UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, Plaintiff, v. PATRICK TORMAY BRITTON-HARR; PROVISTA HEALTH, LLC; AMS ONSITE, INC.; BRITTON-HARR ENTERPRISES, INC; COASTAL LABORATORIES, INC.; and COASTAL MANAGEMENT GROUP, INC., Defendants.	No. UNITED STATES' COMPLAINT

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The United States of America brings this action against Patrick Tormay Britton-Harr; Provista Health, LLC ("Provista"); AMS Onsite, Inc.; Britton-Harr Enterprises, Inc; Coastal Laboratories, Inc. ("Coastal Labs"); and Coastal Management Group, Inc. (collectively, "Defendants") to recover treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729–3733, and to recover funds paid by Medicare to Defendants under the common law causes of action for unjust enrichment and payment by mistake of fact. Seeking to capitalize on the nation's health crisis during the early stages of the COVID-19 pandemic, Defendants caused the presentment of more than 24,000 false claims to Medicare for over 300,000 respiratory pathogen panel tests that were unreasonable and medically unnecessary, performed without a valid physician order, or not performed at all.

I. NATURE OF ACTION

1. In early 2020, the COVID-19 pandemic spread across the United States. At this time, a vaccine was not yet available to protect people from COVID-19.

2. Patients in skilled nursing facilities and long-term care facilities (collectively, "nursing homes") were especially vulnerable to the devastating effects of COVID-19.

3. Many states, including Maryland, instituted emergency policies that required COVID-19 testing of patients in these nursing homes.

4. Defendant Britton-Harr, a self-described "serial entrepreneur" with "expertise [. . .] in understanding and executing on complex healthcare reimbursement mechanisms," sought to profit off the unfolding COVID-19 pandemic by taking advantage of nursing homes that were desperate to obtain COVID-19 tests for their patients.

5. Defendant Britton-Harr and the defendant companies he owned accomplished this by agreeing to perform COVID-19 tests (which at the time were in short supply) at no cost to the nursing homes for their residents, but then also performing and billing Medicare for a large panel of medically unnecessary respiratory pathogen tests. As explained by a senior executive for Defendant Coastal Labs, Defendants were "using COVID testing as an entrée to a new contract" with the nursing homes for the financially lucrative, but medically unnecessary, respiratory pathogen tests.

6. Medicare only pays for medically necessary lab tests, but Defendants billed Medicare for a wide array of medically unnecessary respiratory pathogen tests. These included tests for uncommon organisms such as bordetella bronchiseptica, which causes the illness commonly known as "kennel cough" in dogs (and is very rare in humans), as well as legionella pneumophila (the bacteria that causes Legionnaires' disease).

7. While Medicare only covers lab tests based on a treating physician's individualized assessment of the needs of a beneficiary, the Defendants effectively ordered, performed, and billed Medicare for respiratory pathogen tests for virtually all of the residents at the nursing homes with which they contracted. Defendants accomplished this, in part, by not allowing physicians to order specific lab tests (as opposed to the entire respiratory pathogen panel) and by threatening to withhold COVID-19 testing from nursing homes that complained about the Defendants performing and billing for the full respiratory pathogen panel of tests for their beneficiaries. Defendants also submitted many claims to Medicare that listed the names of physicians as the ordering provider when those physicians never actually ordered the tests.

8. Despite dangling the carrot of no-cost COVID-19 tests, Defendants never actually had the ability to perform COVID-19 testing themselves. Instead, Defendants sent all of their COVID-19 test samples to outside laboratories ("reference labs") to perform the lab tests and failed to disclose that fact on the reimbursement claims it submitted to Medicare. That the Defendants relied so heavily on reference labs created various delays with providing test results to the nursing homes and to various state agencies as required by regulations. Sometimes these delays were multiple weeks long. One nursing home executive described AMS Onsite as follows: "They have delayed results and are piss poor at best. I certainly wish they worried about service as much as they do payment." After further delays of more than two weeks to get test results, the nursing home executive complained to AMS Onsite, "This is SO crazy.... This is extremely unprofessional [. . .] SO SO not fair to our residents and staff…… I'm speechless."

9. Despite the intense need for COVID-19 testing (and before the widespread availability of COVID-19 testing), some nursing homes, potential partners, and even the former owner of Provista recognized that this scheme was potentially problematic and warned

Defendants that respiratory pathogen panel testing must be medically necessary. For example, Defendants received a memo drafted by legal counsel for an outside laboratory that warned that a lab must document the medical necessity "of each and every test ordered." Additionally, an infectious disease physician who was considering partnering with AMS Onsite warned Britton-Harr that "Quarterly nursing home respiratory screening may not be considered 'medically necessary' even if the information used is valuable in tracking and reporting data." Defendants ignored those warnings and continued to cause Provista to submit thousands of claims to Medicare for reimbursement.

10. Provista also submitted claims to Medicare for respiratory pathogen panel tests that were never performed. Defendants had no processes or procedures to ensure that only tests that were properly ordered and actually performed were billed to Medicare. Strikingly, Provista submitted 346 claims (7,527 tests) for 153 different beneficiaries that listed a date for the supposed collection of the test sample after the beneficiary's date of death.

11. Defendants billed and received over $7 million in reimbursement from Medicare before the fraudulent scheme fell apart. The scheme fell apart in the fall of 2020 when Defendants—who no longer had a functioning lab—were unable to find a reference lab that would agree to an arrangement where the reference lab would perform the COVID-19 and respiratory pathogen panel tests while Provista submitted those claims to Medicare and paid the reference lab a portion of the proceeds. Even after the scheme fell apart, Provista continued to submit claims to Medicare through August 2021 for purported dates of service between April 3, 2020, and September 17, 2020.

12. In late summer of 2020, Britton-Harr transferred his financial proceeds from the fraudulent scheme to his other companies and abandoned the healthcare industry. Britton-Harr then used some of the proceeds of this fraudulent scheme to lease or purchase various aircrafts, and he then founded a new company called Aerovanti that provides private charter airplane service. Aerovanti describes itself as a "perfect match" "for those who enjoy the beauty of aviation, who value dedicated service, and who prioritize extravagance over the ordinary." In a statement to the Talbot County (Maryland) Council in support of a request from Aerovanti to

build a hangar at the county airport, Defendant Britton-Harr's father stated that his son "made quite a bit of money in the healthcare industry. And he kind of got tired of the health care industry and wanted to get into aviation."

II. JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1345 because the United States is the Plaintiff and the claims arise under the False Claims Act, 31 U.S.C. §§ 3729-3730.

14. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because each Defendant transacts or transacted business in the District of Maryland, and a substantial portion of Defendants' conduct in violation of 31 U.S.C. § 3729 occurred in the District of Maryland.

15. Venue is appropriate in the District of Maryland under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because a substantial portion of Defendants' conduct giving rise to this action occurred in this District.

III. PARTIES

16. The United States of America is the Plaintiff. The United States brings this action on behalf of the United States Department of Health and Human Services (HHS), including HHS's component, the Centers for Medicare and Medicaid Services (CMS), which administers the Medicare and Medicaid Programs.

17. Defendant Britton-Harr is the founder, owner, and chief executive officer of multiple companies described below. During the relevant period, he resided, at least part-time, in Annapolis, Maryland and conducted business in the State of Maryland and other parts of the United States.

A. Provista

18. Defendant Provista is a Maryland limited liability company. The mailing address and corporate address for Provista is 2 Compromise Street, Annapolis, MD 21401.

19. Provista operated clinical labs at 17301 North Perimeter Drive, Suite 100, Scottsdale, Arizona 85255 and 4530 East Shea Boulevard, Suite 165, Phoenix, AZ 85028 until it sent all of its clinical lab equipment to another unrelated company and abandoned the buildings.

20. Provista was a clinical lab company that provided clinical lab testing, or referred such tests to unrelated reference labs, to beneficiaries in nursing homes in the District of Maryland and throughout the United States.

21. Provista relied upon independent sales representatives (who were contracted with Coastal Labs or AMS Onsite) to solicit clinical lab tests in the District of Maryland and throughout the United States. Provista also relied upon Britton-Harr and others to solicit clinical labs tests.

22. Provista is enrolled as a supplier with Medicare.

23. Medicare reimbursed eligible clinical labs for providing COVID-19 and respiratory pathogen tests for Medicare beneficiaries subject to certain laws, regulations, and conditions.

24. Provista submitted claims to Medicare for clinical lab tests performed in its own lab, for tests performed by reference labs, and for tests that were never performed.

B. AMS Onsite

25. Defendant AMS Onsite is a Delaware corporation headquartered in Maryland. The mailing address and principal place of business for AMS Onsite is 2 Compromise Street, Annapolis, MD 21401.

26. AMS Onsite provided infection control and prevention services to nursing homes and solicited respiratory panel tests for beneficiaries at nursing homes.

27. Britton-Harr is the sole owner of AMS Onsite.

28. Britton-Harr initially served as Chief Executive Officer of AMS Onsite. Britton-Harr then became "chairman" of AMS Onsite when another individual was hired as CEO.

29. Even though AMS Onsite employed a CEO at times, Britton-Harr continued to control the company and directed the company's activities.

30. Britton-Harr controlled the finances of AMS Onsite.

C. Britton-Harr's Other Companies

31. Defendant Coastal Labs is a Delaware corporation headquartered in Maryland. The mailing address and principal place of business for Coastal Labs is 2 Compromise Street, Annapolis, MD 21401.

32. Coastal Management Group provided marketing and sales services for Coastal Labs.

33. Coastal Labs was, and is currently, the sole owner of Provista. Defendant Britton-Harr is the sole owner of Coastal Labs.

34. Coastal Labs and Britton-Harr directed all of Provista's actions.

35. Coastal Labs was a shell company that did not directly own or possess any clinical lab equipment.

36. Defendant Coastal Management Group is a Delaware corporation headquartered in Maryland. The mailing address and principal place of business for Coastal Management is 2 Compromise Street, Annapolis, MD 21401.

37. Britton-Harr is the sole owner of Coastal Management Group.

38. Coastal Management Group had no employees.

39. Defendant Britton-Harr Enterprises is a Delaware corporation headquartered in Maryland. The mailing address and principal place of business for Britton-Harr Enterprises is 2 Compromise Street, Annapolis, MD 21401.

40. Britton-Harr is the sole owner of Britton-Harr Enterprises.

41. Britton-Harr was the only employee of Britton-Harr Enterprises.

42. Britton-Harr used Britton-Harr Enterprises to pay his personal expenses and extract money from his other companies. This included wire transfers of approximately $30,000 per month from Coastal Labs to Britton-Harr Enterprises for Britton-Harr's purported monthly salary.

43. Britton-Harr admitted that he did not even have a personal bank account until September 2020.

44. Britton-Harr served as the Chief Executive Officer of Provista, Coastal Labs, Coastal Management Group, and Britton-Harr Enterprises and directed the activities of, maintains control over, and manages the finances of these companies.

45. Defendants AMS Onsite, Provista, Britton-Harr Enterprises, Coastal Labs, Coastal Management Group, and Provista failed to follow corporate formalities such as keeping accurate financial records, keeping separate and complete business records, filing tax returns, or having board meetings.

46. Britton-Harr also used multiple corporate email addresses interchangeably, often sending emails about AMS Onsite business from his Coastal Management Group email account.

47. Defendants AMS Onsite, Britton-Harr Enterprises, Coastal Labs, Coastal Management Group, and Provista are alter egos of Defendant Britton-Harr.

IV. THE FALSE CLAIMS ACT

48. The False Claims Act provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the United States 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 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains[.]

31 U.S.C. § 3729.

49. For purposes of the False Claims Act,

> the term "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information; and require no proof of specific intent to defraud.

31 U.S.C. § 3729(b).

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

V. THE MEDICARE PROGRAM

51. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare Program, to pay for the costs of certain health care services. 42 U.S.C. § 1395, *et seq*. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1.

52. HHS is responsible for the administration and supervision of the Medicare program. CMS is a component of HHS and is directly responsible for the administration of the Medicare program.

53. To participate in the Medicare program, a healthcare supplier must file an agreement with the Secretary of HHS (Secretary). 42 U.S.C. § 1395u(h)(1). *See also*, Form CMS 460.

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

55. Form CMS-855B requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 2A1 of this application. The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . .
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf.

56. An authorized official must sign the "Certification Statement" in Section 15 of Form CMS-855B, which "legally and financially binds this supplier to the laws, regulations, and program instructions of the Medicare program." *Id.*

57. Medicare reimburses only those services furnished to beneficiaries that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(1)(A).

58. The Secretary is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a). The Secretary acts through formal regulations, and periodically CMS issues industry guidance.

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

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

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

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

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

64. At all times relevant to this Complaint, CMS contracted with private contractors, known as Medicare Administrative Contractors (MACs), to perform various Medicare Part B administrative functions on its behalf, including reviewing and paying Medicare Part B claims

submitted by healthcare suppliers. 42 U.S.C. § 1395u; 42 C.F.R. §§ 421.401 and 421.404. MACs generally act on behalf of CMS to process and pay Medicare claims and perform administrative functions on a regional level. MACs may issue Local Coverage Determinations (LCD) regarding whether a particular item or service is covered. 42 U.S.C. § 1395ff(f)(2).

65. To obtain Medicare reimbursement for certain outpatient items or services, healthcare suppliers submit a claim form known as the CMS 1500 form or its electronic equivalent, known as the 837P format. When a CMS-1500 claim is submitted, the supplier certifies that they are knowledgeable of Medicare's requirements and that the services for which payment is sought were "medically indicated and necessary for the health of the patient."

66. For a claim to be paid by Medicare Part B, it must identify each service rendered to the patient by the provider or supplier. The Healthcare Common Procedure Coding System (HCPCS) is a collection of standardized codes that represent medical procedures, supplies, products, and services. Level I of the HCPCS is comprised of codes defined by the American Medical Association (AMA) and contained in the AMA publication called the Current Procedural Terminology (CPT) Manual. These codes are referred to as "CPT codes." Level II codes of the HCPCS are defined by CMS and are updated throughout the year as necessary. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Each procedure or service is identified by either a five-digit CPT code or by Level II HCPCS code consisting of a single alphabetical letter followed by four numeric digits.

67. The United States uses CPT and HCPCS codes to determine both coverage (if it will pay for the billed procedure) and reimbursement (how much it will pay for the billed medical procedure).

68. In addition to the CPT Manual, the AMA publishes the International Classification of Diseases (ICD) Manual, which assigns a unique numeric identifier to each medical condition. To be payable by Medicare, the claim must identify both the CPT code that the provider or supplier is billing for and the corresponding ICD version 10 (ICD-10) code(s) for

the patient's medical condition that supports the medical necessity of the provider's or supplier's service.

69. When submitting claims on the CMS-1500 (or its electronic equivalent) to Medicare, suppliers certify, among other things, that: (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information in the claim is "true, accurate, and complete"; and (c) the supplier understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." Suppliers further certify that their claims comply "with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law)." CMS-1500 also requires suppliers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

70. When enrolling to submit claims electronically, suppliers certify that they will submit claims that are "accurate, complete, and truthful." *See* EDI enrollment form CMS 10164, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS1215291?DLPage=1&DLEntries=10&DLFilter=enrollment&DLSort=0&DLSortDir=ascending. When a supplier submits an electronic claim, the supplier's identification number and password serve as the supplier's signature, just as if the supplier physically signed the claim form.

71. Healthcare suppliers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1320a-7(b)(7) (healthcare entities may be excluded for fraud, kickbacks, and other prohibited activities).

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

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

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

VI. CLINICAL LABORATORY TESTING

A. Lab Testing Overview

75. Clinical lab services involve the "examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual (MBPM), Pub. 100-02, Ch. 15, § 80.1.

76. Pursuant to Medicare regulations, (1) lab tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (2) lab test orders that are not individualized to patient need, or for which the need is not documented in the medical record, are not covered services; and (3) claims for lab services that do not meet these requirements are ineligible for payment. *See* 42 C.F.R. § 410.32.

77. All diagnostic lab tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a).

78. A lab test order is "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary." MBPM, Ch. 15, § 80.6.1.

Medicare requires that an ordering physician "must clearly document, in the medical record, his or her intent that the test be performed." *Id.*

79. Clinical lab services must be used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a). *See* MBPM, Ch. 15, § 80.1.

80. Lab tests that screen for respiratory pathogens in asymptomatic beneficiaries are excluded from Medicare coverage. 42 U.S.C. § 1395y(a)(1). Noridian, the MAC to which Provista submitted its Medicare claims, issued an LCD explaining that "Syndromic surveillance (testing to improve early detection of outbreaks) and/or public monitoring of disease transmission in nursing homes or other facilities to follow disease transmission or mutational change are not Medicare benefits." LCD (L37315), *MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels*.

81. Noridian's LCD L37315 also stated that respiratory panels targeting six or more pathogens are not covered. The LCD explained that these panels "are effectively a 'one size fits all' diagnostic approach, and do not meet Medicare's 'reasonable and necessary' criteria."

82. Medicare requires proper and complete documentation of lab services rendered to beneficiaries. In particular, the Medicare statute provides that:

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

42 U.S.C. § 1395l(e); *see also* 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) . . . .").

83. A lab's claim for a service is ineligible for payment if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

84. Medicare regulations allow labs to request documentation from physicians regarding medical necessity:

> Medical necessity. The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or

> nonphysician practitioner to document that the services it bills are reasonable and necessary.

42 C.F.R. § 410.32(d)(3)(iii).

B. The Reference Lab Rule

85. Payment from Medicare for covered clinical diagnostic lab tests may only be made to "the person or entity which performed or supervised the performance of such test." 42 U.S.C. § 1395l(h)(5)(A).

86. If a test is "performed at the request of a laboratory by another laboratory," the referring lab can only be paid by Medicare for that test if "not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory . . . receives requests for testing during the year in which the test is performed, are performed by another laboratory." *Id.*

87. This reference lab rule is sometimes called the "shell lab rule" because it precludes pass-through billing arrangements where a lab bills Medicare for more than 30 percent of the tests that were actually performed by another lab.

88. The intent of this rule was to redress abuses of the reference laboratory billing exception, which had been intended to benefit small, rural laboratories which had to send out certain "difficult or sophisticated tests" to other labs. Congress intended to prevent abuses from people who had:

> [. . .] created laboratories that have only a limited capacity to do testing, or indeed have virtually no capacity to do testing, but that act as conduits for referrals to other laboratories. This arrangement allows the owners and operators of the referring laboratory to obtain substantial discounts from the testing laboratory or to make other financial arrangements so that, even though there is a limit on Medicare payments, the referring laboratory is able to make inappropriate profits on testing done for Medicare patients. This is likely to be an inducement for unnecessary testing and contravenes the intent of the direct billing requirement. This is not acceptable to the Committee.

H.R. Rep. No. 247, 101st Cong., 1st Sess. 356 (1989).

89. Medicare instructs the MACs to deny payment to labs that exceed the 30 percent limit on tests referred to reference labs. Additionally, Medicare instructs the MACs to recoup

payments if it is later discovered that a lab has exceeded the 30 percent limit. Medicare Claims Processing Manual, Pub. 100-4, Ch. 16, § 40.1.

90. Medicare requires labs to identify on the claim form which lab performed the test. To do this, labs must add the "90" modifier on the claim to identify all referred lab services. Labs must also report "[t]he name, address, and CLIA number of both the referring laboratory and the reference laboratory" on the claim. Medicare Claims Processing Manual, Ch. 16, § 40.1.1.

C. COVID-19 and Influenza Testing

91. In the early stages of the COVID-19 pandemic, Medicare relaxed the requirement that COVID-19 and certain respiratory pathogen tests (influenza and respiratory syncytial virus) be ordered by a treating physician. Under the May 8, 2020, interim rule, Medicare coverage included COVID-19, influenza, and respiratory syncytial virus tests when ordered by any healthcare professional authorized to do so under state law (not just the treating physician or non-physician practitioner) or no order at all if the results were provided directly to the beneficiary. 85 Fed. Reg. 27550, 27558 (May 8, 2020).

92. Medicare revised the interim rule on September 2, 2020, to allow only one COVID-19 test, one influenza test, and one respiratory syncytial virus test without a physician or other practitioner order and required further tests to be ordered by an authorized healthcare professional. 42 C.F.R. § 410.32(a)(3). While the interim policy relaxed the ordering and documentation requirements for these specific tests, it did not remove other applicable requirements. 85 Fed. Reg. 54820, 54837 (Sept. 2, 2020).

93. Even under the May 8, 2020, and September 2, 2020, interim policies, COVID-19 tests and respiratory pathogen tests must be (1) reasonable and necessary for the treatment of illness or injury; (2) eligible for reimbursement provided as documented; and (3) not procured through payment of kickbacks and bribes to be covered by Medicare.

VII. PROVISTA'S LAB BUSINESS

A. Britton-Harr Created AMS Onsite to Generate a Large Volume of Lab Tests

94. Britton-Harr founded AMS Onsite in November 2019 shortly before the pandemic unfolded.

95. AMS Onsite had a program called "Sterisis" that was designed for nursing homes "to create processes, protocols, training, and other measures to prevent and control infection."

96. The cornerstone of the Sterisis program was "quarterly and systemic non-invasive respiratory testing." Every beneficiary at the nursing home would be tested for respiratory pathogens on a quarterly basis, even beneficiaries who had no symptoms of a respiratory illness.

97. Britton-Harr and AMS Onsite pitched the Sterisis program by saying that it would help nursing homes "be compliant with a complete Antimicrobial Stewardship Program focused on infection control that takes no extra time or effort by your staff." AMS Onsite also claimed that "Unique to the AMS Onsite practice is our access to clinical testing, to include Covid-19."

B. Britton-Harr Attempted to Buy a Lab That Could Perform Lab Tests for AMS Onsite and Would Allow Him to Submit Claims to Medicare

98. Britton-Harr and AMS Onsite sought to partner with an existing lab to test and analyze the specimens AMS Onsite collected through the Sterisis program and to allow Britton-Harr or one of the Defendant companies to submit claims to Medicare for reimbursement to generate funds to cover the expenses of AMS Onsite and to generate a profit.

99. Britton-Harr does not possess any training, certification, or licensure to perform clinical lab tests.

100. Britton-Harr created Coastal Labs in November 2019 to serve as a vehicle to purchase an existing lab to perform the respiratory pathogen panel tests obtained by AMS Onsite through its Sterisis program and to submit claims to Medicare for payment.

101. In late 2019, Britton-Harr and Dr. Tarun Jolly began negotiations for Britton-Harr to purchase Dr. Jolly's Arizona lab, Provista.

102. During the negotiations, the COVID-19 pandemic unfolded, and Britton-Harr urgently sought a lab partner that would be able to provide COVID-19 tests for its nursing home clients along with the quarterly respiratory pathogen panel testing for the Sterisis program.

103. Using the Coastal Labs corporate entity, Britton-Harr ultimately purchased Provista from Dr. Jolly, and that transaction was finalized on March 18, 2020. Coastal Labs is the sole owner of Provista, and Britton-Harr is the sole owner of Coastal Labs.

104. Britton-Harr signed and submitted form CMS-855B to CMS. The CMS-855B form stated that Britton-Harr was "5% or greater direct/indirect owner," "director/officer," "authorized official," and "managing employee" of Provista.

105. At all relevant times, Provista was enrolled as a clinical lab with Medicare and had its own National Provider Identifier number and Clinical Laboratory Improvement Amendments (CLIA) number.

106. Britton-Harr, Provista, and Coastal Labs all failed to update Provista's enrollment status with Medicare when it ceased to be a functioning lab.

C. Defendants Attempted to Profit Off the Pandemic by Aggressively Soliciting Respiratory Panel Tests From Nursing Homes That Were Not Reasonable and Necessary

107. At the start of the COVID-19 pandemic, nursing homes struggled to find COVID-19 testing options for their patients.

108. Some nursing home managers already had a prior relationship with Britton-Harr from healthcare industry groups and from a series of companies that Britton-Harr owned that provided mobile dental services to nursing homes.

109. Britton-Harr was already working with Dr. Jolly to purchase Provista when the pandemic unfolded. Britton-Harr originally planned to use the Provista lab to run the large volume of quarterly respiratory panel tests that AMS Onsite was attempting to obtain as part of its Sterisis program and to submit claims to Medicare for these tests. When the COVID-19 pandemic began, Britton-Harr saw an opportunity to run respiratory panel tests even more frequently than the quarterly testing that Defendants originally pitched with the Sterisis program.

110. Defendants communicated bluntly with the nursing homes about the fiscal realities of testing for COVID-19 only, and either tried to steer them away from this, or let them know they would be refused service altogether if they did not agree to the unreasonable and unnecessary respiratory pathogen panel testing as well.

111. To cement the deal with the nursing homes and ensure Defendants' ability to submit claims to Medicare for the financially lucrative respiratory panel tests, Britton-Harr, AMS Onsite, and Coastal Labs pressured the nursing homes to enter into two separate contracts: one with AMS Onsite and the other with Coastal Labs.

112. AMS Onsite would first execute a contract between AMS Onsite and the nursing home for the Sterisis program. The terms of this contract required AMS Onsite to do the following:

a. "Provide a Laboratory Counselor for Facility and its residents to implement the Antimicrobial/Antibiotic Stewardship program…";

b. "Cause for an individual who is properly trained and/or credentialed to report to each Facility…which includes, without limitation meeting with Facility staff…assisting Facility staff as to the administration of testing samples…and assisting Facility Staff in reviewing Facility patients' records…";

c. "Review the utilization and results of testing performed…and provide reports reflecting AMS's review…";

d. "Bill the resident's primary payer source such as Medicare, Medicaid or Private insurance or other designated person for services provided…";

e. "Provide onsite service and resources to residents and Facility";

f. "Participate in Family Council meetings once per quarter"; and

g. "Offer in-service, on-site staff training monthly in procedures and environmental control."

113. The contract stated that the nursing home was not responsible for any payment to AMS Onsite. However, the nursing home was required to provide a patient census list, demographic information, and insurance information for all patients in the nursing home. This

was key to the scheme because Defendants needed to ensure they could run the respiratory panel tests on nearly every patient at the nursing home—and submit the claims to Medicare—so that they could maximize their profits. In an email dated April 2, 2020, Britton-Harr said to others involved in the scheme, "lets [sic] stay on the full [respiratory] panel and not isolate covid-19 when discussing testing as we lose money on Covid-19 alone."

114. Britton-Harr signed these contracts on behalf of AMS Onsite.

115. Britton-Harr and the CEO of AMS Onsite both interacted with the nursing home managers to convince them to sign the contracts. AMS Onsite also engaged independent sales representatives to market this scheme.

116. Additionally, Coastal Labs entered into separate contracts with the nursing homes for the provision of the respiratory panel tests. The contract stated that Coastal Labs would submit claims to the "applicable third party payor."

117. Exhibit A to the contracts between Coastal Labs and the nursing homes contained a list of the tests in the respiratory panel:

- Respiratory Tract Microbiota Openarray (Format 112) Species
- Staphylococcus aureus
- Bordetella bronchiseptica/parapertussis/pertussis
- Bordetella pertussis
- Chlamydophila pneumoniae
- Mycoplasma pneumoniae
- Streptococcus pneumoniae
- Klebsiella pneumoniae
- Legionella pneumophila
- Haemophilus influenzae
- Adenovirus
- Human Coronavirus HKU1
- Human Coronavirus NL63
- Human Coronavirus 229E

- Human Coronavirus OC43
- COVID-19/SARS-CoV-2
- Human Metapneumovirus (hMPV)
- Human Rhinovirus
- Human Enterovirus (pan assay)
- Human Enterovirus D68
- Influenza A
- Influenza A/H1-2009
- Influenza A/H3
- Influenza B
- Human Parainfluenza virus 1
- Human Parainfluenza virus 2
- Human Parainfluenza virus 3
- Human Parainfluenza virus 4
- Human Respiratory Syncytial Virus A (RSVA)
- Human Respiratory Syncytial Virus B (RSVB)
- Human Bocaviras
- Human herpesvirus 4 (HHV4 - Epstein-Barr Virus)
- Human herpesvirus 5 (HHV5- Cytomegalovirus)
- Human herpesvirus 6 (HHV6)
- Human herpesvirus 3 (HHV3 - Varicella zoster Virus)

118. Exhibit A to the Coastal Labs contracts also included the following language: "Test Panel Fee: $200.00." This contract language allowed a fee to be charged to the nursing home if the beneficiary was covered by Medicare Part A because lab services are already included in the Part A bundled payment to the nursing home, and therefore, Coastal Labs/Provista would be unable to receive payment from Medicare Part B for these services. While the contract allowed Coastal Labs to bill the nursing home $200 for each Part A

beneficiary, Defendants anticipated receiving over $900 from Medicare for each respiratory panel for a Part B beneficiary.

119. Defendants rarely, if ever, sought or received payment from the nursing homes for beneficiaries whose tests were only covered by Medicare Part A.

120. Exhibit A to the Coastal Labs contract only included the fee for the entire panel of respiratory tests. It did not contain any information as to the cost of tests if a physician would only select certain tests instead of the full panel.

121. While Coastal Labs' respiratory panel included tests for two common viruses—influenza and respiratory syncytial virus—the respiratory panel primarily included tests for many less common pathogens.

122. For example, the respiratory panel included a test for Bordetella bronchiseptica, which is common in dogs and wildlife (typically "kennel cough" illness in dogs) but is rarely found in humans "despite the considerable exposure of humans to animal sources of the microorganism." Bert F. Woolfrey BF & Julia A. Moody, *Human Infections Associated with Bordetella Bronchiseptica*, 4 Clin. Microbiology Rev. 243 (1991), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC358197/.

123. While Britton-Harr used the Coastal Labs entity to market the respiratory pathogen testing, he used the Provista entity to submit claims to Medicare because Provista was enrolled as a lab with Medicare.

124. The following chart shows the CPT code, code description, number of claims, quantity of tests, amount billed, and amount paid to Provista for dates of services between February 2020 and October 2020.

CPT Code	Procedure Code Description	Number of Claims	Quantity of Tests Billed	Amount Billed	Amount Paid to Provista
87798	Detection test by nucleic acid for organism, amplified probe technique	22,871	213,414	$7,488,632.71	$3,885,044.42
U0004	2019-ncov coronavirus, sars-cov-2/2019-ncov (covid-19), any technique,	19,097	19,554	$1,955,075.45	$982,566.00

	multiple types or subtypes (includes all targets), non-cdc, making use of high throughput technologies as described by cms-2020-01-r				
87502	Detection test by nucleic acid for multiple types influenza virus	11,607	11,991	$1,148,737.80	$912,197.60
87532	Detection test by nucleic acid for herpes virus-6, amplified probe technique	20,469	20,925	$734,258.25	$348,751.99
87541	Detection test by nucleic acid for legionella pneumophila (water borne bacteria), amplified probe technique	20,490	20,931	$734,468.79	$348,751.99
87640	Detection test by nucleic acid for Staphylococcus aureus (bacteria), amplified probe technique	20,485	20,998	$734,503.88	$348,681.81
87581	Detection test by nucleic acid for Mycoplasma pneumoniae (bacteria), amplified probe technique	20,493	20,938	$734,714.42	$348,576.54
87496	Detection test by nucleic acid for Cytomegalovirus (CMV), amplified probe technique	20,468	20,941	$734,819.69	$348,542.15
87486	Detection test by nucleic acid for Chlamydia pneumoniae, amplified probe technique	20,492	20,965	$735,240.77	$348,331.61
87498	Detection test by nucleic acid for enterovirus (intestinal virus), amplified probe technique	11,606	11,993	$412,442.03	$326,770.82
U0002	2019-ncov coronavirus, sars-cov-2/2019-ncov (covid-19), any technique, multiple types or subtypes (includes all targets), non-cdc	1,652	1,652	$165,200.00	$22,779.39
87633	Detection test by nucleic acid for multiple types of respiratory virus, multiple types or subtypes, 12-25 targets	11,815	11,871	$4,947,595.38	$1,242.00

87634	Detection test by nucleic acid for respiratory syncytial virus, amplified probe technique	2,152	2,152	$167,834.48	$842.40
U0001	Cdc 2019 novel coronavirus (2019-ncov) real-time rt-pcr diagnostic panel	3	3	$300.00	$71.82
87641	Detection test by nucleic acid for Staphylococcus aureus, methicillin resistant (MRSA bacteria), amplified probe technique	1	1	$35.09	$0.00

125. Nearly every nursing home beneficiary received the same exact respiratory panel tests from Provista or one of the reference labs used by Defendants. If the MAC denied the claim for payment, Britton-Harr and Provista would change the CPT codes and resubmit the claim.

126. In a February 7, 2020, email to potential investors, Britton-Harr explained the strategy as follows:

> I went through the CMS – CPT codes and identified the applicable ones based on the Lab Respiratory Panel Requisition forms which comes out to approximately $849.90 . . . Keep in mind, Pricing does not normally change, what changes are limitations when it comes it [sic] ICD-10 codes of appropriate symptoms to order such tests based on Local coverage Determinations as stated by the specific benefit plan of each member. 90+% of patients we service will be covered by Medicare Part B. The additional 10% will have to be evaluated on a case by case basis. Therefore 90% of patients will have reimbursement of $849.90 regardless of where they live, the 10% will be a ??

127. Britton-Harr hired a relative without any medical billing experience to serve as Vice President of Patient Administration at Coastal Labs and oversee the claims submission process for Provista/Coastal Labs. Britton-Harr personally instructed this person on how he wanted claims filled out. Britton-Harr did not arrange for any outside training for his relative on medical billing or claims submissions.

128. Defendants (including Defendant Britton-Harr) did not hire a billing compliance officer and did not have any sort of billing compliance program at any of the Defendant companies.

129. Britton-Harr, on behalf of Coastal Labs and Provista, hired interns to fill out the electronic claim forms. Britton-Harr's instructions to the interns were that the CPT codes "will always be the same." The Vice President of Patient Administration for Coastal Labs explained in an email to a potential lender that Provista and Coastal Labs "bill out o[u]r same 9 codes everytime [sic]." There was no individual determination of need for these respiratory panel tests and few, if any, beneficiaries ever received only a portion of the Provista/Coastal Labs respiratory pathogen test panel test.

130. Provista, Coastal Labs, and AMS Onsite used the same nasal swab sample to test for COVID-19 and for the respiratory panel. During the early part of the fraudulent scheme when Provista still possessed some lab equipment, the sample would first be submitted by AMS Onsite to the reference lab to perform COVID-19 testing. Following the COVID-19 testing, the test sample would be shipped to Provista for the respiratory panel testing. Due to its limited capacity to perform respiratory panel tests, Provista would frequently ship the sample to yet another reference lab to complete the respiratory panel testing.

131. Beneficiaries without any symptoms of a respiratory illness received the vast majority of the respiratory panel tests. Britton-Harr, AMS Onsite, and Coastal Labs specifically marketed their services to test both symptomatic and asymptomatic beneficiaries.

VIII. DEFENDANTS' FRAUDULENT SCHEMES

A. Provista Submitted False Claims for Respiratory Panel Tests That Were Never Performed Including Claims With Dates of Service After the Beneficiary's Date of Death

132. Provista and Britton-Harr submitted claims to Medicare for respiratory panel tests that were never performed.

133. Medicare regulations require that the date of service for a clinical lab test be the date that the specimen was collected. 42 C.F.R. § 414.510; Medicare Claims Processing Manual, Pub. 100-04, Ch. 16, Section 40.8.

134. Defendants Britton-Harr, AMS Onsite, Provista, and Coastal Labs had no processes in place to ensure that claims were only submitted for lab tests actually performed and results delivered.

135. The Provista/Coastal Labs billing team created claims solely based on "face sheets" provided by Britton-Harr who received them from the nursing homes.

136. A face sheet is a short document containing demographic information for a nursing home patient. The "primary physician" listed on the face sheet is often the physician who was treating the beneficiary prior to the nursing home admission but not treating the beneficiary while the beneficiary is at the nursing home.

137. The face sheets typically had one or more hand-written dates of service. The face sheets did not contain any information regarding orders for the respiratory panel tests. The face sheets also did not contain any current clinical information supporting the medical necessity of tests.

138. The Provista/Coastal Labs billing team was not provided with any documentation that the team could use to verify that the respiratory panel tests were actually performed and that the results were provided to the nursing home.

139. The Provista/Coastal Labs billing team did not verify that the respiratory panel tests were actually performed prior to generating and submitting a claim to Medicare.

140. One example of tests not actually performed involved deceased beneficiaries. Provista submitted 346 claims (for 7,527 tests) for 153 different beneficiaries that included a date of service for the collection of the test sample after the beneficiary's date of death.

141. Beneficiary 1 died on July 10, 2020, yet Provista submitted eight claims to Medicare for 176 tests (eight COVID-19 tests and 168 respiratory panel tests) with the following dates of service (the day the sample was supposedly collected) after Beneficiary 1's death: 7/15/2020, 7/22/2020, 7/29/2020, 8/5/2020, 8/12/2020, and 8/19/2020.

142. Beneficiary 2 died on July 30, 2020, yet Provista submitted four claims to Medicare for 88 tests (four COVID-19 tests and 84 respiratory panel tests) with the following

dates of service (the day the sample was supposedly collected) after Beneficiary 2's death: 8/5/2020, 8/7/2020, 8/12/2020, and 8/19/2020.

143. Provista and Coastal Labs could not have performed these tests because the date the sample was supposedly collected was after the beneficiary had already died, and therefore, these claims are false.

144. After receiving claim denials from the MAC due to the date of service being after the beneficiary's death, Coastal Labs' Vice President of Patient Administration told Britton-Harr that she had concerns about whether the claims were being billed correctly.

145. The Coastal Labs Vice President of Patient Administration asked Britton-Harr for an explanation as to what caused claims to be submitted for dates of service after a beneficiary's death, and Britton-Harr failed to provide an answer to her.

146. The Vice President of Patient Administration resigned from the company shortly thereafter.

B. Provista Submitted False Claims to Medicare for Respiratory Panel Tests Performed Without the Required Physician Order

147. Virtually none of the respiratory panel tests that Provista billed to Medicare were performed pursuant to a valid order from the beneficiary's treating physician.

148. Defendants also failed to comply with the May 8th and September 2nd, 2020, interim rules that permitted COVID-19, influenza, and RSV tests to be performed without an order if the results were provided directly to the beneficiary.

149. Defendants did not provide results directly to beneficiaries.

150. Therefore, a valid physician order was required for all tests for which Provista submitted claims to Medicare.

151. Defendants failed to obtain a valid order for the respiratory panel tests because Defendants themselves—and not the beneficiary's treating physician—chose to perform the respiratory panel tests.

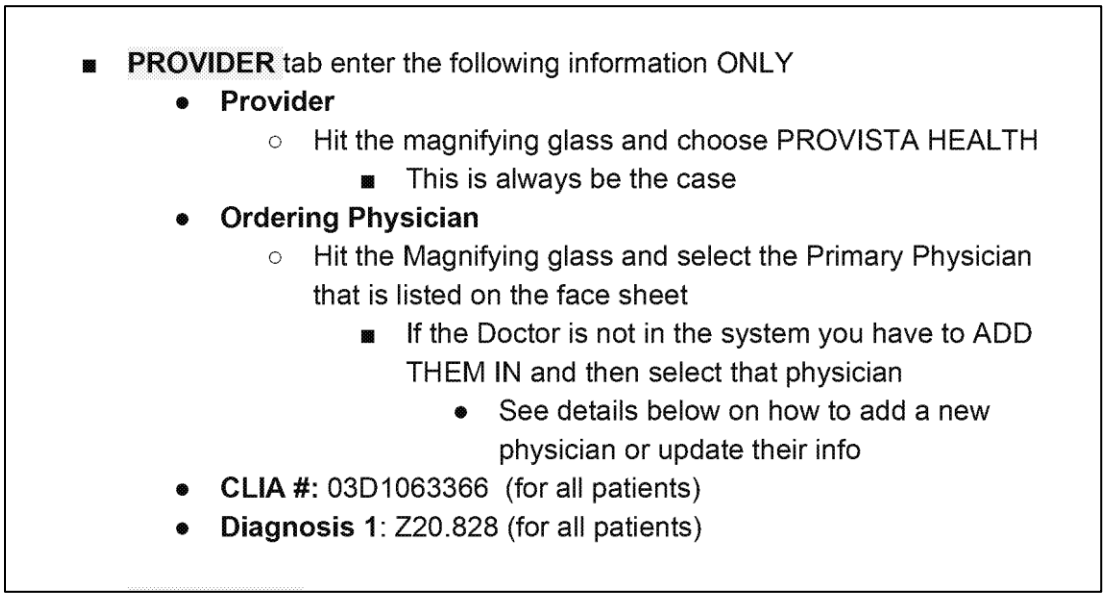
152. Such tests performed without a valid order are not covered by Medicare and constitute false claims.

i. Defendants Submitted False Claims to Medicare Without the Knowledge and Approval of the Physician Identified as Ordering the Respiratory Panel Tests

153. Multiple nursing home medical directors denied ordering the respiratory panel tests even though Provista listed their names as the ordering physicians on the claims it submitted to Medicare.

154. Britton-Harr and Coastal Labs' Vice President of Patient Administration instructed the interns who were completing the claim forms to "select the Primary Physician that is listed on the face sheet" and insert that name for the ordering physician.

155. The following image is from a document used by Britton-Harr and Coastal Labs to teach the interns how to code and submit claims.



- **PROVIDER** tab enter the following information ONLY
  - **Provider**
    - Hit the magnifying glass and choose PROVISTA HEALTH
      - This is always be the case
  - **Ordering Physician**
    - Hit the Magnifying glass and select the Primary Physician that is listed on the face sheet
      - If the Doctor is not in the system you have to ADD THEM IN and then select that physician
        - See details below on how to add a new physician or update their info
  - **CLIA #:** 03D1063366 (for all patients)
  - **Diagnosis 1**: Z20.828 (for all patients)

156. Britton-Harr, Coastal Labs, and Provista did not instruct the interns to verify that the "primary physician" actually ordered the COVID-19 or respiratory panel test. No such verification ever occurred.

157. Provista submitted 222 claims (for 3,417 tests) that listed Physician A, a physician medical director for Layhill Nursing and Rehabilitation Center, as the ordering physician for the respiratory panel tests. For example, Provista submitted 17 claims for 303 respiratory panel tests

for Beneficiary 3 that listed Physician A as the ordering physician. Provista received $10,114.07 for the tests for Beneficiary 3 as shown in Exhibit 1.

158. Physician A denied ordering these respiratory panel tests and denied ordering any respiratory panel tests for beneficiaries at that nursing home.

159. An administrator for Layhill Nursing and Rehabilitation Center also stated that he did not want the AMS Onsite and Coastal Labs respiratory panel testing at his nursing home and that he believed the regional physician medical directors were also not in favor of such respiratory panel testing.

160. Because Physician A did not order the tests, the tests were performed without a valid physician order, and therefore, are not covered by Medicare. The claims submitted for these tests constitute false claims.

161. Provista submitted 243 claims (for 3,703 tests) that listed Physician B, a physician for PruittHealth High Point nursing home, as the ordering physician for respiratory panel tests (excluding influenza tests). For example, Provista submitted four claims for 38 respiratory panel tests for Beneficiary 4 that listed Physician B as the ordering physician. Provista received $2,559.47 for these tests as shown in Exhibit 1. Provista billed $172,804.00 to Medicare for respiratory panel tests (excluding influenza tests) that listed Physician B as the ordering physician on the claim and received $68,361.10.

162. Physician B denied ordering these respiratory panel tests.

163. Because Physician B did not order the respiratory panel tests, the tests were performed without a valid physician order, and therefore, are not covered by Medicare. The claims submitted for these tests constitute false claims.

ii. Defendants' Online Ordering System Did Not Allow Nursing Homes to Choose Which Tests Were Supposedly Ordered by the Physician

164. Prior to July 2020, the clerical staff members at the nursing homes would place orders for COVID-19 tests electronically through an online ordering interface in a Laboratory Information Management System (LIMS) operated by Coastal Labs.

165. The online ordering system for Coastal Labs (and AMS Onsite and Provista) was designed specifically to track orders and results for only COVID-19 tests. The user interface available to the nursing homes only allowed them to enter the following information: patient name, patient date of birth, ordering physician, and specimen ID.

166. The interface contained no place for the nursing homes to select which tests the physician supposedly ordered for the patient. The patients automatically received COVID-19 testing and the entire respiratory panel.

167. Furthermore, the interface contained no mechanism for the clerical staff member at the nursing home to include any portion of the patient's medical record where the physician supposedly ordered the tests or any diagnosis codes to supposedly explain the clinical need for the tests. The interface is shown in the following picture:

168. The data in the LIMS system showed no indication that respiratory panels were actually ordered by a physician for any patients, yet the claims data showed that Provista billed Medicare for respiratory panel tests for nearly all the beneficiaries who received COVID-19 tests.

169. In some instances, instead of relying on a physician order, Defendants Britton-Harr, Provista, Coastal Labs, and AMS Onsite impermissibly attempted to rely upon the contract executed between the nursing home and Coastal Labs as the purported justification for performing and submitting claims for the respiratory panel testing. These facility-wide contracts do not satisfy Medicare's requirements for ordering a clinical lab test for multiple reasons including that there was no individual determination of need for each beneficiary by the treating physician.

170. Even though the contracts failed to satisfy the Medicare requirement for ordering a clinical lab test, Defendants believed that executing both contracts was so crucial to the scheme that Defendants aggressively pushed the nursing homes to sign both contracts. Britton-Harr emphasized that the contracts worked "in parlay" with each other. The AMS Onsite CEO referred to the contracts as "investor stuff" and that it "commits no $$$ fees to [the nursing home]."

171. For example, PruitHealth owns and/or operates a chain of nursing homes and desired to have AMS Onsite and Coastal Labs perform COVID-19 tests for its patients. PruitHealth did not want the full respiratory panel for all patients.

172. On May 28, 2020, a Senior Vice President from PruittHealth sent an email to AMS Onsite informing AMS Onsite that PruittHealth's nursing homes had been receiving test results back from Provista/Coastal Labs for full respiratory panel tests that "we are not ordering." The Senior Vice President reiterated "we just want the COVID-19 [tests]."

173. Despite this notice of wrongdoing, Provista continued to submit claims for respiratory panel tests for beneficiaries at PruittHealth facilities despite the tests not being ordered by the treating physicians.

174. Beneficiary 5 resided at a PruittHealth nursing home in Augusta, Georgia, throughout 2020. Provista submitted 19 separate claims for 339 respiratory panel tests for Beneficiary 5 for the following dates of service after the May 28, 2020, email from PruittHealth stating that it did not want such tests: 6/5/2020, 6/9/2020, 6/10/2020, 6/19/2020, 6/23/2020, 6/24/2020, 6/29/2020, 7/6/2020, 7/8/2020, 7/13/2020, 7/20/2020, 7/22/2020, 7/27/2020,

8/3/2020, 8/5/2020, 8/10/2020, and 8/17/2020. Provista received $12,118.78 for these tests as shown in Exhibit 1. Provista listed Physician C as the ordering physician for all of these tests. Physician C denied ordering such tests.

175. Consequently, the beneficiary's treating physician did not choose the specific tests that were performed. Defendants made that choice themselves.

176. The Medicare statute and regulations do not permit a clinical lab, like Defendants, to decide what respiratory tests to perform and bill to Medicare. That decision rests with the beneficiary's treating physician.

iii. Even After Switching to Paper Requisition Forms, Defendants Still Performed the Full Respiratory Panel for Nearly Every Beneficiary Regardless of Which Tests Were Selected on the Form

177. Defendants lost access to the LIMS system in July 2020 as a result of a payment dispute with the developer of the LIMS system. AMS Onsite, Provista, and Coastal Labs then began to utilize paper requisition forms.

178. Defendants AMS Onsite, Provista, and Coastal Labs used the paper requisition forms on an inconsistent basis. Many of the claims submitted to Medicare for the respiratory panel tests did not have a corresponding paper requisition form. Provista and Coastal Labs simply used the insurance information obtained from the beneficiaries' face sheets, the short form containing the beneficiary's demographic and insurance information, to fill out the claims for the respiratory panel tests.

179. Defendants AMS Onsite, Provista, and Coastal Labs, at the direction of Britton-Harr, sometimes attempted to backfill paper test requisition forms after the tests had already been completed (including mass printing of completed forms) when no paper requisition form was completed prior to performing the respiratory panel tests and submitting the claims.

180. A business consultant for Coastal Labs suggested to the Chief Operating Officer (COO) for Coastal Labs, that Defendants should "retroactively fill out requisitions for the samples we have run" and that it would be "prudent to obtain all the reports, all the facesheets, and fill out reqs [order forms] that correspond with the testing we did for these patients." The consultant explained that on "a first level appeal of a [claim] denial we are going to want to show

documentation." The COO of Coastal Labs agreed with this plan and responded that "we should be anticipating needing to produce these documents for billing" and that it would be a "great project for a summer worker." She then hired college students as interns to complete this task.

181. These paper requisition forms were often completed by Coastal Labs employees and not the ordering physician. For example, when the Coastal Labs COO visited Provista's building in Arizona, she found drawers stuffed with face sheets from beneficiaries who had been tested or had testing samples taken that were not yet tested. She simply placed all of the face sheets in a suitcase and took them back with her to Coastal Labs' office in Annapolis for the interns to use to generate claims for respiratory panel tests.

182. Some requisition forms only included a request for a COVID-19 test, yet Provista submitted claims for all tests on the respiratory panel.

183. For example, a requisition form for Beneficiary 6 only had the box for COVID-19 testing selected yet Provista submitted a claim for the entire respiratory panel test, which included 16 tests as shown in Exhibit 1. Provista received $586.36 for these respiratory panel tests that were not ordered.

184. Some requisition forms had no date of collection or date of service listed. In those instances, someone at Coastal Labs would write multiple dates at the bottom of form in an attempt to use the same form for multiple test dates over multiple months.

185. Most of the paper forms were not signed by the physician listed as the ordering physician on the claims submitted by Provista. Some paper forms had no signature at all.

186. Neither Coastal Labs' Vice President of Patient Administration nor the interns ever saw the paper requisition forms, and they were not used by Coastal Labs or Provista to generate and submit claims to Medicare.

187. These respiratory panel tests are, therefore, not reasonable and necessary—and not covered by Medicare—because there is no documentation to support that the beneficiary's treating physician ordered the tests or that that tests were medically necessary. The claims submitted for these tests constitute false claims.

iv. Defendants Had No Mechanism or Procedure to Inform the Reference Labs What Specific Respiratory Tests Were Ordered

188. After Provista sent all of its lab equipment to an unrelated company in July 2020, Defendants relied exclusively on reference labs to perform all of the COVID-19 and respiratory panel tests, as described more fully below.

189. Defendants Britton-Harr, AMS Onsite, Provista, and Coastal Labs had no mechanism to inform the reference labs what specific respiratory panel tests were ordered.

190. The communication to the reference lab simply said "COVID-19" and "RPP" (respiratory pathogen panel) and contained no details as to what exact tests in the RPP were supposedly ordered. As such, nearly every beneficiary who had a sample collected for respiratory panel testing received the full respiratory panel test regardless of physician intent.

191. Because physicians did not actually select or order these tests, Defendants Britton-Harr, AMS Onsite, Provista, and Coastal Labs never bothered to create such a mechanism to specifically identify which tests the reference labs should be performing because Provista nearly always submitted claims to Medicare for the entire respiratory panel.

192. These respiratory panel tests are, therefore, not reasonable and necessary—and not covered by Medicare—because there is no documentation to support that the beneficiary's treating physician ordered the tests or that that tests were medically necessary. The claims submitted for these tests constitute false claims.

C. Provista Submitted False Claims to Medicare for Unreasonable and Medically Unnecessary Respiratory Panel Tests

i. Provista Submitted False Claims to Medicare for Respiratory Panel Tests Without an Individual Determination of Need for Each Beneficiary and the Results Were Not Used to Treat the Beneficiary

193. Provista submitted thousands of false claims to Medicare for respiratory panel tests that Defendants knew were not based on an individualized determination of need for each test ordered for each beneficiary.

194. Defendants' scheme involved performing respiratory panel testing for nearly every beneficiary at a nursing home. This included many beneficiaries without signs or

symptoms of a respiratory illness. Defendants, including Britton-Harr, projected rapid financial growth by testing a large number of beneficiaries and projected revenue of $120 million in 2020, $300 million in 2021, and $500 million in 2022.

195. Defendants Britton-Harr, AMS Onsite, Provista, and Coastal Labs specifically marketed their tests for such asymptomatic beneficiaries. This scheme involved performing respiratory panel tests on a quarterly basis for infection surveillance of patients without any signs or symptoms of respiratory illness to generate a large volume of tests for which Defendants would submit claims to Medicare for reimbursement.

196. But surveillance respiratory panel tests for beneficiaries without any signs or symptoms of a respiratory illness are not covered by Medicare and are not eligible for reimbursement.

197. Medicare regulations require that lab tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury. Lab test orders that are not individualized to patient need, or for which the need is not documented in the medical record, are not covered services.

198. The asymptomatic beneficiaries who received respiratory panel tests as part of the quarterly screening program did not have a specific illness that needed to be treated.

199. Provista and the other Defendants did not possess any documentation explaining the individualized need for the respiratory panel tests. Defendants, including Britton-Harr, never even attempted to obtain such information when they utilized the online ordering portal to obtain beneficiary information from the nursing homes. As shown above, the online ordering portal did not contain any fields for diagnosis code or patient need.

200. Even when Defendants AMS Onsite, Provista, and Coastal Labs switched to a paper requisition form, they failed to pay attention to what was documented on the form regarding what tests were ordered or what diagnosis code was most appropriate.

201. Throughout the entire scheme, Provista only used the Z20.828 diagnosis code ("Contact with and (suspected) exposure to other viral communicable diseases") on the claims submitted to Medicare. Provista used Z20.828 for all 398,329 tests without ever using a different

code as the diagnosis to supposedly justify the test with an individual determination of patient need. For example, the paper requisition form for Beneficiary 6 contains no selection for the diagnosis code, yet Provista used code Z20.828 on every claim for his tests.

202. Because Britton-Harr intended to bill every Medicare beneficiary for the exact same respiratory panel tests, he instructed AMS Onsite staff to obtain a "standing order" for each nursing home, not for each individual beneficiary residing at that nursing home.

203. Defendants Britton-Harr, AMS Onsite, Provista, and Coastal Labs sometimes purported to rely upon these "protocols" or "standing orders" that covered every beneficiary in the nursing home regardless of the beneficiary's medical condition, symptoms, or history. Defendants Britton-Harr, AMS Onsite, and Coastal Labs explained this to nursing homes in their marketing efforts.

204. In a deposition, the CEO of AMS Onsite was asked, "So how would a standing order work in connection with a respiratory panel testing? It would just be a physician just says, 'Everyone in this facility needs a respiratory panel every quarter,' something like that?" The CEO responded, "Yes. Usually, they last for a year." The CEO said nothing about individual determinations of need for each beneficiary tested in any of his answers.

205. According to one physician medical director, AMS Onsite representatives set up the quarterly testing protocols at the nursing homes, not the nursing home physicians. Provista submitted claims for 11,744 tests listing this physician as the ordering physician even though the protocol was set up by AMS Onsite and not the physician. Provista received $188,122.84 for these tests.

206. Even though Provista pitched "quarterly" respiratory panel testing to the nursing homes, Provista frequently disregarded the physician's supposed "standing order" and submitted claims for respiratory panel tests that were performed much more frequently than quarterly. For example, Provista submitted claims for respiratory panel tests for Beneficiary 7 at PruittHealth Walterboro with dates of service of 4/23/2020, 5/7/2020, 5/21/2020, 6/4/2020, 6/10/2020, 6/24/2020, 7/1/2020, and 7/8/2020, 7/15/2020, 7/22/2020, 7/29/2020, 8/5/2020, 8/12/2020, and 8/19/2020, which resulted in testing intervals ranging as low as 6 days.

207. Moreover, the test results were oftentimes worthless to the supposed ordering physician because the nursing homes would wait weeks for the respiratory panel results. This delay prevented the results from being used to actually treat any illnesses.

208. In June 2020, Provista had a backlog of more than 6,600 samples that were collected but not yet tested.

209. The COO for Coastal Labs told Britton-Harr that Defendants could not bill for respiratory panel tests because the results were not available for more than three weeks and that "many [of the beneficiaries] are now dead from COVID." Provista still submitted claims to Medicare for many of these tests anyway.

210. Consequently, the respiratory panel tests failed to satisfy the Medicare requirements of being reasonable and medically necessary, and thus, constitute false claims.

ii. Defendants Failed to Heed Warnings Regarding the Problematic Nature of the Respiratory Panel Testing

211. Defendants Britton-Harr, AMS Onsite, and Coastal Labs used the carrot of COVID-19 test availability to leverage nursing homes into agreeing to the quarterly respiratory panel testing for all beneficiaries in the nursing homes including beneficiaries without any symptoms of respiratory illness.

212. Dr. Jolly, the former owner of Provista, sent an email to Britton-Harr on July 2, 2020 informing Britton-Harr about the recently released HHS-OIG workplan to address fraud and abuse issues. Dr. Jolly advised Britton-Harr that "I think you should run this by your regulatory council [sic]."

213. Dr. Jolly included a forwarded email from a billing consultant that said, "OIG is looking closely at RPP and COVID testing closely for fraud and abuse." The email stated that "there is a potential that RPP when added with COVID is [fraud]." The email further warned that if the only diagnosis code used was COVID-specific like "Z20.828 suspected exposure" that OIG "may have footing to argue that there was no need for a full RPP test."

214. Despite this warning, Defendants continued to engage in the fraudulent scheme and submit false claims to Medicare.

215. Throughout the entire scheme, Provista **only** used the Z20.828 diagnosis code on the claims submitted to Medicare. None of the claims submitted by Provista included a diagnosis code referencing any symptoms of a respiratory illness.

216. An infectious disease physician who was considering partnering with Defendants also warned Defendants that aspects of their scheme could be illegal. On July 27, 2020, this physician said in email to Britton-Harr that "Quarterly nursing home respiratory screening may not be considered 'medically necessary' even if the information used is valuable in tracking and reporting data." He also said that "Although signatures are not required by CMS, clear documentation that the ordering medical provider (doctor, PA or NP) intended for a particular test to be done should be documented."

217. Internal emails from AMS Onsite's and Coastal Labs' client CommuniCare (a company managing multiple nursing homes) show that nursing home medical directors were adamantly against ordering the respiratory panel tests for asymptomatic beneficiaries.

218. In an email dated August 31, 2020, one CommuniCare medical director told the CEO of AMS Onsite and other AMS Onsite employees that "The issue is that when we have a regulatory need for a covid19 screening panel, Dr Wayne, my national medical director anmd [sic] I do not want full other viral and bacterial screening. (which we are now sometimes getting)." He further explained that "Broader testing (bacterial or viral) should only occur with a specific prescriber made decision, which should be justified by the clinical situation."

219. Nevertheless, Provista continued to submit claims to Medicare for respiratory panel tests for asymptomatic beneficiaries listing the medical director as the ordering physician.

220. When the senior leadership of CommuniCare insisted that the respiratory panel testing of asymptomatic beneficiaries be halted, Defendants threatened to stop performing COVID-19 testing of the nursing homes' beneficiaries because it was not sufficiently profitable.

221. The CEO for AMS Onsite said in an email dated August 31, 2020, to CommuniCare, "Know however that if we are to be your Covid-19 only testing partner (with the occasional [full respiratory] panel test) either [CommuniCare] has to pay our standard fee of

$4,000/month/home for our above-mentioned program (there may be CARES Act funds available to you for this), or we have to move on…"

222. Without other readily available COVID-19 testing options, the Defendants put CommuniCare in the untenable position of having to choose between allowing respiratory panel tests it believed were medically unnecessary or potentially foregoing the ability to test its residents for COVID-19. The medical director stated he "will provide the orders to nursing to do what we to do within our contract commitment" to continue to have access to the needed COVID-19 testing.

223. Ultimately, CommuniCare decided to end its relationship with AMS Onsite, Provista, and Coastal Labs, but not before Provista had already billed respiratory panel tests for many residents across nursing homes managed by CommuniCare.

iii. Defendants Knew Their Business Model Needed the Unreasonable and Unnecessary Respiratory Panel Tests to Remain Profitable

224. Defendants, including Britton-Harr, knew their business model was problematic and that they needed the unreasonable and unnecessary respiratory panel tests to financially support themselves.

225. In an email conversation on April 9, 2020, a senior executive for Coastal Labs summarized the issue by saying, "The issue is that [the COVID-19 test] cost[s] more to do then [sic] we can get reimbursed so we would need to be assured of additional business either on the same swab, or later in the year."

226. Another email conversation in late July 2020 between Britton-Harr and the CEO of AMS Onsite included a discussion of the "doomsday scenario" if two of the largest nursing home chains pushed back against the frequent respiratory panel testing. In that email conversation, the CEO asked Britton-Harr, "What do we do if Pruitt and Vita (the two I'm most concerned about) don't want us to do quarterly respi panels starting in Aug/Sept. What is our reaction to that?" Britton-Harr responds by saying that "I don't see that happening but we need the AMS team to really get engaged with these homes from the environmental side. I think a visit

to the homes may be important or hold a webinar for Pruitt bi-weekly/monthly etc... Meaning we do more so they get to see the benefits of AMS."

227. Without the frequent respiratory panel testing, Defendants knew their scheme would fall apart because their cost to perform only COVID-19 testing (using a reference lab because none of the Defendants ever had the capability of performing COVID-19 tests themselves) was greater than the amount reimbursed by Medicare.

228. Also, in late July 2020 (after Provista was no longer a functioning lab), Britton-Harr attempted to arrange an agreement between GTI Labs and AMS Onsite where GTI Labs would pay AMS Onsite for referrals of respiratory panel tests. In a deposition, the CEO of AMS Onsite explained that "[I]f [the nursing homes] don't do quarterly testing, then we cannot be compensated by the [reference] laboratory because there's no quarterly respiratory panels being executed. So no test, no revenue."

229. Documents and reports prepared for potential investors of AMS Onsite, Coastal Labs, and Provista also projected large financial growth based upon a rapidly increasing volume of quarterly respiratory panel tests. In one email chain, Coastal Labs estimated 200,000 beneficiaries could be enrolled in the quarterly testing with a potential upside of $1 billion.

230. These investor documents did not include any reference to a clinical need for the wide-spread use of these tests such as an outbreak of a non-COVID-19 respiratory disease.

D. Provista Used Inaccurate CPT Codes to Fraudulently Obtain Reimbursement from Medicare for Respiratory Pathogen Tests Not Covered by Medicare

231. In the Medicare Program Integrity Manual, CMS lists examples of Medicare fraud including (1) "Incorrect reporting of diagnoses or procedures to maximize payments", and (2) "Unbundling or 'exploding' charges." *See* Medicare Program Integrity Manual, Pub. 100-8, Ch. 4, Section 4.2.1.

232. Defendants inappropriately unbundled CPT codes by disguising the fact that the respiratory tests were performed as part of a single respiratory panel.

233. Provista used advanced laboratory machines from Thermo-Fisher to perform the respiratory pathogen tests as a single panel. The machine analyzed the nasal swab sample to test

for many different respiratory pathogens and then reported all of the results together. The reference labs used by Defendants followed a similar process.

234. The appropriate CPT code for the respiratory panel tests performed by Provista (and the reference labs) is 87633, which is defined as "respiratory virus (e.g. adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiple reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12–25 targets."

235. CPT codes 87631 and 87632 are defined in the same way except CPT code 87631 includes 3–5 targets, and CPT code 87632 includes 6–11 targets.

236. The CPT manual informs labs to "Use 87631-87633 for nucleic acid assays [tests] which detect multiple respiratory viruses in a multiplex reaction *i.e.* single procedure with multiple results" and "For assays [tests] that include influenza virus with additional respiratory viruses, see 87631-87633."

237. The CPT manual also includes code 87798, which is defined as "amplified probe technique, each organism." The CPT manual explains that this code is to be used when the respiratory pathogen is not listed elsewhere in the manual: "For each specific organism nucleic acid detection from a primary source, see 87471–87660. For detection of specific infectious agents **not otherwise specified**, see 87797, 87798, or 87791 **1 time for each agent**." (emphasis added).

238. At Britton-Harr's direction, Provista submitted claims for the respiratory panel to Medicare using CPT code 87633.

239. However, as explained in paragraph 81, respiratory panels targeting six or more pathogens are not covered because they "are effectively a 'one size fits all' diagnostic approach, and do not meet Medicare's 'reasonable and necessary' criteria." LCD (L37315), *MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels*

240. The MAC further explains in a Local Coverage Article that "tests that include more than 5 viral pathogens are not covered" and the CPT code 87633 is "not covered." Local

Coverage Article (A57340), *Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels*.

241. Britton-Harr also directed Provista to submit additional CPT codes along with CPT code 87633 for the same respiratory panel tests—even though CPT code 87633 already covered all of the tests on the respiratory panel— to increase the amount of reimbursement received from Medicare.

242. Provista accomplished this impermissible unbundling by using CPT codes 87798, 87502, 87532, 87541, 87640, 87581, 87496, 87486, and 87498 at the same time as CPT code 87633.

243. For example, Provista (at the direction of Defendant Britton-Harr) also submitted claims to Medicare for "7 units of Bordetella bronchiseptica" on each respiratory panel using CPT code 87798 and received an extra $245.63 for each of these thousands of claims.

244. Provista inappropriately used code 87798 to obtain funds to which it was not entitled because (1) the test was already covered by CPT code 87633, and (2) even if it was not covered, Provista submitted 7 units for this code even though the definition of the code allowed it to be used only one time per pathogen.

245. After submitting thousands of claims using CPT code 87633, Defendants discovered that Medicare denied payment for this CPT code on nearly all of the claims and was taking steps to recoup any payments that Provista received from this code.

246. The Coastal Labs Vice President of Patient Administration (who directed the activities of the interns who were submitting the claims on behalf of Provista) said in an email that "We received an overpayment from Medicare for procedure code 87633 on several of our claims. Medicare is now withholding from what would have been paid claims to Coastal until the balance of overpaid claims is paid back in full."

247. Undeterred by the claim denials and overpayment recoupment, Defendants simply changed their billing pattern to obtain funds using different CPT codes. The Vice President of Patient Administration said in an email that "We have since adjusted our procedure codes and

will recoup all the money we were billing for code 87633 with the new codes from Medicare within 30 days of resubmitting [the claims]."

248. The Vice President of Patient Administration further explained in a different email that "We also learned that code 87633 was no longer accepted by Medicare, and that to make up for it we could add six more units to code 87798 (the max is 13) and two new codes 87502 for 1 unit and 87498 for 1 unit."

249. CPT code 87502 is defined as "influenza virus, for multiple-types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types." CPT Code 87498 is defined as "enterovirus, amplified probe technique, includes reverse transcription when performed."

250. In other words, Defendants simply had Provista further unbundle the respiratory panel tests, even though the tests were performed on a single panel, to make it appear to Medicare that it was performing these tests separately.

251. Defendants also deceived Medicare by adding even more units to CPT code 87798 even though Provista did not separately perform 13 separate tests for pathogens not specified elsewhere in the CPT manual.

252. In total, Provista submitted 22,871 claims using CPT code 87798.

253. Defendants received funds from Medicare for which they were not entitled as a result of this fraudulent use of CPT codes.

E. Provista Lied About Its Use of Reference Labs on Medicare Claim Forms to Evade Detection of Its Violation of the Laws Limiting the Use of Reference Labs

254. Defendants Britton-Harr, AMS Onsite, Coastal Labs, Britton-Harr Enterprises, Coastal Management Group, and Provista knew about Medicare's limit on the use of reference labs to no more than 30% of a lab's tests. Britton-Harr admitted that he was aware of the 30% limit on the use of reference labs.

255. Defendants did not own or operate a lab with the required Emergency Use Authorization to perform COVID-19 tests.

256. All of Defendants' COVID-19 tests submitted by Provista to Medicare for reimbursement were actually referred to reference labs and not performed by Defendants' themselves.

257. Despite Provista never performing its own COVID-19 tests, every claim submitted by Provista to Medicare for COVID-19 tests listed Provista as the lab performing the test, listed Provista's CLIA number, and did not include the CPT modifier code to indicate that the test was performed by a different lab.

258. Britton-Harr admitted that Provista could no longer perform any respiratory panel testing itself after Provista sent all of its lab equipment to Dr. Jolly on or about July 2020.

259. Even after Provista no longer possessed lab equipment and abandoned its building in July 2020, Provista still submitted claims to Medicare attesting that it was performing the respiratory panel tests, when in fact, the tests were being performed by a reference lab. For these claims, Provista listed itself as the performing lab, listed Provista's CLIA number, and did not include the CPT modifier code indicating that the test was performed by a reference lab.

260. Despite submitting 24,224 claims to Medicare for 398,329 tests, Provista did not disclose the use of a reference lab on a single claim.

261. Provista submitted claims for 21,209 COVID-19 tests (during the entire 2020 calendar year) and 148,808 respiratory panel tests (from July 2020 through October 2020, after Provista no longer was a functioning lab) that could not have been performed by Provista itself out of a total of 398,329 tests submitted on claims by Provista to Medicare in 2020. This results in at least 42% of the tests billed by Provista were for tests that were performed by a reference lab (if they were performed at all). The actual percentage is much higher because Provista also referred most of the respiratory panel tests prior to July 2020 to reference labs.

F. Defendants Conspired to Violate the FCA

262. Defendants worked together to advance the scheme to violate the FCA. Each corporate entity and individual communicated and worked together to execute the scheme.

263. Coastal Management Group executed a "Marketing Services Agreement" with Coastal Labs in March 2020 to provide "management and related services that are necessary for

the proper marketing operation and management of [Coastal Labs'] antibiotic stewardship programs . . . within long-term care facilities that are subject to this Agreement." Britton-Harr signed this agreement on behalf of both companies.

264. AMS Onsite also executed a "Marketing Services Agreement" with Coastal Labs in March 2020 to provide "management and related services that are necessary for the proper marketing operation and management of [Coastal Labs'] antibiotic stewardship programs . . . within long-term care facilities that are subject to this Agreement." Britton-Harr signed this agreement on behalf of Coastal Labs.

265. Britton-Harr Enterprises executed a "Clinical Laboratory Management Agreement" with Coastal Labs in November 2019 to provide "sole and exclusive development, management administrative and clinical laboratory services with respect to all functions relating to the facilitation of Clinical Laboratory Services." Britton-Harr signed this agreement on behalf of both companies.

266. AMS Onsite, Coastal Management Group, and Britton-Harr, all marketed the free Sterisis program and the availability of COVID-19 tests to nursing homes to induce the nursing homes to provide the demographic and insurance information for the nursing homes' beneficiaries to Defendants that Provista then used to submit claims for medically unnecessary and improperly ordered respiratory panel tests.

267. AMS Onsite, Coastal Management Group, and Britton-Harr, all worked together to convince the nursing homes to sign a contract with AMS Onsite that required the nursing home to provide the beneficiaries' demographic and insurance information which would be used to submit the false claims to Medicare.

268. AMS Onsite and Britton-Harr collected, or facilitated the collection of, the nasal swab test samples which were then shipped to either Provista or the reference lab.

269. AMS Onsite, Coastal Management Group, and Britton-Harr all knew, or should have known, that these respiratory panel tests were not covered by Medicare because they were medically unnecessary and not properly ordered by the beneficiaries' treating physician. AMS Onsite, Coastal Management Group, and Britton-Harr willfully failed to request or collect any

documentation from the nursing homes showing that the tests were medically necessary and properly ordered.

270. Coastal Labs and Britton-Harr executed the testing contract with the nursing homes that generated the respiratory panel tests. Britton-Harr, AMS Onsite, Coastal Labs, and Coastal Management Group worked together to encourage the nursing homes to sign the contract with Coastal Labs as well as the related contract with AMS Onsite.

271. Provista submitted the false claims to Medicare for the respiratory panel tests that were not medically necessary, not ordered by the beneficiaries' treating physician, and sometimes not even performed at all. Coastal Labs, as the sole owner of Provista, directed all actions performed by Provista including the submission of the false claims to Medicare. Britton-Harr, as the sole own of Coastal Labs, directed all actions performed by Coastal Labs and Provista including the submission of the false claims to Medicare by Provista.

272. Britton-Harr Enterprises participated in the scheme by paying Britton-Harr a salary for his work on behalf of AMS Onsite, Coastal Labs, and Coastal Management Group as part of the fraudulent scheme described above.

273. Britton-Harr, Britton-Harr Enterprises, AMS Onsite, Provista, Coastal Labs, and Coastal Management Group, all received the financial proceeds from the scheme when Britton-Harr transferred the fraudulent funds received from Medicare to their bank accounts via wire transfer or check.

274. The two heads of the operation—the CEO of AMS Onsite and Britton-Harr as CEO of Provista, Coastal Labs, Coastal Management Group, and Britton-Harr Enterprises—communicated frequently via email, test message, and phone regarding the fraud schemes. Britton-Harr and the CEO of AMS Onsite both communicated with the reference labs and the nursing homes to further the fraudulent scheme.

275. The CEO of AMS Onsite described AMS Onsite and Coastal Labs by saying that "We're two companies blended as one."

276. AMS Onsite directed the nursing homes to create broad standing orders that were used as the purported basis for running the respiratory panel tests. Defendants knew, or should have known, that these respiratory panel tests were not covered by Medicare.

277. Defendants knew that Provista submitted claims to Medicare for these fraudulent tests.

278. Britton-Harr used funds in the Britton-Harr Enterprises bank accounts to purchase various airplane related items as he started his new aircraft charter company, Aerovanti. During the time of this fraudulent scheme, Britton-Harr Enterprises only received funds from Medicare (via Provista) and did not receive funds from any other unrelated sources.

279. While Britton-Harr purportedly executed some contracts between the various Defendant corporate entities, those contracts contained only vague references to general services to be provided under the contract. The contracts contained no clear picture as to what specific tasks were actually performed to justify the transfers of money between the corporate entities.

280. Britton-Harr's father-in-law, James Deckman, was the controller for Coastal Labs. Deckman explained that he was responsible for paying expenses and payroll for Coastal Labs. Deckman further explained that all payroll went through Coastal Labs including for work being performed by AMS Onsite.

281. Deckman also said that he did not exercise any independent judgment in managing the finances of Coastal Labs, AMS Onsite, Provista, and Coastal Management Group and that he simply paid exactly what Britton-Harr told him to pay and made wire transfers as instructed by Britton-Harr. Deckman explained that he often did not know the purpose of the transfers or understand the cash-flow or financial position of Coastal Labs.

282. Deckman stated that he was not included on any items related to incoming payments from Medicare (via Provista) or other sources (such as investors) even though he was controller.

283. Debts from one Defendant were frequently paid from accounts from a different Defendant.

COUNT I
(Against All Defendants)
False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
Presenting False Claims for Payment

284. The United States re-alleges and incorporates herein by reference paragraphs 1 through 283 as if fully set forth herein.

285. During the period of February 1, 2020, to December 31, 2021, all defendants knowingly submitted and/or caused Provista to submit the following four categories of claims for payment to Medicare that were false or fraudulent, and not payable.

286. First, all defendants knowingly submitted and/or caused Provista to submit to Medicare claims for laboratory tests that were false or fraudulent, and not payable, because the tests were never performed. Examples of these claims are described in paragraphs 141 and 142.

287. Second, all defendants knowingly submitted and/or caused Provista to submit to Medicare claims for laboratory tests that were false or fraudulent, and not payable, because the tests were performed without a valid order from the beneficiary's treating physician. Examples of these claims are described in paragraphs 174 and 183.

288. Third, all defendants knowingly submitted and/or caused Provista to submit to Medicare claims for laboratory tests that were not reasonable and necessary for the diagnosis or treatment of an illness or injury. Examples of these claims are described in paragraph 206.

289. Fourth, all defendants knowingly submitted and/or caused Provista to submit to Medicare claims for laboratory tests that were not reimbursable by Medicare because the tests exceeded 30% statutory limit on the use of reference labs. These claims are described in paragraphs 254 through 261.

290. Fifth, all defendants knowingly submitted and/or caused Provista to submit to Medicare claims for laboratory tests using inaccurate CPT codes and units of service. These claims are described in paragraphs 231 through 253.

291. Had Medicare known these facts, the United States would not have paid these claims.

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

COUNT II
(Against All Defendants)
False Claims Act, 31 U.S.C. § 3729(a)(1)(B)
Making or Using False Records or Statements

293. The United States re-alleges and incorporates herein by reference paragraphs 1 through 292 as if fully set forth herein.

294. During the period of February 1, 2020, to December 31, 2021, all defendants knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false and fraudulent claims by the United States was a reasonable and foreseeable consequence of those defendants' statements and actions.

295. These false records and statements included false certifications on enrollment forms and false and misleading representations on claims forms that Provista's claims to Medicare for laboratory testing complied with applicable laws and regulations.

296. These false records and statements included (1) Provista's claims to Medicare for laboratory testing were reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, when in fact those claims were not reasonable and necessary; (2) Provista's claims to Medicare for laboratory testing were ordered by the physician listed on the claims when in fact they were not ordered by that physician; (3) unbundling of the respiratory panel tests by using separate CPT codes when the tests were actually performed together as panel and should have been billed using the CPT code for the applicable panel; (4) falsely claiming it performed additional separate tests for pathogens not otherwise specified in the CPT manual by submitting 7 or 13 units of CPT code 87798; (5) laboratory tests included on Provista's claims to Medicare were performed by Provista when in fact they were performed by a reference laboratory; and (6) laboratory tests included on

Provista's claims to Medicare were performed by Provista when in fact they were never performed at all.

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

298. Had Medicare known of these facts, the United States would not have paid these claims.

299. By virtue of these false or fraudulent claims, the United States was damaged by Defendants in the full amount of the false claims paid by Medicare, in an amount to be determined at trial, subject to trebling under the FCA. Furthermore, Defendants are liable for civil penalties of not less than $5,500 and up to $23,331 for each violation, with the number of violations to be determined at trial.

COUNT III
(Against All Defendants)
False Claims Act, 31 U.S.C. § 3729(a)(1)(C)
Conspiracy to Submit False Claims

300. The United States re-alleges and incorporates herein by reference paragraphs 1 through 299 as if fully set forth herein.

301. Britton-Harr, AMS Onsite, Coastal Labs, Coastal Management Group, Britton-Harr Enterprises, and Provista knowingly entered into an unlawful agreement among themselves and one or more others to present false or fraudulent claims to the United States and performed acts in furtherance of this conspiracy. Specifically, Defendants agreed to a plan by which, among other things, (1) AMS Onsite, Coastal Management Group, and Britton-Harr solicited requests for medically unnecessary and unreasonable respiratory panel tests, or otherwise obtained beneficiary demographic and insurance information to submit claims for respiratory panel tests that were not ordered; (2) Provista and Coastal Labs performed respiratory panel tests, referred the COVID-19 test and respiratory panel tests to a reference laboratory, or otherwise pretended to perform respiratory panel testing when no such testing was actually performed; (3) Provista submitted claims to Medicare for these COVID-19 and respiratory panel

tests; and (4) Provista received reimbursement from Medicare for these tests and then transferred the funds from Medicare to Coastal Labs, which in turn, transferred the funds to the remaining Defendants.

302. Defendant AMS Onsite performed acts in furtherance of this conspiracy by, among other things, marketing the scheme to nursing homes and entering into contracts with nursing homes to provide free infection control services to induce the nursing homes to arrange for respiratory panel tests to be performed by Defendants Provista and Coastal Labs.

303. Defendant Coastal Management Group performed acts in furtherance of this conspiracy by, among other things, providing marketing services to Defendant AMS Onsite to induce nursing homes to enter into contracts with Defendants AMS Onsite and Coastal Labs.

304. Defendant Provista performed acts in furtherance of this conspiracy by, among other things, submitting claims to Medicare for respiratory panel tests, which were solicited by the other defendants, that were performed by Provista, performed by a reference laboratory, or not performed at all.

305. Defendant Coastal Labs performed acts in furtherance of this conspiracy by, among other things, (1) entering into contracts with nursing homes to generate requests for respiratory panel tests, (2) purchasing, owing and operating Defendant Provista for purpose of submitting claims to Medicare for COVID-19 and respiratory panel tests; (3) transferring the Medicare funds received by Provista into Coastal Labs' bank accounts; and (4) further transferring those funds to the other defendants.

306. Defendant Britton-Harr Enterprises performed acts in furtherance of this conspiracy by, among other things, receiving the Medicare funds and paying Britton-Harr a purported salary for his work in carrying out this scheme.

307. Defendant Britton-Harr performed acts in furtherance of this conspiracy by, among other things, (1) directing the actions of Defendants AMS Onsite, Provista, Coastal Labs, Coastal Management Group, and Britton-Harr Enterprises in carrying out this scheme; (2) directly marketing the scheme to nursing homes; (3) managing the funds received by Medicare; and (4) transferring a portion of the funds received by Medicare for his personal use.

308. Had Medicare known of these facts, the United States would not have paid these claims.

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

COUNT IV
(Against All Defendants)
Unjust Enrichment

310. This is a claim by the United States for unjust enrichment under the common law arising from Defendants' unjust receipt of Medicare funds while engaged in the illegal conduct described herein. This Court has jurisdiction to adjudicate this claim pursuant to 28 U.S.C. § 1345.

311. The United States re-alleges and incorporates by reference paragraphs 1 through 309 as though fully set forth herein.

312. By virtue of the wrongful acts described herein, from February 2020 through the August 2021, Defendants obtained Medicare funds to which they were not entitled.

313. The false representations on the Medicare claims form regarding whether the lab actually performed the respiratory panel tests were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

314. The false representations on the Medicare claims form regarding which lab actually performed the respiratory panel and COVID-19 tests were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

315. The false representations on the Medicare claims form regarding which provider ordered the respiratory panel tests were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

316. The false representations on the Medicare claims form regarding whether the respiratory panel tests were reasonable and necessary were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

317. The false representations on the Medicare claims form that the respiratory tests were performed separately (unbundling of the respiratory panel tests by using separate CPT codes when the tests were actually performed together as panel and should have been billed using the CPT code for the applicable panel) were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

318. The false representations on the Medicare claims form that additional separate tests for pathogens not otherwise specified in the CPT manual were performed (by submitting 7 or 13 units of CPT code 87798) were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

319. Based on the above, Defendants have been unjustly enriched, and the circumstances dictate that, in equity and good conscience, the money should be returned to the United States.

COUNT V
(Against All Defendants)
Payment by Mistake of Fact

320. This is a common law claim by the United States for payment by Medicare to Defendants based on a mistake of fact. This Court has jurisdiction to adjudicate this claim pursuant to 28 U.S.C. § 1345.

321. The United States re-alleges and incorporates by reference paragraphs 1 through 319 as though fully set forth herein.

322. By virtue of the wrongful acts described herein, from February 2020 through August 2021, Defendants obtained and kept Medicare funds to which they were not entitled by submitted false claims to Medicare and by not reimbursing Medicare for such claims.

323. The false representations on the Medicare claims form regarding whether the lab actually performed the respiratory panel tests were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

324. The false representations on the Medicare claims form regarding which lab actually performed the respiratory panel and COVID-19 tests were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

325. The false representations on the Medicare claims form regarding which provider ordered the respiratory panel tests were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

326. The false representations on the Medicare claims form regarding whether the respiratory panel tests were reasonable and necessary were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

327. The false representations on the Medicare claims form that the respiratory tests were performed separately (unbundling of the respiratory panel tests by using separate CPT codes when the tests were actually performed together as panel and should have been billed using the CPT code for the applicable panel) were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

328. The false representations on the Medicare claims form that additional separate tests for pathogens not otherwise specified in the CPT manual were performed (by submitting 7 or 13 units of CPT code 87798) were material to Medicare's decision to provide reimbursement to Defendants. Had Medicare known the facts described above, the United States would not have provided the reimbursement.

329. Based on the foregoing, Medicare mistakenly overpaid the Defendants, and the circumstances dictate that, in equity and good conscience, the amount of these overpayments should be returned to the United States.

PRAYER FOR RELIEF

The United States requests that judgment be entered in its favor against the Defendants identified above as follows:

(a) On Counts I–III (False Claims Act), for treble the United States' damages, together with the maximum civil penalties allowed by law;

(b) On Count IV (Unjust Enrichment), for the amounts by which the Defendants were unjustly enriched plus interest, costs, and expenses, and for all such other relief as the Court deems equitable;

(c) On Count V (Payment by Mistake of Fact), for the amount by which Defendants were overpaid by Medicare plus interest, costs, and expenses, and for all such other relief as the Court deems equitable; and

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

JURY DEMAND

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

Dated: July 18, 2023

Respectfully submitted,

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