4 **Defendants Violated the Anti-Kickback Statute in Soliciting and Inducing Orders
5 for Lab Services**

6 269. From in or around May 2020 and continuing through March 2023 in the
7 jurisdiction of this Court, Defendants and Does 1-10 knowingly and willfully conspired and
8 agreed with third parties including Company 1, Company 2, Individual 1, Individual 2, and
9 others to commit offenses against the government to violate as follows:

- 10 a) Title 42, United States Code, Section 1320a- 7b(b)(1)(A), by soliciting and
11 receiving any remuneration, specifically, kickbacks and bribes, directly and
12 indirectly, overtly and covertly, in cash and in kind, in return for referring an
13 individual to a person for the furnishing and arranging for the furnishing of any
14 item and service for which payment may be made in whole and in part by a
15 Federal health care program; and to violate
16 b) Title 42, United States Code, Section 1320a- 7b(b)(2)(A), by offering and paying
17 any remuneration, specifically, kickbacks and bribes, directly and indirectly,
18 overtly and covertly, in cash and in kind, to any person to induce such person to
19 refer an individual to a person for the furnishing and arranging for the furnishing
20 of any item and service for which payment may be made in whole and in part by
21 a Federal health care program.

22 270. It was the **goal** of the conspiracy for Defendants Yang, Okuniewski, Lekov,
23 Sterling, and their co-conspirators to unlawfully enrich themselves by, among other things,
24 soliciting, receiving, offering, and paying kickbacks and bribes in return for recruiting and
25 referring Medicare and Medicaid beneficiaries to Sterling for diagnostic testing, including
26 COVID-19 testing.

27 271. The **manner and means** by which Defendants Yang, Okuniewski, Lekov,
28 Sterling and their co-conspirators sought to accomplish the goal of the conspiracy included,
among other things, the following:

1 a) Defendants Yang, Okuniewski, and Sterling agreed to and did offer and pay
2 illegal kickbacks and bribes to Company 1 and/or Individual 1 and Company 2
3 and/or Individual 2 in exchange for signed requisition forms and/or specimens
4 that were sent to Sterling and Elite for the purpose of performing tests that
5 were billed to Medicare and Medicaid, and the government under the CARES
6 Act and HRSA COVID-19 Uninsured Program.

7 b) Defendants Yang, Okuniewski, and Sterling agreed to and did pay Company 1
8 and/or Individual 1 and Company 2 and/or Individual 2 a percentage of the
9 Medicare and Medicaid reimbursement for specimens and signed requisition
10 forms that Company 1 and Company 2 referred to Sterling.

11 c) Individual 1 and Individual 2 worked together to generate referrals for COVID-
12 19 testing targeting immigrant communities in California. Specifically,
13 Individual 1, and Individual 2 in large part dispatched Chinese speaking
14 agents to set up booths to persuade immigrant Medicare and Medicaid
15 beneficiaries to submit to laboratory testing, including COVID-19 testing, by
16 providing their driver's license and insurance information. Defendants and
17 Does 1-10 signed the electronic claims and testing requisition forms generated
18 by Individual 1 and Individual 2 through their community dispatchers and
19 submitted these to the government for payment.

20 d) To disguise the scheme, Defendants Yang, Okuniewski, Sterling, Elite, Chang,
21 Individual 1, and Individual 2 created sham documentation, including "LSA"
22 and ledgers, to conceal and disguise the illegal kickbacks and bribes paid by
23 Defendants in exchange for signed requisition forms and specimen referrals.

24 **272. In furtherance of the conspiracy** and to accomplish their goals, Defendants
25 their co-conspirators committed, and caused to be committed, the following acts in
26 California and elsewhere:

27 a) From on or about January 6, 2022 to January 4, 2023, Defendants Yang,
28 Okuniewski, and Sterling wrote multiple checks in amounts totaling \$276,235.71

1 payable to Company 2 and/or Individual 2 and drawn on the Sterling bank
2 account, in exchange for specimens and requisitions referred by Company 2.

3 b) On or about November 8, 2022, Defendants Yang, Okuniewski, and Sterling
4 wrote checks in amounts totaling approximate \$129,000, payable to Company 1
5 and/or Individual 1, and drawn on the Sterling bank account, in exchange for
6 specimens and requisition forms referred by Company 1 and Individual 1.

7 273. Sterling's illicit marketing scheme to recruit patients (specimens) for largely
8 unnecessary laboratory tests between late 2020 to early 2023 was wildly profitable and
9 successful. At the relevant times, Sterling collected roughly \$100-\$200 per specimen from
10 the Government, while *incurring* fees to cappers of \$18-\$39 per recruited and procured
11 patient and sharing approximately 5-6% commission on its gross collections to Elite and
12 Chang.

13 274. Defendants Yang, Okuniewski, and Sterling incurred or paid Individual 1
14 and/or Company 1 and Individual 2 and/or Company 2 approximately \$550,000 in exchange
15 for diagnostic testing referrals, including COVID-19 testing and other laboratory referrals,
16 that they caused to be referred to Sterling.

17 275. Furthermore, Defendants offered and paid cash or cash equivalents to runners,
18 cappers, and health care providers to induce orders for their tests, or to allow Defendants
19 access to independent third-party information collectors to bill for eligible government
20 beneficiaries.

21 276. Sterling represented a capacity for performing "33,000" COVID tests per week,
22 all of which were compensated either by Medicare, Medicaid, or the government through
23 the CARES Act and the HRSA COVID-19 Uninsured Program.

24 277. Defendants and others, through Sterling, submitted or caused the submission
25 of approximately \$75,000,000 in claims to Medicare, Medicaid, the CARES Act, and the
26 HRSA COVID-19 Uninsured Program, including claims for beneficiaries residing in **King**
27 **County**, which resulted in reimbursement for laboratory tests that were generated
28 procured by the payment of kickbacks and bribes.

1
2 **D. FOURTH CLAIM : Making Or Using False Record Or Statement To**
3 **Cause Federal False Claim To Be Paid**

4 By Plaintiff United States Against All Defendants and Does 1-10

5 278. Plaintiff repeats and re-alleges all preceding paragraphs of the Complaint
6 inclusive, as if fully set forth herein.

7 279. Throughout the statutory period, Defendants knowingly made, used, or caused
8 to be made or used, false records or statements material to false or fraudulent claims,
9 contrary to 31 U.S.C. § 3729(a)(1)(B). Specifically, Defendants knowingly created or utilized
10 false documentation asserting that their tests complied with coverage requirements when
11 submitting claims for payment to the government.

12 280. The specific conduct of the Defendants was material to the government's
13 decision to pay these claims. The submission of these false records or statements induced
14 the Centers for Medicare & Medicaid Services (CMS) to disburse funds that it would not
15 have paid had it known the truth about Defendants' non-compliance with coverage
16 requirements. Each submission of a false record or statement is a separate violation of the
17 FCA.

18 281. Defendants used these false records and statements to secure unlawful
19 payments for numerous beneficiaries, including but not limited to Patients 1,2,3,4, and 5 as
20 outlined in Section VII.

21 282. By reason of the false or fraudulent records or statements that Defendants
22 knowingly made or used, the United States suffered significant financial harm, the precise
23 amount of which will be proven at trial. This harm is directly attributable to the Defendants'
24 violations of 31 U.S.C. § 3729(a)(1)(B).

25
26 **E. FIFTH CLAIM : Conspiring To Submit Federal False Claims**

27 By Plaintiff United States Against All Defendants and Does 1-10
28

1 283. Plaintiff repeats and re-alleges all preceding paragraphs of the Complaint
2 inclusive, as if fully set forth herein.

3 284. As set forth above, Defendants' and Does 1-10's directors, managing agents,
4 and other employees conspired with each other and unnamed parties to seek and obtain
5 payments by submitting claims based on fraudulent representations and records.

6 285. Yang, Okuniewski, and Sterling conspired to boost Sterling's revenues through
7 upcoding and unbundling schemes. They charged one or more special stain codes for every
8 specimen processed, intending to double or triple Sterling's per specimen revenues

9 286. Drs. Yang and Lekov agreed to employ "generic" physician names on Pathology
10 reports and to self-order and bill unnecessary special stains codes for each specimen
11 processed at Sterling, generating false and fraudulent Pathology reports to defraud the
12 government.

13 287. Yang and Okuniewski, agreed to execute institutional wide upcoding policies
14 whereby special stains were pre-ordered for all or nearly all Pathology specimens submitted
15 to Sterling. As an overt act in furtherance of their conspiracy to defraud health carriers, the
16 conspirators developed reflex algorithms whereby specimens would have "special stains"
17 attached, thereby all conspirators stood to substantially benefit from their unlawful acts.

18 288. Yang, Okuniewski, and Lekov then agreed to implement institutional wide
19 policies whereby special stains were ordered for all or nearly all Pathology specimens
20 submitted to Sterling. Thus, when Yang was unavailable or out of town, Lekov would sign
21 or authorize the transcriptionist to stamp her signature on fraudulent Pathology reports
22 with phantom "special stains" which were typically not even performed.

23 289. Yang, Okuniewski, and Lekov also entered into an agreement with their fellow
24 in training Dr. Kimberly Woodward to also assist Sterling and agreed to perform and adhere
25 to Sterling's special stain scheme.

26 290. Sterling, Yang, Okuniewski, and Lekov entered into an agreement among
27 themselves, implementing a purported policy that "2 pathologists would view each case..."
28

1 and one pathologist either Yang or Lekov primarily would sign the reports where
2 Defendants caused to have false and fraudulent charges for “special stains”.

3 291. Yang, Lekov, Okuniewski, and Sterling conspired with Elite, Chang, and Does
4 1-10 to bill the government for false special stain codes based on fabricated Pathology
5 reports. All co-conspirators agreed to collect and retain government funds for services that
6 did not meet the billing requirements for laboratory services. Defendants verbally directed
7 their employees to electronically transit the false claims or in some cases mail the false claim
8 forms to the government for payments.

9 292. Elite Medical Billing Corporation and Jenny Chang agreed with Defendants to
10 enter the false claims, process upcoded entries, and electronically transmit false
11 remittances for government payment. In exchange for their role in Sterling’s fraud, Elite
12 and Chang retained 5-6% of gross collections from Sterling’s unlawful billing.

13 293. As a result of their conspiracy, Sterling, Yang, Lekov, and Okuniewski caused
14 to be submitted false and fraudulent special stains claims, which they knew were neither
15 reasonable nor necessary. Defendants’ scheme has evaded government detection, resulting
16 in severe damages to the government and taxpayers. The conduct is also ongoing.

17 294. From at least 2012 onward, all co-conspirators caused the submission of
18 hundreds of thousands of false laboratory claims to the government in furtherance of their
19 conspiracy.

20 295. Accordingly, Defendants knowingly conspired to defraud the United States by
21 getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(3)
22 (1986) and conspired to commit violations of 31 U.S.C. §§ 3729(a)(I)(A) and 3729(a)(I)(B),
23 in violation of 31 U.S.C. § 3729(a)(I)(C) (2009).

24 296. By reason of the false or fraudulent claims that Defendant conspired to get
25 allowed or paid, or by reason of its conspiracy to violate 31 U.S.C. §§ 3729(a)(I)(A) and
26 3729(a)(I)(B), the United States has been damaged in a substantial amount, to be proven at
27 trial.

28

1
2 **F. SIXTH CLAIM : Improperly Avoiding An Obligation To Pay Or**
3 **Transmit Money To The Government**

4 By Plaintiff United States Against All Defendants and Does 1-10

5 297. Plaintiff repeats and re-alleges all preceding paragraphs of the Complaint
6 inclusive, as if fully set forth herein.

7 298. Under 42 U.S.C. I 320a-7k(d), Defendants were obligated to report and return
8 each overpayment to the MAC. They were also required to notify the MAC in writing of the
9 reason for the overpayment "by the later of (A) ... 60 days after the date on which the
10 overpayment was identified; or (8) the date any corresponding cost report is due."

11 299. Under 42 C.F.R. § 401.305(a)(2) "A person has identified an overpayment when
12 the person has, or should have through the exercise of reasonable diligence, determined that
13 the person has received an overpayment and quantified the amount of the overpayment."

14 300. Defendants knew or had reason to know that they had been overpaid by
15 Medicare and Medicaid for tests that did not meet the requirements for reimbursement
16 under Medicare's LCD. Further, Defendants were on notice of these overpayments as soon
17 as other carriers and Medicare either denied their claims or started seeking refunds.

18 301. Nevertheless, Defendants continued to systematically and aggressively submit
19 claims and receive payment from CMS for claims that did not meet LCD requirements.

20 302. As a result of the fraud described herein, Defendants have received
21 overpayments from the MAC which Defendants failed to return. Each failure to comply with
22 the obligations of 42 U.S.C. 1320a-7k(d) is a separate violation of 31 U.S.C. § 3729(a)(1)(G).

23 303. By reason of Defendants' violations of 31 U.S.C. § 3729(a)(1)(O), the United
24 States has been damaged in a substantial amount, to be proven at trial.

25
26 **G. SEVENTH CLAIM: Unjust Enrichment**

27 By Plaintiffs United States and the State of California Against All Defendants and Does 1-10
28

1 304. Plaintiffs repeat and re-allege all preceding paragraphs of the Complaint
2 inclusive, as if fully set forth herein.

3 305. Defendants unjustly received and retained payments from the United States
4 and California, based on fraudulently submitted claims using fraudulent records. Given the
5 circumstances surrounding Defendants' receipt of these funds, it would be inequitable and
6 unconscionable to allow Defendants to retain such monies. The precise amount of these
7 funds will be determined at trial.

8 306. Sterling claimed a capacity for performing "33,000" COVID tests per week, all
9 compensated by Medicare, Medicaid, or the government through the CARES Act and the
10 HRSA COVID-19 Uninsured Program.

11 307. During 2021 and 2022, Sterling caused to be collected more COVID-19 samples
12 than they could test due to their illicit marketing and recruitment practices. Despite lacking
13 the resources required to timely or adequately process these specimens, Sterling continued
14 to collect samples. Consequently, Sterling was unable to process numerous specimens and
15 failed to provide results, despite billing the government for all collected samples, regardless
16 of whether they were tested.

17 308. Knowing the potential for the discovery of their fraudulent activities, especially
18 during the COVID-19 pandemic, Defendants proactively orchestrated a complex network of
19 shell companies, corporate entities, bank accounts, and foreign trusts and investments to
20 distribute, divert, and conceal their ill-gotten gains. This scheme was designed to hide the
21 tens of millions of dollars obtained from the government through their deceptive laboratory
22 billing practices.

23
24 **PRAYER FOR RELIEF**

25 WHEREFORE, Plaintiffs and Relator pray for judgment against Defendants as
26 follows:

- 27 (1) That Defendants cease and desist from Violating 31 U.S.C. §3279 and California
28 Government Code § 12650-12656;

1
2 (2) That the Court enter Judgment against Defendants and in favor of the United
3 States pursuant to 31 U.S.C. § 3729 *et seq.* in an amount equal to three times the
4 amount of damages the United States has sustained as a result of Defendants'
5 actions, plus the prevailing maximum civil penalty of \$27,018⁸ for each violation
6 of the False Claims Act;

7
8 (3) That as to all Claims for Relief, the Court enter an award for Relator for the
9 maximum award permitted under 31 U.S.C. § 3730(d);

10
11 (4) That the Court enter Judgment against Defendants and in favor of the State of
12 California pursuant to Cal. Government Code Section 12651 subdivision (a),
13 three times the damages which the State sustained as a result of Defendants'
14 false claims, plus the prevailing civil penalty of \$11,000 for each violation of the
15 California False Claims Act;

16
17 (5) That as to all Claims for the State, pursuant to Government Code § 12652(g)(3)
18 the Relator be awarded no less than 25% and no more than 50% of the State's
19 proceeds;

20
21 (6) That the Court award to the United States, California, and to Relator for costs of
22 court, including costs of investigation, and for pre- and post-judgment interest at
23 the rates permitted by law;

24
25
26
27
28

⁸ Annual inflationary adjustments to the FCA's civil monetary penalties are set by statute
and the prevailing rate increases annually.

1 (7) That the Court enter an award for Relator's reasonable attorneys' fees, expenses,
2 and costs of suit, incurred in prosecuting this action pursuant to 31 U.S.C. §
3 3730(d) and Cal. Gov't Code § 12652(g)(8);

4
5 (8) That by reason of Defendants' unjust enrichment, the Court enter an order
6 requiring Defendants to disclose and disgorge all monies they received as a result
7 of the illicit scheme described herein including those in foreign accounts; and
8

9 (9) That the United States, The State, and Relator recover all such other relief as
10 the Court deems just and proper.

11
12 **DEMAND FOR JURY TRIAL**

13 Pursuant to Rule 38(b) of the federal rule of Civil procedure, Plaintiffs and Relator
14 demand a trial by jury on all claims so triable.

15
16 Respectfully submitted,

17
18 Dated: April 24, 2023

19 \s\ Gloria Juarez
20 Gloria Morin Juarez, CA SBN 109115
21 **LAW OFFICES OF GLORIA JUAREZ**
22 28202 Cabot Road, Suite 300
23 Laguna Niguel, CA 92677
24 Tel: 949-288-3042
25 Email: gloria@thegjlaw.com
26 ATTORNEYS FOR RELATOR AMERICAN
27 INTEGRA LLC
28

CERTIFICATE OF SERVICE

I hereby certify that on May 12, 2023, I caused a true copy of the Complaint in the matter captioned **UNITED STATES OF AMERICA AND CALIFORNIA EX REL. AMERICAN INTEGRA V. STERLING PATHOLOGY MEDICAL CORPORATION ET. AL** to be served upon the following,

Person(s) and/or Entity(s) to whom mailed:

By Certified U.S. Mail

Attorney General of the United States
950 Pennsylvania Avenue, Northwest
Washington, DC 20530-0001

By U.S. Mail

Civil Process Clerk
United States Attorney's Office for the
Eastern District of California
501 I St Ste 10-100
Sacramento, CA 95814

By Electronic Mail

Colleen M. Kennedy
Chief, US Attorney's Office
Affirmative Civil Enforcement Unit
Eastern District of California
501 I St Ste 10-100
Sacramento, CA 95814
Tel.: 916-554-2826
Email: colleen.m.kennedy@usdoj.gov

Jennifer S. Gregory
Deputy Attorney General California Department of Justice
Division of Medi-Cal Fraud and Elder Abuse, Civil Section
2329 Gateway Oaks Drive, Suite 200
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1 Office of the Attorney General
2 California Department of Justice
3 Supervising Deputy Attorney General
4 Division of Medi-Cal Fraud and Elder Abuse
5 1300 "I" Street
6 Sacramento, CA 95814-2919
7 Phone: (916) 445-9555
8 E-mail: AGelectronicsservice@doj.ca.gov

9 Todd Spitzer
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11 300 N. Flower Street, Santa Ana, CA 92702-0808
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S/GJuarez
Gloria M. Juarez

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

United States

(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Gloria Juarez, CA SBN 109115; Law Offices of Gloria Juarez; 28202 Cabot Road, Suite 300; Laguna Niguel, CA 92677; Tel: 949-288-3402

DEFENDANTS

Elite Medical Billing Corporation, Sterling Pathology Medical Corporation, et. al.

County of Residence of First Listed Defendant King County (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

Large table with categories: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes checkboxes for various legal claims like 110 Insurance, 310 Airplane, 365 Personal Injury, etc.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District (specify), 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 31 U.S.C. 3279. Brief description of cause: False healthcare billing to government for laboratory testing including pathology and COVID-19 testing.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: [X] Yes [] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE April 24, 2023 SIGNATURE OF ATTORNEY OF RECORD S/G Juarez Gloria M. Juarez

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Exhibit A

LABORATORY SERVICES AGREEMENT

- 1.2 Sterling Pathology will provide diagnostic laboratory testing services (“Laboratory Services”) as described in Attachment 1, together with such other additional testing services as the Parties may agree in writing, in accordance with the following process:
 - 1.2.1 Upon receipt of testing order(s) transmitted by Client, Sterling Pathology will perform the requested laboratory testing.
 - 1.2.2 Sterling Pathology will perform verification/validation in accordance with Food and Drug Administration (FDA) guidelines for tests conducted pursuant to Emergency Use Authorization (EUA), in accordance with all requirements for Laboratory Developed Tests (LDTs) and the Clinical Laboratory Improvement Amendments (CLIA).
 - 1.2.3 Sterling Pathology agrees, when possible and barring and extenuating circumstances beyond their control, that test processing and sample drop-off can be scheduled with twenty-four (24) hours’ notices from Client, and that it will deliver COVID test result reports to Client no later than twenty-four hours (24 hrs.) of receiving the samples.
 - 1.2.4 Sterling Pathology will report all cases to the California Department of Public Health, California Reportable Disease Information Exchange (CalREDIE) or other federal or state entities as required and in compliance with reporting state guidelines.
- 1.3. The Parties agree to comply with all state and federal patient confidentiality and privacy laws regarding patient records. The Parties shall fully comply with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and state privacy laws and regulations in all states where Practice operates, including without limitation all confidentiality rules and legal restrictions placed on patient records. In furtherance thereof, the Parties are entering into a Business Associate Agreement of even date hereof in the form attached hereto as **Attachment 2**. Sterling Pathology agrees to archive data on its servers in accordance with this paragraph, and to make laboratory reports available to Client electronically upon request.

2. COMPENSATION

- 2.1 Sterling Pathology will reimburse Client in accordance with the payment terms set forth in **Attachment 1** and applicable federal and state statutes and regulations.
- 2.2 Invoices payable by Client under this Agreement will be paid at the fees set forth in **Attachment 1**. Unless otherwise agreed by the Parties in a signed writing, these fees shall remain in effect through the initial contract term identified below. Sterling Pathology acknowledges that Client is the sole responsible party for billing purposes.

LABORATORY SERVICES AGREEMENT

Billing Information. Sterling Pathology requires that all requisitions be completed with the necessary patient insurance billing information at the time of Service.

Required insurance billing information consists, but not limited to, of the following:

- Patient name, address, date of birth, sex, phone number
- Responsible party/subscriber full name, address, date of birth,
- Patients' relationship to responsible party/subscriber
- Insurance company name, address, and phone number
- Copy of the front and back of the insurance card
- Insurance group and policy number
- Employer
- Worker's compensation information (date of injury, cases or claim number)
- Diagnosis code(s) for all tests ordered

- 2.3 Client will provide complete and accurate information to accompany each order for Laboratory Services. Such information includes, without limitation and to the extent applicable to a given order, complete and accurate (1) patient demographic information, (2) diagnosis codes in the form of ICD-10 codes (or any successor codes to ICD-10 codes). Client will provide complete and accurate information in compliance with the required reporting agencies to include but not be limited to:
- 2.4 All pricing contained herein and attached hereto shall be in effect for one (1) year from the Effective Date. Thereafter, the Parties may renegotiate pricing by mutual agreement.
- 2.5 If any Authority creates, enforces, interprets and/or implements laws, rules, regulations, or otherwise takes a position (or threatens to do so), that Sterling Pathology is required to extend the pricing under this Agreement to any third party including but not limited to Medicare, Medicaid or any other governmental program, Sterling Pathology may immediately terminate this Agreement, or (ii) notify Client of the occurrence of one of the foregoing events and increase the pricing under this Agreement to the level of any such governmental program, provided that if Client notifies Sterling Pathology of an objection to such increase in prices within ten (10) days of Client's receipt of notice from Sterling Pathology, this Agreement will terminate upon Sterling Pathology receipt of Client's notice. For purposes of this section, "Authority" shall include, but is not limited to, any court, legislative or authority body, and/or any branch of state, federal or local government (e.g., the Office of Inspector General, Department of Justice, Department of Health and Human Services, Centers for Medicare and Medicaid Services, and/or any state Medicaid

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agency Department of Health Care Services). Sterling Pathology may likewise immediately terminate this Agreement if it, in its sole discretion, determines that any portion of this Agreement may or does violate any law, rule, regulation or governmental policy, or any interpretation thereof.

- 2.6 No Referral. No amount paid hereunder is intended to be, nor shall it be construed to be, an inducement or payment for referral of, or recommending referral of, patients by Sterling Pathology to Client. The Parties intend that the sole purpose of the fees paid hereunder is to compensate the Parties at fair market value for the provision of the Services under this Agreement, not to influence Client with regard to any referrals of patients or other healthcare items or services to Sterling Pathology.

3. RECORDS

If any services to be provided hereunder are; (i) federally funded, or otherwise subject to the requirements of the Department of Health and Human Services (HHS), until the expiration of four (4) years after the furnishing of Laboratory Services pursuant to this Agreement, (ii) the amount paid under this Agreement is \$10,000 or more over a twelve (12) month period and (ii) as required by law, Sterling Pathology shall, upon written request, make available to the Secretary of HHS, the Comptroller General, or any of their duly authorized representatives, this Agreement, and any books, documents and records that are necessary to certify the nature and extent of the costs incurred by Clinic under this Agreement. The availability of Sterling Pathology' books, documents and records will at all times be subject to such criteria and procedures for seeking or obtaining access as may be promulgated by the Secretary of HHS in regulations, and other applicable laws. No disclosure under this provision shall be construed as a waiver of any legal rights to which either Party may be entitled under statute or regulation. As detailed in **Attachment 2**, Sterling Pathology shall be responsible for any disclosures to the California Department of Public Health, California Reportable Disease Information Exchange (CalREDIE) or other entities that are mandated by federal or state law.

4. TERM AND TERMINATION

- 3.1 The initial term of this Agreement shall commence on the Effective Date, continuing for one (1) year and thereafter continuing until terminated by either party. Notwithstanding the above, either party can terminate this Agreement at any time, without cause, upon sixty (60) days prior written notice to the other party. At the end of the year and thereafter, the Agreement will automatically renew for additional one (1) year terms unless and until terminated.
- 3.2 Either party may terminate this Agreement at any time, with cause, by providing the other party with thirty (30) days prior written notice of the cause for the termination, giving the breaching party thirty days to cure the breach. If not cured within the thirty-day time period, then the agreement will terminate immediately upon the breaching party's receipt of subsequent notice that the breach has not been cured and that the contract is terminated.

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- 3.3 The Parties may terminate this Agreement by mutual written agreement.
- 3.4 Either Party shall have the right, but not the obligation, to terminate this Agreement immediately upon its receipt of notice of any of the following events:
- 3.4.1 The conviction of any shareholder, officer, or director of the other Party of any crime punishable as a felony under federal or state law; or
 - 3.4.2 The merger, consolidation, reorganization, conversion, sale, liquidation, dissolution, or other disposition of all or substantially all of the assets of either Party.

5. INSURANCE

Sterling Pathology and Client each agree to maintain general and professional liability insurance in amounts adequate to cover their respective acts and omissions. The parties agree that such coverage shall be, at a minimum, \$1,000,000 per claim and \$3,000,000 aggregate and that the parties shall maintain such insurance (or "tail" coverage thereon) for a period of at least four (4) years after the termination of this Agreement. Sterling Pathology and Client agree upon request to furnish each other upon request with a current and valid Certificate of Insurance, or proof of adequate self-insurance, evidencing their insurance coverage. The provisions of this section shall survive termination of this Agreement.

6. EXCLUSION OF INCIDENTAL/CONSEQUENTIAL/PUNITIVE DAMAGES.

In no event shall either party or its respective officers, directors, employees, agents or affiliates be liable for any special, exemplary, incidental, consequential or punitive damages, whether in contract, warranty, tort, strict liability or otherwise. These limitations shall apply notwithstanding any failure of essential purpose of any limited remedy and shall survive termination of this Agreement.

7. COMPLIANCE WITH LAW.

The Parties have made all reasonable efforts to ensure that this Agreement complies with all federal and state laws and regulations in all states where the Services are provided. The Parties understand and acknowledge that such laws may change, be amended, have guidance or have a different interpretation and the Parties intend to comply with such laws in the event of such occurrences. Each of the parties represents and warrants to the other party that it will comply with all applicable laws, rules or regulations related to their respective obligations under this Agreement ("Applicable Laws"), including, but not limited to, the federal Physician Self-Referral Law, 42 U.S.C. 1395nn, and the regulations promulgated thereunder (together, the "Stark Law"), similar state physician self-referral laws and regulations (together with the Stark Law, the "Self-Referral Laws"), the federal Medicare/Medicaid Anti-kickback Law and regulations promulgated thereunder (the "Federal Anti-kickback Law") and similar state Anti-kickback laws and regulations (together with the Federal Anti-kickback Law,

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the "Anti-kickback Laws") and the Health Insurance Portability and Accountability Act (HIPAA"). This paragraph will survive the termination of this Agreement.

8. LICENSING OF INTELLECTUAL PROPERTY.

- 8.1 Sterling Pathology acknowledges that Client owns all of the property rights and related intellectual property (IP) rights and any other IP developed and utilized by the Parties for purposes of this Agreement. Sterling Pathology understands and acknowledges that Client is not transferring or providing to Sterling Pathology the IP hereunder and Sterling Pathology is expressly prohibited from asserting any rights in the nature of a license or grant for any rights in the IP of any nature whatsoever except as expressly set forth in this Agreement. If for any reason Sterling Pathology becomes aware that any third party makes a claim that the IP infringes on such third party's patent or other rights, Sterling Pathology shall immediately notify Client of such claim.
- 8.2 Sterling Pathology agrees to execute such documents and take all such further acts as may be requested by Client to assure the continued ownership of its property rights in the IP.
- 8.3 During the term of the Agreement and at all times thereafter, Client shall preserve the confidential nature of, and shall not disclose, reveal, or make accessible to anyone, any and all information, knowledge, trade secrets, names and lists of licensors, suppliers and customers, programs, pricing, marketing, specifications, data of or pertaining to Sterling Pathology, including but not limited to any information regarding any business with which Sterling Pathology or any of its subsidiaries or affiliates may do business with, or any prospective or current business opportunity actively targeted or solicited by Sterling Pathology at any time during the Term of this Agreement, including but not limited to, an opportunity to secure, sell, purchase, manage, obtain, consult, advise, procure, market, develop, license or otherwise service an Assigned Account, surgical center medical doctor's office, hospital, or other healthcare facility or any other IP rights of Sterling Pathology (collectively, hereinafter referred to as "Confidential Information").
- 8.4 Client shall not make use of Confidential Information for Client's own gain, apart from the earning of commissions pursuant to this Agreement. The restrictions on the disclosure of Confidential Information imposed by this Section shall not apply to any Confidential Information that (a) was part of the public domain at the time of its receipt by Client; (b) becomes part of the public domain in any manner other than by an act of Client; or (c) information Client is legally compelled to disclose, in which event Client shall provide Sterling Pathology with prompt notice of such requirement so that Sterling Pathology may seek a protective order or another appropriate remedy. Upon the termination of this Agreement for any reason, Client shall promptly deliver to Sterling Pathology all Confidential Information which Client may then possess or have under his or her control.

9. CONFIDENTIALITY AND NON-INTERFERENCE

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- 9.1 Both Parties may gain access to confidential, privileged, or proprietary information regarding the other Party's business activities and operations (collectively referred to herein as "Confidential Information"). The Parties agree that Confidential Information includes, but is not limited to, the Party's financial records and data, information related to Third Party Agreements, and the terms of this Agreement. Both Parties further acknowledge that the other Party, in connection with its business, has developed and/or may develop certain operating manuals, symbols, trademarks, trade names, service marks, designs, client information, patient lists, referral sources, procedures, processes and other copyrighted, patented, trademarked or other legally protectable information that is proprietary and confidential to the Party (collectively, "Trade Secrets"). Sterling Pathology acknowledges and agrees that information related to Client's clients constitute "Trade Secrets." Both Parties agree that they will not use, release, disclose, misappropriate or disseminate, directly or indirectly, to any person or entity, during the course of this Agreement or at any time after termination thereof for any reason, any Confidential Information or Trade Secrets. Both Parties acknowledge that they are each prohibited from using any Confidential Information or Trade Secrets for their own benefit, to solicit or communicate with the other Party's clients, or in any manner that would interfere with the ongoing business and employment relationships of the other Party, and that this prohibition continues after termination of this Agreement for any reason, and that such unauthorized use may result in the imposition of damages, attorney's fees and costs, and/or injunctive relief. The Parties agree that the solicitation of the other Party's clients or other interference with business relationships would constitute unfair competition and misappropriation of Trade Secrets. The Parties further agree that, upon termination of this Agreement, they will return all Confidential Information and Trade Secrets in print and delete all Confidential Information and Trade Secrets maintained digitally, unless otherwise agreed in writing. Both Parties recognize that irreparable injury will result to the other Party, its business and its property if that Party breaches any of the provisions in this paragraph, and will be a basis for injunctive relief and damages.
- 9.2 The Parties agree that they shall not, for a period of one (1) year immediately following the termination of this Agreement for any reason, either directly or indirectly, and whether on either of their behalf or that of any other person or entity: (i) make known to any person or entity the names and addresses of any of the other Party's clients, customers or referral sources or any other information pertaining to them; (ii) call on, solicit, or take away any of the other Party's clients, customers or referral sources for whom such Party provided services; or (iii) attempt to persuade any organization or individual for which the other Party provides service to discontinue utilizing those services or to terminate any agreement with such Party.
- 9.3 **Non-Solicitation of Employees:** During the Term of Agreement and for a period of 24 months following the Parties termination of that Agreement with the Company, the Parties shall not, without the written permission of the Company or an affected affiliate, directly or indirectly (i) solicit, employ or retain, or have or cause any other person or entity to solicit, employ or retain, any person who is employed by the Company or was employed by the Company during the 24-month period prior to such solicitation,

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employment, or retainer, (ii) encourage any such person not to devote his or her full business time to the Company, or (iii) agree to hire or employ any such person.

10. MISCELLANEOUS

- 10.1 It is understood that Sterling Pathology and Client are independent contractors engaged in the operation of their own respective businesses. Nothing contained herein shall be construed as creating a trustee, fiduciary, joint venture, employment, or other relationship between the Parties.
- 10.2 This Agreement is not assignable by either party without the other party's prior written consent.
- 10.3 This Agreement constitutes the entire agreement between the parties with regard to the subject matter hereof, supersedes all prior agreements or understandings and may only be modified in a writing signed by both parties.
- 10.4 Any notice required to be given hereunder will be deemed to have been served properly, if mailed by certified or registered mail, postage prepaid (or Federal Express or equivalent courier), properly addressed and posted in a United States depository to the respective parties hereto at the following addresses:

To Sterling Pathology: **Sterling Pathology**
3030 old Ranch Parkway, Suite 430
Seal Beach, CA 90740
Attn: Michael Okuniewski
M: 804-405-7447
F: 562-286-8026

To Client:	
Attn:	
M:	
F:	
eMail:	

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- 10.5 The individuals signing this Agreement represent that they have the authority to sign this Agreement on behalf of the respective parties. This Agreement is not binding until signed by the authorized representatives Client and Sterling Pathology.
- 10.6 Each party represents and warrants that it has not been convicted of a crime related to healthcare or is not currently listed by a federal agency as debarred, excluded or otherwise ineligible for participation in federally funded programs (including, without limitation, federally funded healthcare programs, such as Medicare and Medicaid). If the foregoing representation changes during the term of this Agreement, the affected party shall provide reasonable and timely written notice to the other party.
- 10.7 The parties acknowledge that they may not use the other parties' names and logos without the prior written consent of that party. Any communications regarding the relationship between the parties shall be mutually agreed upon in writing by authorized representatives of each party.
- 10.8 Arbitration. Any Dispute which cannot be otherwise resolved by the Parties shall be resolved by final and binding arbitration (the "Arbitration"). The Arbitration shall be initiated and administered by and in accordance with the then current Rules of JAMS. The Arbitration shall be held in Los Angeles County, unless the parties mutually agree to have such proceeding in some other locale; the exact time and location shall be decided by the arbitrator(s) selected in accordance with the then current Rules of JAMS. The arbitrator(s) shall apply California substantive law, or federal substantive law where state law is preempted. The arbitrator(s) selected shall have the power to enforce the rights, remedies, duties, liabilities, and obligations of discovery by the imposition of the same terms, conditions, and penalties as can be imposed in like circumstances in a civil action by a court of competent jurisdiction of the State of California. The arbitrator(s) shall have the power to grant all legal and equitable remedies provided by California law and award compensatory damages provided by California law, except that punitive damages shall not be awarded. The arbitrator(s) shall prepare in writing and provide to the parties an award including factual findings and the legal reasons on which the award is based. The arbitration award may be enforced through an action thereon brought in the Superior Court for the State of California in Los Angeles County. Each party in any Arbitration hereunder shall be awarded reasonable attorneys' fees, expert and non-expert witness costs and any other expenses incurred directly or indirectly with said Arbitration, including without limitation the fees and expenses of the arbitrator(s)
- 10.9 THIS ELECTION OF AN ALTERNATIVE DISPUTE PROCESS IS AN AFFIRMATIVE WAIVER OF THE PARTIES' RIGHTS TO A JURY TRIAL UNDER CALIFORNIA LAW, Cal. C. Civ. Pro. Sec 631. BY SIGNING BELOW, EACH PARTY IS EXPLICITLY WAIVING JURY TRIAL AND AUTHORIZING ANY AND ALL PARTIES TO FILE THIS WAIVER WITH ANY COURT AS THE WAIVER REQUIRED UNDER Cal. C. Civ. Proc. Sec. 631(f)(2):

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JURY TRIAL WAIVED:

By: __

- 10.10 Each party agrees to execute and deliver any and all such other and additional instruments and documents and do any and all such other acts and things as may be necessary or expedient (for purposes of complying with laws or otherwise) to effectuate this Agreement fully and to carry out the relationship contemplated hereunder.
- 10.11 Each party agrees to indemnify, defend, and hold the other party and each of the other party's consultants, partners, shareholders, officers, and agents harmless from any liability, loss or claim, including costs, expenses, and reasonable attorneys' fees, arising, directly or indirectly, from injury, damage, or loss to any person or property resulting from the action, omission, misconduct, or behavior of the other party.
- 10.12 This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which, when taken together, will constitute one and the same instrument. Each counterpart may be delivered by facsimile transmission or e-mail (as a .pdf or similar unmediatable attachment), which transmission shall be deemed delivery of an originally executed counterpart hereof.
- 10.13 Waiver of any agreement or obligation set forth in this Agreement by any Party shall not prevent that Party from later insisting upon full performance of such agreement or obligation and no course of dealing, partial exercise or any delay or failure on the part of any Party in exercising any right, power, privilege, or remedy under this Agreement or any related agreement or instrument shall impair or restrict any such right, power, privilege or remedy or be construed as a waiver therefor. No waiver shall be valid against any Party unless made in writing and signed by the Party against whom enforcement of such waiver is sought.
- 10.14 Subject to the provisions set forth in this Agreement, this Agreement shall be binding upon and inure to the benefit of the Parties and upon their respective successors and assigns.
- 10.15 If any one or more of the provisions of this Agreement is adjudged to any extent invalid, unenforceable, or contrary to law by a court of competent jurisdiction, each and all of the remaining provisions of this Agreement will not be affected thereby and shall be valid and enforceable to the fullest extent permitted by law.
- 10.16 Each Party shall be excused for failures and delays in performance of its respective obligations under this Agreement due to any cause beyond the control and without the fault of such Party, including without limitation, any act of God, war, terrorism, bio-terrorism, riot or insurrection, law or regulation, strike, flood, earthquake, water shortage, fire, explosion or inability due to any of the aforementioned causes to obtain necessary labor, materials or facilities. This provision shall not release such Party from using its best efforts to avoid or remove such cause and such Party shall continue

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performance hereunder with the utmost dispatch whenever such causes are removed. Upon claiming any such excuse or delay for non-performance, such Party shall give prompt written notice thereof to the other Parties, provided that failure to give such notice shall not in any way limit the operation of this provision.

IN WITNESS WHEREOF, the Parties agree to the foregoing terms of agreement through the execution below by their respective, duly authorized representatives as of the Effective Date.

Sterling Pathology National Laboratories

By: _____
Name: Michael Okuniewski
Title: Vice President
Date: 9/17/21

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ATTACHMENT 1

Facility Name:	
Address:	
City, ST ZIP:	
Effective Date:	9/1/2021
Supersedes Date:	

SERVICES

	<u>SERVICE</u>	<u>TEST DESCRIPTION</u>	<u>FEE</u>
ITEM #1	Patient Service Fee Per Test	COVID-19 NAA Test. Expedited cases 12-24 hours.	\$21.00 per test
ITEM #2	Patient Service Fee Per Test	COVID-19 NAA Test. 24-48 hours.	\$18.00 per test

MATERIALS

NOTE:

- Item #1:**

 - Fee paid to Client per sample as patient service fee.
 - Client to Provide necessary information for CARE’s billing to Sterling Pathology
- Item #2:**

 - Private Insurance Samples to be billed by Sterling Pathology and a Fee of \$18.00 per sample to be paid to Client for the contracted services outlined below and billed by Elite Services.
 - Client to provide Collection Personal to collect and transport samples to Sterling Pathology. Sterling Pathology to process and result COVID-19 sample results.
 - Client to provide patient demographics (CA ID/Driver’s License) and Front/Back copies of primary insurance details to Sterling Pathology to assist in a clean bill to patient’s insurance.
- Item #3:**

 - Fee paid to Client at the end of each month.

Service Payment Agreement

Sterling Pathology Medical Corporation DBA Sterling Pathology National Labs
3030 Old Ranch Parkway #430 Seal Beach, CA 90740

Agent Name:

Agent provided nasal specimen collection services for COVID testing by Sterling Pathology Medical Corporation ("Sterling"). To the extent the specimens were properly documented by Agent, Sterling submitted billing to insurance payers and to the HRSA COVID-19 Uninsured Program and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) for specimen services.

The Agent submitted collected samples to Sterling over the period of January 1, 2020 through May 1, 2022 for the processing and results. Sterling will pay Agent the final sum of one-hundred and seventy-one thousand, seven-hundred and fifty-two dollars (\$171,752.00) upon receipt of execution of this letter agreement.

Upon payment of such sums, Agent releases and discharges Sterling and its agents, officers, directors, shareholders and representatives, and each of them, from any and all claims, demands, or causes of action of any nature whatsoever which have been raised, or which could have been raised between them on or before execution of this Agreement regardless of whether said claims are known or unknown, contingent or otherwise, from the beginning of time to the date of this agreement which related to nasal specimen collections, including all rights which may be reserved to it by section 1542 of the California Civil Code. Agent acknowledges that it is familiar with the provisions of section 1542 of the California Civil Code which reads:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

Acting with knowledge of the provisions of section 1542, and upon the advice of their respective counsel, Agent expressly waives all rights which may be reserved to it by the provisions of said statute. The person executing this agreement represents and warrants that he or she is authorized to do so on behalf of the party for whom he or she is executing this agreement.

Sterling Pathology Medical Corporation

By: _____
Name: **Michael Okuniewski**
Title: **Vice President**
Date: _____

By: _____
Name: _____
Title: **CEO**
Date: **5/18/2022**