Lon R. Leavitt 1 HALUNEN LAW PLLC LODGED VFILED 2 COPY Arizona Bar No. 35825 RECEIVED 2155 West Pinnacle Peak Road, Suite 201 3 JUL 0 1 2020 Phoenix, Arizona 85027 Telephone: (602) 535-2203 4 CLERK U.S. DISTRICT COURT DISTRICTOR ARIZONA Fax: (612) 605-4099 5 leavitt@halunenlaw.com 6 Nathaniel F. Smith\* 7 HALUNEN LAW PLLC Minnesota Bar No. 397276 8 80 South 8th Street, Suite 1650 9 Minneapolis, Minnesota 55402 Telephone: (612) 605-4098 10 Fax: (612) 605-4099 11 smith@halunenlaw.com 12 Timothy J. Granitz\* 13 Mahany Law Wisconsin Bar No. 1088934 14 8112 West Bluemound Road, Suite 101 15 Wauwatosa, Wisconsin 53213 Telephone: (414) 258-2375 16 Fax: (414) 777-0776 17 tgranitz@mahanylaw.com SEALED 18 Attorneys for Plaintiff/Relator 19 UNITED STATES DISTRICT COURT 20 DISTRICT OF ARIZONA 21 United States of America ex rel. William Case No.: CV-20-1313-PHX-GMS 22 Denner, 23 **COMPLAINT FOR** Plaintiff-Relator, VIOLATIONS OF THE FALSE 24 **CLAIMS ACT** 25 V. JURY TRIAL DEMANDED 26 AZ-Tech Radiology & Open M.R.I., L.L.C., Rakesh Pahwa, and Deepak Narang. 27 FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 28 Defendants. 3730(b)(2)

Pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. §§ 3729 et seq. ("the FCA"), qui tam Plaintiff-Relator William Denner ("Relator"), through his attorneys, brings this case on behalf of the United States of America, acting through its various agencies and departments ("the Government"), and on his own behalf. Relator brings this case against AZ-Tech Radiology & Open M.R.I., L.L.C., Rakesh Pahwa, and Deepak Narang (collectively "AZ-Tech" or "Defendants") based on their knowing submission of materially false and fraudulent medical claims for reimbursement to various government health insurance programs, including, but not limited to, Medicaid, Medicare, and TRICARE in violation of the FCA. For his Complaint Relator alleges, based on personal knowledge, relevant documents, and related information and belief, as follows:

#### I. INTRODUCTION

- 1. Since at least 2014, Defendants fraudulently administered contrast dye/media to government health insurance beneficiaries in preparation for magnetic resonance imaging ("MRI") and computerized tomography ("CT") diagnostic studies when there were no physicians on site to provide the required direct supervision.
- 2. Defendants' fraudulent conduct not only caused financial losses to the government health care programs, but also compromised patient safety. Relator directly observed two patients suffer adverse reactions to contrast dye injections performed at Defendants' Maricopa facility—yet no physician was on site to help. In panic, non-physician staff on site ran door-to-door to try and find a doctor who could help. Critical minutes were wasted. In both events, fortunately, a doctor from another practice was able to help, but in one of the incidents, Relator had to call 911 for an emergency response. Additionally, while Relator was working at the Tempe facility, an adverse reaction occurred, and, with no physician on site, he summoned the on-site nurse practitioner. When the patient did not immediately respond, site manager A.R. called 911.
- 3. Even when patients did not suffer adverse consequences due to the lack of required physician supervision, at times their scans were sent to unknown reviewers in

another country. In direct contradiction of Medicare, Medicaid, and TRICARE requirements, and without regard to proper standards of patient care, Defendants then billed the government for services provided by radiologists located outside the United States—falsely representing they were properly done in the United States.

- 4. As a result of Defendants' fraudulent billing practices, government officials and contractors approved, paid, and continue to approve and pay claims under Medicare, Medicaid, and TRICARE that they were prohibited by law from approving or paying given the false and fraudulent nature of Defendants' representations and claims.
- 5. As a result of the conduct described in this Complaint, Defendants not only caused harm to patients, they also charged the Government for medical services that were not properly reimbursable.
- 6. This is an action to recover damages and civil penalties on behalf of the Government arising from materially false and/or fraudulent statements, records, and claims that Defendants and/or their agents and employees knowingly made and caused to be made in violation of the FCA.

#### II. PARTIES

- 7. Relator William Denner ("Relator") is an Arizona resident and is a former employee of AZ-Tech. He worked for AZ-Tech from approximately December 2012 through January 2019 at various facilities, including those located in Apache Junction, Tempe, Chandler, Gilbert, Phoenix/Osborn, Maricopa, and Ahwatukee. Relator held various jobs at AZ-Tech, including becoming the site manager of AZ-Tech's largest facility located in Gilbert and later the administrative technologist. In this role, Relator oversaw all of AZ-Tech's radiology technicians. Relator's credentials include at least five certifications and licenses in CT, MRI, and x-ray. Relator repeatedly encountered Defendants' rampant fraudulent practices and has direct, personal knowledge of the allegations in this Complaint.
- 8. Defendant AZ-Tech Radiology & Open M.R.I., L.L.C., is an Arizona LLC that does business under its trade name, AZ-Tech Radiology & Open MRI. It employs

- approximately 80 people and operates eight radiology service centers in Arizona, including locations in Maricopa, Tempe, Ahwatukee, Apache Junction, Osborn, Gilbert, Mesa-Women's Center/Corporate, and Casa Grande. AZ-Tech provides several different types of imaging procedures, including MRI, open MRI, CT scans, x-rays, ultrasounds, 4D ultrasounds, biopsy, mammography, positron emission tomography ("PET") scans, and others. These facilities operate as independent diagnostic testing facilities ("IDTFs"), with the possible exception of the Chandler facility.
- 9. Defendant Rakesh Pahwa is an Arizona resident and a former owner and member-manager of AZ-Tech. In late 2018, Pahwa sold his interest in AZ-Tech to Whiterabbit.ai, Inc., which is located at 530 East Lakeside Drive, Suite 290, Sunnyvale, California 94085.
- 10. Defendant Deepak Narang is an Arizona resident and a former owner and member-manager of AZ-Tech. Narang and Pahwa were business partners before they sold AZ-Tech to Whiterabbit.ai., Inc.

#### III. JURISDICTION AND VENUE

- 11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.
- 12. Relator is aware of no subject matter or other jurisdictional bars set forth in the FCA that would be applicable to this action.
- 13. There has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4) (1986) or as that section was amended in 2010. Moreover, even if such a disclosure had occurred, Relator would qualify as an original source of the information in this Complaint under either version of the statute. Before filing this action, Relator voluntarily disclosed to the Government the information on which the allegations or transactions in this Complaint are based. Additionally, Relator has direct and independent knowledge about the misconduct alleged herein and that knowledge is independent of and materially adds

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to any publicly disclosed allegations or transactions relevant to his claims.

- 14. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process, because Defendants have minimum contacts with the United States, and because Defendants have offices in and transact substantial business in the District of Arizona.
- 15. Venue is proper in the District of Arizona pursuant to 28 U.S.C. § 1391(b), 28 U.S.C. § 1395(a), and 31 U.S.C. § 3732(a) because one or more of the Defendants can be found in, transact business in, or have transacted business in this district. At all times relevant to this Complaint, one or more of the Defendants regularly conducted, and continue to conduct, substantial business within this district, maintain employees and offices in this district, and/or reside in this district.
  - 16. Relator has standing to bring this action pursuant to 31 U.S.C. § 3730(b)(1).

#### IV. APPLICABLE LAW

- A. The False Claims Act
- 17. The FCA is "the Government's primary litigative tool" for combating schemes to fleece the government. False Clams Amendment Act of 1986, S. Rep. No. 99-345, at 2 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274. It is broadly drafted to reach beyond common law fraud.
- 18. The FCA prohibits any person from knowingly making, or causing to be made, a false or fraudulent claim for payment to the United States. 31 U.S.C. § 3729(a)(1)(A).
- 19. The FCA also prohibits knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B).
- 20. In addition, the FCA prohibits knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States. 31 U.S.C. § 3729(a)(1)(G).

- Under the FCA, the term "claim" means any request or demand for money, whether under a contract or otherwise, presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2)(A)(i). A "claim" is also a request or demand for money made to a contractor or other recipient if (a) the money is to be spent or used on the Government's behalf or to advance a Government program or interest and (b) if the Government provides, has provided, or will reimburse such contractor or other recipient for any portion of the money requested or demanded. 31 U.S.C. § 3729(b)(2)(A)(ii).
- 22. The FCA defines the term "obligation" to mean an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment. 31 U.S.C. § 3729(b)(3).
- 23. A false or fraudulent claim under the FCA may take many forms, "the most common of which is a claim for payment for goods and services not provided or provided in violation of contract terms, specification, statute or regulation." S. Rep. No. 99-345, at 9 (1986).
- 24. The FCA defines the term "material" objectively, not subjectively, 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).
- 25. The FCA defines knowingly to include actual knowledge, reckless disregard, and deliberate ignorance. 31 U.S.C. § 3729(b)(1)(A). No specific intent to defraud need be shown. 31 U.S.C. § 3729(b)(1)(B).

#### B. Medicare

- 26. Title XVIII of the Social Security Act ("Medicare") is a federally subsidized health insurance system for persons who are eligible based on age (over 65), disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A.
- 27. The United States Department of Health and Human Services ("HHS") is responsible for the administration and supervision of the Medicare program. The Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care

Financing Agency ("HCFA"), is an agency of HHS and is directly responsible for the administration of the Medicare program.

- 28. CMS contracts with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs") to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. Fiscal intermediaries, typically insurance companies, are responsible for processing and paying claims for reimbursement.
- 29. Like Medicaid, Medicare's general coverage parameters only include items that are "provided economically and only when, and to the extent, medically necessary ..." 42 U.S.C. § 1320c-5(a)(1). It also excludes goods and services that are not medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k).
- 30. To seek reimbursement from Medicare and the other government health care programs described below, a health care provider must obtain a unique billing identification number known as an NPI number. The provider also must submit an enrollment application.
- 31. Medicare is divided into four parts with separate coverage authorities: Medicare Part A (hospital insurance); Medicare Part B (medical insurance); Medicare Part C (Medicare Advantage); and Medicare Part D (prescription drug coverage). In this action, only Medicare Part B is relevant.

#### a. Medicare Part B

- 32. Medicare Part B is a voluntary subscription program of supplementary medical insurance covering outpatient care, including physician services and ancillary services. 42 U.S.C. § 1395k.
- 33. Defendants billed Medicare, or caused Medicare to be billed, under Part B, which covers certain medical services furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k(a)(2)(B).

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- 34. Typically, physicians are compensated for the services they provide Medicare patients on a fee-for-service basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, physicians must deliver a compensable service, certify that the service was medically necessary for the health of the patient, certify that the service was personally furnished by the physician (or under his or her immediate supervision), and determine the appropriate diagnosis and procedure code to describe the problem and service for billing.
- 35. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).
- 36. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent known as the 837P form. Among the information the provider or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the NPI of the "rendering provider" and the "referring provider or other source."
- 37. Medicare only pays for Part B services that are actually rendered and are reasonable and medically necessary. 42 U.S.C. § 1395y(a). Part B providers also must certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).
- 38. Medicare requires proper and complete documentation of the services rendered to beneficiaries. 42 U.S.C. § 1395l(e).
- 39. At all relevant times, Noridian Healthcare Solutions, LLC ("Noridian") was the MAC that administered Medicare Part B claims in Arizona. Because Defendants performed all of their services at facilities in Arizona, they submitted all claims to this Medicare contractor.

## b. Ineligible Part B Claims Are Actionable Under the FCA

- 40. A provider must enroll in the Medicare program to receive Medicare reimbursement for covered services provided to eligible beneficiaries. To participate in the Medicare program, a provider must file a provider agreement with the Secretary of HHS ("the Secretary"). 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the program. *Id*.
- 41. Among other things, participating providers are prohibited from making false statements or representations of material facts concerning payment requests. 42 U.S.C. §§ 1320a-7b(a)(1) and (2); 42 U.S.C. § 1320a-7a(1); 42 C.F.R. § 1001.101(a). Providers are also required to know the information contained in HHS, CMS, and fiscal intermediary notices, including manual issuances, bulletins, and other written guides and directives. 42 C.F.R. § 411.406.
- 42. The enrollment application includes a certification statement requiring the enrolling provider to certify the provider's adherence to a list of requirements, including, among others, the following:
  - a. Familiarity with and agreement to abide by applicable Medicare or other federal health care program laws, regulations, and program instructions, which are available through the Medicare contractor.
  - b. Understanding that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law), and on a provider/supplier complying with any applicable conditions of participation in any federal health care program.
  - c. Agreement not to knowingly present or cause to be presented a false or fraudulent claim for payment by the Medicare or other federal health care programs and not to submit claims with deliberate

 ignorance or reckless disregard of their truth or falsity.

- 43. At all times material to this action, Defendants had signed a Medicare enrollment application and/or had entered a Medicare provider agreement as described above.
- 44. By signing an enrollment application (Form CMS 855-B) Defendants certified that their signature legally and financially bound AZ-Tech to the laws, regulations, and program instructions of the Medicare program.
- 45. By signing the Form 855-B, Defendants also expressly agreed to abide by applicable Medicare laws, regulations, and program instructions, which they acknowledged are available through the Medicare contractor. Defendants also certified that they 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 and on their own compliance with all applicable conditions of participation in Medicare.
- 46. Following enrollment, physicians and other health care providers who provide services to Medicare beneficiaries submit to the appropriate Medicare fiscal intermediary a claim for reimbursement through a CMS 1500. Regulations adopted by CMS require that a provider's services and procedures must be entered onto a CMS 1500 by using CPT codes published by the American Medical Association. 45 C.F.R. § 162.1002. Providers submit these claims for reimbursement by mail or electronically pursuant to an "Electronic Data Interchange (EDI) Enrollment Form" ("EDI Form") (and other documents) signed by the provider.
- 47. At all times material to this action, Defendants submitted, or caused to be submitted, Forms CMS 1500 by one or both of these methods.
- 48. Pursuant to the EDI Form, the provider, among other things, (a) certifies that it will submit claims that are accurate, complete, and truthful; (b) agrees that all claims are claims for payment under the Medicare program that will be paid from federal funds; and (c) agrees that falsifying or misrepresenting (or causing the falsification or

 misrepresentation of) any record or information relating to such claims violates applicable federal law. In addition, the electronic claims themselves contain a certification of accuracy and veracity. At all relevant times, Defendants had entered and were obligated by such an agreement.

- 49. Medicare requires provider certifications in order to pay claims for services.
- 50. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful."
- 51. A participating provider must properly document in the patient's medical record the service or procedure performed. 42 C.F.R. § 431.107(b)(1).
- 52. Health care providers 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. 42 U.S.C. §§ 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).
- 53. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides.
- 54. 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 providers, the program relies on providers to comply with Medicare requirements and to submit truthful and accurate certifications and claims.
- 55. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.
- 56. Using electronic and other means, Defendants routinely and knowingly submitted false claims, or caused false claims to be submitted, to the Government because Defendants knowingly billed Medicare or knowingly caused Medicare to be billed for beneficiaries who did not meet Medicare benefit eligibility requirements.

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#### C. Medicaid/AHCCCS

- 57. In 1965, Congress established the Grants to States for Medical Assistance Programs under Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-2 ("Medicaid"). Medicaid provides medical and health-related assistance for society's neediest and most vulnerable individuals. Those eligible for Medicaid include pregnant women, children, and persons who are blind or suffer from other disabilities and who cannot afford the cost of health care. 42 U.S.C. § 1396d.
- 58. Medicaid is a joint federal-state health care program. 42 U.S.C. § 1396b. If a state elects to participate in the program, the costs of Medicaid are shared between the state and the federal government. 42 U.S.C. § 1396a(a)(2). In order to receive federal funding, a participating state must comply with requirements imposed by the Act and regulations promulgated thereunder.
- 59. Medicaid is administered at the federal level by the Secretary of HHS, through CMS, which promulgates regulations, including minimum coverage parameters.
- 60. Each state has its own Medicaid agency, which is responsible for developing CMS-approved programs, setting its own guidelines regarding eligibility and services, and administering claims.
- 61. The federal portion of Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). As a result, the federal matching funds range from 50-75%.
- 62. In this FCA action, the practical effect of Medicaid's dual funding mechanism is that the FCA will recover the FMAP of each affected claim submitted in any state or territory.
- 63. To qualify for these federal matching funds, each state Medicaid program must submit a plan to the Secretary of HHS for approval. *See* 42 C.F.R. § 430 Subpart B, and § 488.303.

64. Arizona participates in the Medicaid program, known as the Arizona Health Care Cost Containment System ("AHCCCS"). The federal government, through CMS, provides over 60% of the funds used by AHCCCS to provide medical assistance to persons enrolled in the Medicaid program, as shown in the following chart:

I.Y	FMAP	Multiplier
2020	70.02%	2.34x
2019	69.81%	2.31x
2018	69.89%	2.32x
2017	69.24%	2.25x
2016	68.92%	2.22x
2015	68.46%	2.17x
2014	67.23%	2.05x
2013	65.68%	1.91x
2012	67.30%	2.06x

- 65. In return for receipt of federal subsidies, Arizona is required to administer its Medicaid program in conformity with a state plan that satisfies the requirements of the Act and accompanying regulations. 42 U.S.C. §§ 1396–1396w.
- 66. AHCCCS contracts with private managed care contractors ("MCCs") through contracts that must follow the requirements of 42 U.S.C. § 1395mm, along with any related federal rules and regulations.
- 67. The MCCs contract directly with providers to provide health care services to eligible AHCCCS beneficiaries. AHCCCS distributes the combined state and federal Medicaid funding to the MCCs, which then pay participating providers for treatment of AHCCCS beneficiaries.
- 68. The administration and payment of claims submitted by providers is handled by each state Medicaid program, which then submits claims information to the federal government in order to obtain the requisite FMAP. As a result, each claim for

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payment submitted to Medicaid is both a "claim" for payment submitted directly to the relevant state, and a "claim" for payment submitted indirectly to the United States.

#### D. TRICARE

- 69. TRICARE is a medical benefits program established by federal law. 10 U.S.C. §§ 1071-1110b. TRICARE covers eligible beneficiaries, which include active duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. The federal government reimburses a portion of the cost of health care services and prescription medications provided to TRICARE beneficiaries. TRICARE is administered by the Defense Health Agency.
- 70. TRICARE uses contractors to administer the TRICARE program, including the processing and payment of claims for reimbursement of physician and mid-level providers' services from TRICARE.
- 71. TRICARE covers only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (in duration or intensity) the level of care which is needed to provide safe, adequate, and appropriate diagnosis and treatments. See 32 C.F.R. § 199.4(a)(1)(i) and applicable definitions at 32 C.F.R. § 199.2. TRICARE regulations defining "medical necessity" also require that services and supplies be "furnished economically." 32 C.F.R. § 199.4(a)(1)(i).
- 72. TRICARE may not pay for services that are not authorized by law or that are fraudulently billed. 32 C.F.R. § 199.7(i)(3).
- 73. TRICARE regulations also provide that TRICARE may deny payment in "abuse situations." 32 C.F.R. § 199.9(b). To avoid abuse situations, providers are obligated to provide services and supplies under TRICARE that are: "[f]urnished at the

appropriate level and only when and to the extent medically necessary . . .; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be required under this part . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." *Id*.

- 74. TRICARE has specified examples of fraud or abuse against the TRICARE program as including "[m]isrepresentations of . . . description of services rendered." 32 C.F.R. § 199.9(c).
- 75. The TRICARE regulations, in turn, define "appropriate" medical care as that which is, among other things, "[f]urnished economically"—i.e., "in the least expensive level of care or medical environment adequate to provide the required medical care." 32 C.F.R. § 199.2.
- 76. TRICARE requires maintenance of appropriate medical records to substantiate that billed services were actually rendered. 32 C.F.R. § 199.7(b)(3). Failure to document the care billed will result in denial of payment by TRICARE. *Id.*; TRICARE Policy Manual 6010.60-M, Ch. 1, § 5.1, ¶ 3.2.
- 77. TRICARE requires a prescription from the beneficiary's physician for laboratory tests.
- 78. Some TRICARE options require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. § 199.4(f). A provider of services cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. § 199.4(f)(9).
- 79. As with Medicare, providers submit claims to TRICARE using the CMS 1500 or an electronic equivalent. Providers therefore make the same certifications in submitting claims to TRICARE as they do when submitting claims to Medicare.
- 80. Because it is not feasible for the TRICARE program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with TRICARE requirements and to submit truthful and accurate certifications and claims.

#### E. Regulations Governing Physician Supervision and IDTFs

- 81. Medicare coverage of diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests is authorized by 42 U.S.C. § 1395x(s)(3) and is paid under Medicare Part B as a "Medical and Other Health Service."
- 82. Diagnostic tests must be performed under the supervision of a physician and a failure to provide such supervision makes the corresponding medical claim submission non-reimbursable. The regulations provide that

all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of physician supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraphs (b)(3)(ii) or (b)(3)(iii) of this section, respectively. (However, diagnostic tests performed by a physician assistant (PA) that the PA is legally authorized to perform under State law require only a general level of physician supervision.) When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test.

- 42 C.F.R. § 410.32(b)(2) (emphasis added).
  - 83. The levels of physician supervision are as follows:
    - (i) General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
    - (ii) *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.
    - (iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

42 C.F.R. § 410.32(b)(3)(i)-(iii).

- 84. Medicare, Medicaid, and TRICARE reimburse diagnostic services at amounts that assume a licensed physician is in attendance in a "direct supervision" capacity at the imaging session either by directly supervising the imaging services or by being "immediately available to furnish assistance and direction through the performance of the procedure." Procedures requiring direct supervision include, but are not limited to, the administration of intravenous contrast for CT and MRI procedures.
- 85. Medicare reimburses diagnostic claims using the National Physician Fee Schedule Relative Value File ("PFS"). The PFS is categorized by individual CPT code and indicates, among other requirements, what level of supervision, if any, is required for the CPT code to be reimbursable. The CPT codes for diagnostic imaging with contrast dye require direct supervision, which is evidenced by the "02" indicator appearing in the "Physician Supervision of Diagnostic Procedures" column. Indicator "02" means that a procedure must be performed under the direct supervision of a physician. Additionally, Noridian, the MAC assigned to Arizona, also publishes a chart demonstrating that direct supervision is required for contrast dye testing.<sup>1</sup>
- 86. Certain diagnostic tests involve some inherent risk of harm to the patient. For example, MRI and CT scans involve injection of contrast media to which the patient may have an adverse or allergic reaction. For these contrast MRI and CT procedures, Medicare requires direct supervision of a physician in order to be payable. When diagnostic tests do not include such contrast dye/media, general supervision is typically allowable. As CMS explained:

the administration of the contrast material is included in the procedure and requires personal physician supervision for the entire radiological procedure. . . . The law does not speak to the "supervision of the administration of contrast media", but rather, is a distinction drawn as to the degree of difficulty in the performance and the interpretation of

https://med.noridianmedicare.com/web/jfb/specialties/idtf/independent-diagnostic-testing-facility-idtf-physician-and-technician-qualification-requirements (last visited July 1, 2020).

the procedure. This degree of difficulty of the test is assigned to the levels of supervision and the warranted payment of the professional component of the CPT code. The supervision levels for all diagnostic tests (general, direct, personal supervision) are set nationally by CMS. Each code has one supervision level. We do not have the authority to split a procedure codes into multiple or "dual supervision" levels. The administration of the contrast cannot be separated out from the supervision of the procedure/CPT code. CT with contrast is one procedure code. A radiologist is required to supervise MRI and CT procedures in an IDTF.<sup>2</sup>

- 87. An IDTF is a fixed location, a mobile entity, or an individual non-physician practitioner that provides diagnostic tests independent of a physician's office or a hospital. 42 C.F.R. § 410.33(a)(1). IDTFs can bill Medicare for the diagnostic tests so long as they enroll in Medicare through an application, CMS-855B. As part of the application, the applicant-provider agrees to comply with all Medicare laws, regulations, and program instructions, including that it will identify all supervising physicians and will alert CMS if there is a change in supervising physicians.
- 88. To be payable, Medicare requires all IDTF medical claims to have a physician supervision component and all IDTFs to have a supervising physician. The IDTF's supervising physician is limited to providing general supervision to no more than three IDTF sites. 42 C.F.R. § 410.33(d). The supervision requirements defined in 42 C.F.R. § 410.32 apply to IDTFs.
- 89. When "direct supervision" is required for a diagnostic test, the regulations require that "[i]n the case of a procedure requiring the direct or personal supervision of a physician as set forth in § 410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision." 42 C.F.R. § 410.33(b)(2). At all times, the IDTF "must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished." *Id.* In short, CMS bargains and pays for not only performance of the procedure itself by a

https://downloads.cms.gov/medicare-coverage-database/lcd\_attachments/31626\_1/131626\_phys078\_finalcomments.pdf (last visited July 1, 2020).

competent technician, but also for a heightened level of safety for the patient in the form of a licensed physician immediately available "in the office suite."

- 90. According to the CMS physician fee schedule, non-physicians used by the IDTF must be licensed or certified by the appropriate state health or education department:
  - (c) Nonphysician personnel. Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

42 C.F.R. § 410.33(c).

- 91. The technicians performing diagnostic tests must also be disclosed to CMS. Noridian also requires that IDTFs have proper technical staff on duty with the appropriate credentials to perform tests.<sup>3</sup>
- 92. In order to submit reimbursement claims to Medicare, IDTFs must meet 17 specific certification standards as described in 42 C.F.R. § 410.33(g). The first standard is that the IDTF must certify that it "operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients." 42 C.F.R. § 410.33(g)(1). This includes the requirement, set forth in 42 C.F.R. § 410.33(b)(2), that if a procedure requires the direct or personal supervision of a physician as set forth in 42 C.F.R. § 410.32(b)(3), the carrier shall ensure that the IDTF's supervisory physician furnishes this level of supervision.
- 93. In addition to providing supervision, providers, such as AZ-Tech, are required to disclose to CMS a "list all physicians for whose diagnostic test interpretations it will bill." Since AZ-Tech billed for interpretations, it was required to disclose these

https://med.noridianmedicare.com/web/jfb/specialties/idtf/independent-diagnostic-testing-facility-idtf-physician-and-technician-qualification-requirements (last visited July 1, 2020).

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physicians.<sup>4</sup> If physician supervision or ownership changed, AZ-Tech was required to alert CMS. Upon information and belief, including the State of Arizona's imposition of civil penalties against AZ-Tech for failing to disclose the change of ownership, Defendants did not inform CMS and Noridian of the ownership change within the required 30-day time period. 42 C.F.R. § 410.33(g)(2).

#### F. Medicare Coverage for Services Provided Outside the United States

- 94. With narrow exceptions not applicable here, "Medicare does not pay for services furnished outside the United States." 42 C.F.R. § 411.9(a). This binding regulation, which providers agree to follow when they become Medicare providers, is further explained in other Medicare publications, including the Medicare Claims Processing Manual (Chapter 13, Section 150).<sup>5</sup>
- 95. Thus, as outlined in the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 16, Section 60) and other Medicare coverage bulletins, "[p]ayment may not be made for a medical service (or a portion of it) that was subcontracted to another provider or supplier located outside the United States."
- 96. "For example, if a radiologist who practices in India analyzes imaging tests that were performed on a beneficiary in the United States, Medicare would not pay the radiologist or the U.S. facility that performed the imaging test for any of the services that were performed by the radiologist in India."

Medicare Program Integrity Manual, Chapter 15, Section 15.5.19.3, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R898PI.pdf (last visited July 1, 2020) (effective prior to June 16, 2020); Medicare Program Integrity Manual, Chapter 10, Section 10.2.2, available at https://www.cms.gov/files/document/r10138PI.pdf (last visited July 1, 2020) (effective June 16, 2020).

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c13.pdf (last visited July 1, 2020).

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf (last visited July 1, 2020); https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5427.pdf (last visited July 1, 2020).

<sup>&</sup>lt;sup>7</sup> *Id*.

#### V. DEFENDANTS' FRAUDULENT CONDUCT

- A. AZ-Tech Did Not Provide Physician Supervision at its Maricopa Facility When Administering Contrast Dye
- 97. Beginning on June 11, 2018, Relator worked at AZ-Tech's Maricopa facility. He normally worked at the facility Tuesday, Wednesday, and Thursday each week. The facility is located in a strip mall that also included other medical practices unrelated to AZ-Tech. Relator remained at the facility until his termination on January 29, 2019.
- 98. While Relator worked at the Maricopa facility, AZ-Tech routinely and frequently failed to have a physician on site, and it never had a radiologist on site. In fact, Relator does not recall a single occasion when either a physician or a radiologist was present at this location.
- 99. The enumeration date for the Maricopa site's NPI was March 9, 2009. From the time Relator began as a student in November 2011 to his termination more than seven years later on January 29, 2019, no radiologist was ever at the Maricopa location. Upon information and belief, there still is no radiologist present to this day.
- 100. Even though there was no physician physically located at the Maricopa facility, AZ-Tech required that its employees inject or administer contrast dye to beneficiaries of federal health care programs.
- 101. In lieu of staffing a physician for supervision, AZ-Tech told its Maricopa staff that a pediatric nurse practitioner, S.A., would provide supervision. AZ-Tech commonly employed non-physician personnel for apparent supervision. For instance, a nurse practitioner was stationed at the Tempe facility in lieu of a physician. Relator believes that many of the non-physician providers, including S.A., were neither employees nor independent contractors of AZ-Tech.
- 102. Even assuming S.A. was employed by AZ-Tech, he is not a physician. Because of this, any supervision that he may have provided does not meet the direct supervision requirements, or any supervision requirements, required by Medicare and other federal health care programs.

- 103. The direct supervision requirements exist so that patients may be safely treated in case of adverse reactions to contrast dye. Admitting the importance of physician supervision, and understanding S.A. may be unavailable or unwilling to assist in an emergency, Narang and Pahwa told their Maricopa staff that if S.A. was unavailable, the staff should call 911.
- 104. During Relator's tenure at the Maricopa facility, at least two patients adversely reacted to the administration of contrast dye when no physician was physically present in the facility. That is, no physician was immediately available to respond.
- 105. In the first instance, AZ-Tech personnel administered contrast dye in preparation for a CT scan. The patient adversely reacted to the contrast dye, and no physician was in the facility to respond. The Maricopa site supervisor, K.W., left the facility and went next door to S.A.'s office to get his assistance. K.W. was told S.A. was unavailable to respond. K.W. then asked other medical personnel offices, which also were located in the same strip mall as AZ-Tech, for immediate help in responding. Eventually, after nearly 10 minutes, physician H.F. responded.
- 106. In the second instance, AZ-Tech personnel administered contrast dye in preparation for a CT scan in November 1, 2018. The patient adversely reacted to the contrast dye, and no physician was in the facility to respond. AZ-Tech employee J.H. left the facility and went next door to S.A.'s office to get his assistance. As in the previous incident, J.H. was told S.A. was unavailable to respond. J.H. then sought physician H.F.'s assistance, who agreed to respond to the patient. When the patient did not recover or improve, Relator called 911 for an emergency response. Relator spoke to the manager of the location about how dangerous this situation was for everyone and informed his regional manager of his concerns during a phone conversation. Despite Relator's reports and stated concerns, the circumstances did not change.
- 107. The direct supervision requirements exist to prevent scenarios like these in which patient safety was placed in severe jeopardy. Yet, despite not providing direct supervision, AZ-Tech continued to administer contrast dye and submit reimbursement

claims to federal health care programs for these procedures using various CPT codes, including, but not limited to, the following:

CPT Code	CPT Modifier	Procedure Description	2014 Medicare Reimbursement
70460	26	CT head/brain with dye	\$57.05
70460	TC	CT head/brain with dye	\$112.29
70460		CT head/brain with dye	\$169.35
70470	26	CT head/brain without and with dye	\$64.52
70470	TC	CT head/brain without and with dye	\$138.87
70470		CT head/brain without and with dye	\$203.38
70481	26	CT orbit/ear/fossa with dye	\$70.22
70481	TC	CT orbit/ear/fossa with dye	\$222.48
70481		CT orbit/ear/fossa with dye	\$292.69
70482	26	CT orbit/ear/fossa without and with dye	\$73.43
70482	TC	CT orbit/ear/fossa without and with dye	\$250.11
70482		CT orbit/ear/fossa without and with dye	\$323.54
70487	26	CT maxillofacial with dye	\$65.95
70487	TC	CT maxillofacial with dye	\$184.57
70487		CT maxillofacial with dye	\$250.52
70488	26	CT maxillofacial without and with dye	\$72.00
70488	TC	CT maxillofacial without and with dye	\$227.79
70488		CT maxillofacial without and with dye	\$299.79
70491	26	CT soft tissue neck with dye	\$69.88
70491	TC	CT soft tissue neck with dye	\$175.71
70491		CT soft tissue neck with dye	\$245.59
70492	26	CT soft tissue neck without and with dye	\$73.43
70492	TC	CT soft tissue neck without and with dye	\$218.23
70492		CT soft tissue neck without and with dye	\$291.66
70496	26	CT angiography head	\$88.75
70496	TC	CT angiography head	\$357.81
70496		CT angiography head	\$446.57
70498	26	CT angiography neck	\$88.40
70498	TC	CT angiography neck	\$375.18
70498		CT angiography neck	\$463.57
70542	26	MRI orbit/face/neck with dye	\$82.32
70542	TC	MRI orbit/face/neck with dye	\$330.53
70542		MRI orbit/face/neck with dye	\$412.86
70543	26	MRI orbit/face/neck without and with dye	\$108.38
70543	TC	MRI orbit/face/neck without and with dye	\$397.14

1	70543		MRI orbit/face/neck without and with dye	\$505.52
	70545	26	MRI angiography head with dye	\$60.95
2	70545	TC	MRI angiography head with dye	\$338.33
3	70545		MRI angiography head with dye	\$399.28
	70546	26	MRI angiograph head without and with dye	\$91.59
4	70546	TC	MRI angiograph head without and with dye	\$517.24
5	70546		MRI angiograph head without and with dye	\$608.84
	70548	26	MRI angiography neck with dye	\$60.95
6	70548	TC	MRI angiography neck with dye	\$365.26
7	70548		MRI angiography neck with dye	\$426.20
	70549	26	MRI angiography neck without and with dye	\$91.25
8	70549	TC	MRI angiography neck without and with dye	\$521.50
9	70549		MRI angiography neck without and with dye	\$612.75
.	70552	26	MRI brain stem with dye	\$90.88
10	70552	TC	MRI brain stem with dye	\$242.67
11	70552		MRI brain stem with dye	\$333.55
	70553	26	MRI brain stem without and with dye	\$116.20
12	70553	TC	MRI brain stem without and with dye	\$277.39
13	70553		MRI brain stem without and with dye	\$393.59
14	71260	26	CT thorax with dye	\$63.09
14	71260	TC	CT thorax with dye	\$176.42
15	71260		CT thorax with dye	\$239.51
16	71270	26	CT thorax without and with dye	\$69.52
10	71270	TC	CT thorax without and with dye	\$219.29
17	71270		CT thorax without and with dye	\$288.81
18	71275	26	CT angiography chest	\$97.31
	71275	TC	CT angiography chest	\$276.33
19	71275		CT angiography chest	\$373.64
20	71551	26	MRI chest with dye	\$87.68
	71551	TC	MRI chest with dye	\$382.97
21	71551		MRI chest with dye	\$470.65
22	71552	26	MRI chest without and with dye	\$114.09
	71552	TC	MRI chest without and with dye	\$478.27
23	71552		MRI chest without and with dye	\$592.37
24	71555	26	MRI angiography chest without and with dye	\$91.26
25	71555	TC	MRI angiography chest without and with dye	\$324.16
25	71555		MRI angiography chest without and with dye	\$415.41
26	72126	26	CT neck spine with dye	\$62.02
27	72126	TC	CT neck spine with dye	\$177.48
27	72126		CT neck spine with dye	\$239.50
28	72127	26	CT neck spine without and with dye	\$64.16
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1	72127	TC	CT neck spine without and with dye	\$220.71
	72127		CT neck spine without and with dye	\$284.87
2	72129	26	CT chest spine with dye	\$62.02
3	72129	TC	CT chest spine with dye	\$177.48
	72129		CT chest spine with dye	\$239.50
4	72130	26	CT chest spine without and with dye	\$64.16
5	72130	TC	CT chest spine without and with dye	\$223.89
	72130		CT chest spine without and with dye	\$288.06
6	72132	26	CT lumbar spine with dye	\$62.02
7	72132	TC	CT lumbar spine with dye	\$176.77
	72132		CT lumbar spine with dye	\$238.79
8	72133	26	CT lumbar spine without and with dye	\$64.16
9	72133	TC	CT lumbar spine without and with dye	\$221.06
10	72133		CT lumbar spine without and with dye	\$285.22
10	72142	26	MRI neck spine with dye	\$90.54
11	72142	TC	MRI neck spine with dye	\$244.09
12	72142		MRI neck spine with dye	\$334.63
12	72147	26	MRI chest spine with dye	\$90.54
13	72147	TC	MRI chest spine with dye	\$240.90
14	72147		MRI chest spine with dye	\$331.44
	72149	26	MRI lumbar spine with dye	\$90.88
15	72149	TC	MRI lumbar spine with dye	\$239.48
16	72149		MRI lumbar spine with dye	\$330.36
İ	72156	26	MRI neck spine without and with dye	\$116.20
17	72156	TC	MRI neck spine without and with dye	\$277.75
18	72156		MRI neck spine without and with dye	\$393.95
ľ	72157	26	MRI chest spine without and with dye	\$116.20
19	72157	TC'	MRI chest spine without and with dye	\$278.10
20	72157		MRI chest spine without and with dye	\$394.30
۱۱ ۱	72158	26	MRI lumbar spine without and with dye	\$116.88
21	72158	TC	MRI lumbar spine without and with dye	\$275.97
22	72158		MRI lumbar spine without and with dye	\$392.85
,,	72159	26	MRI angiography spine without and with dye	\$90.59
23	72159	TC	MRI angiography spine without and with dye	\$342.23
24	72159	-	MRI angiography spine without and with dye	\$432.82
25	72191	26	CT angiography pelvis without and with dye	\$91.60
<sup>د</sup> ـــ	72191	TC	CT angiography pelvis without and with dye	\$296.88
26	72191		CT angiograph pelvis without and with dye	\$388.47
27	72193	26	CT pelvis with dye	\$59.16
- 11	72193	TC	CT pelvis with dye	\$176.42
28	72193		CT pelvis with dye	\$235.58
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\$236.29
\$297.96
\$90.58
\$244.80
\$335.38
\$82.68
\$335.14
\$417.82
\$108.74
\$403.87
\$512.61
\$82.68
\$307.51
\$390.19
\$108.74
\$374.82
\$483.56
\$86.67
\$340.10
\$426.77
\$59.16
\$177.48
\$236.64
\$61.66
\$233.81

	73702		CT lower extremity without and with dye	\$295.48
	73706	26	CT angiography lower extremity w/ & w/o dye	\$95.88
	73706	TC	CT angiography lower extremity w/ & w/o dye	\$277.04
	73706		CT angiography lower extremity w/ & w/o dye	\$372.92
	73719	26	MRI lower extremity with dye	\$82.68
	73719	TC	MRI lower extremity with dye	\$336.56
	73719		MRI lower extremity with dye	\$419.24
Н	73720	26	MRI lower extremity without and with dye	\$108.38
П	73720	TC	MRI lower extremity without and with dye	\$407.06
	73720		MRI lower extremity without and with dye	\$515.44
	73722	26	MRI joint of lower extremity with dye	\$83.02
	73722	TC	MRI joint of lower extremity with dye	\$312.47
	73722		MRI joint of lower extremity with dye	\$395.48
	73723	26	MRI joint lower extremity w/ & w/o dye	\$108.74
l	73723	TC	MRI joint lower extremity w/ & w/o dye	\$376.24
ı	73723		MRI joint lower extremity w/ & w/o dye	\$484.97
	73725	- 26	MRI ang lower extremity without and with dye	\$91.62
	73725	TC	MRI ang lower extremity without and with dye	\$329.83
	73725		MRI ang lower extremity without and with dye	\$421.44
	74160	26	CT abdomen with dye	\$64.52
	74160	TC	CT abdomen with dye	\$175.71
	74160		CT abdomen with dye	\$240.23
	74170	26	CT abdomen without and with dye	\$70.93
	74170	TC	CT abdomen without and with dye	\$206.53
	74170		CT abdomen without and with dye	\$277.47
	74174	26	CT angiography abdomen/pelvis w/ & w/o dye	\$111.20
	74174	TC	CT angiography abdomen/pelvis w/ & w/o dye	\$431.86
	74174		CT angiography abdomen/pelvis w/ & w/o dye	\$543.07
	74175	26	CT angiography abdomen without and with dye	\$96.24
	74175	TC	CT angiography abdomen without and with dye	\$290.50
	74175		CT angiography abdomen without and with dye	\$386.74
	74177	26	CT abdomen and pelvis w/contrast	\$92.32
	74177	TC	CT abdomen and pelvis w/contrast	\$232.04
	74177		CT abdomen and pelvis w/contrast	\$324.37
	74178	26	CT abdomen and pelvis 1/> regions	\$101.95
	74178	TC	CT abdomen and pelvis 1/> regions	\$275.62
	74178		CT abdomen and pelvis 1/> regions	\$377.57
	74182	26	MRI abdomen with dye	\$87.68
	74182	TC	MRI abdomen with dye	\$376.59
	74182		MRI abdomen with dye	\$464.27
ſ	74183	26	MRI abdomen without and with dye	\$114.09

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74183	TC	MRI abdomen without and with dye	\$405.64
74183		MRI abdomen without and with dye	\$519.74
74185	26	MRI angiography abdomen w/ & w/o dye	\$90.90
74185	TC	MRI angiography abdomen w/ & w/o dye	\$330.53
74185		MRI angiography abdomen w/ & w/o dye	\$421.43
75635	26	CT angiography abdominal arteries	\$119.82
75635	TC	CT angiography abdominal arteries	\$298.26
75635		CT angiography abdominal arteries	\$418.08

## B. AZ-Tech Did Not Provide Direct Physician Supervision at its Tempe and Ahwatukee Facilities When Administering Contrast Dye

- 108. From approximately January 2017 through November 2018, just as it failed to have a physician on site at its Maricopa facility, AZ-Tech almost never staffed a physician at its Tempe facility when contrast dye was injected in beneficiaries of federal health care programs. Despite knowing that it lacked any physician supervision on site, AZ-Tech required employees to administer contrast dye.
- 109. Instead of providing a physician to supervise the administration of contrast media, AZ-Tech staffed a nurse practitioner at the facility. Accordingly, it failed to meet the physician supervision requirements for reimbursement of these services.
- 110. On June 1, 2018, Caterina Rhodes, Director of Operations at AZ-Tech, sent an email to AZ-Tech personnel that identified which physicians were assigned to specific facilities. The email confirms there was no radiologist assigned to the Maricopa, Tempe, or Ahwatukee facilities.
- 111. In late 2018, a female patient, AZ-Tech Patient A, had an adverse reaction to contrast dye at the Tempe facility, which was administered prior to the patient's MRI test. Relator was working at the Tempe facility when the adverse reaction occurred, and, with no physician on site, he summoned the nurse practitioner. When the patient did not immediately respond, site manager A.R. called 911.
- 112. As they failed to do at the Tempe and Maricopa facilities, Defendants failed to provide direct physician supervision when contrast media was administered to beneficiaries of federal health care programs at its AZ-Tech facility in Ahwatukee.

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- The Ahwatukee facility has lacked direct physician supervision since at least mid-2015.
- In sum, despite its failure to provide direct physician supervision at Tempe, 114. Maricopa, and Ahwatukee, AZ-Tech submitted reimbursement claims for diagnostic tests provided to government health insurance beneficiaries. Such claims were knowingly false and, therefore, were not reimbursable, resulting in violations of the FCA.
- Pursuant to its Medicare Enrollment Applications, AZ-Tech was required to disclose all supervising physicians for each of its facilities. If the procedure requires "direct or personal supervision," the IDTF's supervising physician "must personally furnish this level of supervision" 42 C.F.R. 410.33(b)(2). Because AZ-Tech's supervising physicians did not provide the required direct or personal supervisions, such representations on AZ-Tech's Medicare Enrollment Applications were knowingly false when made and/or were later rendered false upon AZ-Tech's failure to provide the requisite level of physician supervision.
- Furthermore, by signing the Medicare Enrollment Applications, Defendants 116. undertook to comply with all Medicare requirements material to receiving payment from Medicare. Therefore, when Defendants submitted, or caused to be submitted, claims for payment to Medicare using certain CPT codes for MRIs and CTs "with contrast." those claims for payment impliedly certified that AZ-Tech had complied with the corresponding physician supervision level specified in the CMS fee schedule.
- Additionally, each supervising physician is required to certify to Medicare the types of tests that he or she will supervise. The supervising physician must check the appropriate box (personal, direct, or general) for the type of supervision he or she will provide. After choosing the type of supervision that the physician will provide, the physician further certifies:

I hereby acknowledge that I have agreed to provide (IDTF Name) with the Supervisory Physician services checked above for all CPT-4 and HCPCS codes reported in this Attachment. (See number 2 below if all reported CPT-4 and HCPCS codes do not apply). I also hereby

certify that I have the required proficiency in the performance and interpretation of each type of diagnostic procedure, as reported by CPT-4 or HCPCS code in this Attachment (except for thoseCPT-4 or HCPCS codes identified in number 2 below). I have read and understand the Penalties for Falsifying Information on this Enrollment Application, as stated in Section 14 of this application. I am aware that falsifying information may result in fines and/or imprisonment. If I undertake supervisory responsibility at any additional IDTFs, I understand that it is my responsibility to notify this IDTF at that time.

CMS-855B, Attachment 2: Independent Diagnostic Testing Facilities, Section E: Supervising Physicians, p. 47.

118. AZ-Tech physicians did not provide direct supervision at multiple AZ-Tech facilities, which resulted in the patient harm that regulations are in place to prevent. Because the supervising physicians certified that they would provide direct supervision, and they failed to do so, such certifications were false when made and/or were later rendered false upon the physician's failure to provide the requisite level of supervision.

## C. AZ-Tech Improperly Submitted Reimbursement Claims to Medicare for Offshore Teleradiology Services

- 119. Beginning in at least 2014 and continuing through at least January 2019, AZ-Tech used an offshore company (located in Nigeria and/or India) known as "AccuRead" to provide radiology services. Medicare does not pay for services provided outside of the United States, making any services provided by AccuRead non-reimbursable.
- and belief, Sharma is a close friend of Pahwa and Narang and is the owner or controlling member of Global Radiology Consultants, LLC, an Arizona limited liability company headquartered at 3447 East Glenhaven Drive, Phoenix, Arizona, and 7GEN Healthcare, LLC, which is located at the same address. Sharma was an AZ-Tech employee that was stationed at the Osborn location. His title was "AccuRead Manager."
- 121. In 2014, AZ-Tech's business was growing in terms of the number of imaging tests it was providing. Due to this growth, AZ-Tech radiologists were getting

behind in interpreting the images, especially ultrasounds and x-rays. As the reimbursement for MRI and CT interpretations was higher than for ultrasounds and x-rays, AZ-Tech radiologists gave priority to interpreting MRI and CT images.

- 122. To deal with the ever-growing backlog of ultrasound and x-ray images, instead of hiring additional staff, AZ-Tech contracted with AccuRead to interpret images from locations outside the United States. Before using AccuRead, AZ-Tech was growing concerned that its slow turnaround time for producing interpretations and sending them to the referring physicians would cost it significant business. At this time, it was taking longer than the referring physicians expected for routine imaging and interpretations, so it devised the plan to use AccuRead.
- 123. AZ-Tech used an electronic medical record ("EMR") product called Intergy to store patient records, including scanned documents, and a product called NovaPacs to send diagnostic images. Each patient's EMR saved in Intergy listed the proposed CPT codes. This was done so that the technician could verify that the correct images were being obtained.
- 124. Based on Relator's observation, approximately 60-70% of CTs had contrast and approximately 40% of MRIs had contrast. A majority of CTs were abdomen and pelvis exam with contrast. During a normal patient encounter at one of its locations, the paperwork generated for the patient's exam were scanned and uploaded to the patient's electronic health record. The diagnostic images were then sent to the radiologists through NovaPacs to interpret. After they were interpreted, a "reports coordinator" would forward the radiology reports to the patient's referring physician.
- 125. Each facility had its own reports coordinator who was responsible for providing the patients' scanned documents to the radiologist and forwarding the radiology reports to the referring physician. In order to implement the scheme with AccuRead, every reports coordinator had an electronic folder saved on his or her individual computer titled "AccuRead." The folder was shared across all locations but was only accessible through the reports coordinators' computers. Importantly, Sharma

 had remote access to all of the reports coordinators' AccuRead folders.

- 126. When the number of patient cases waiting for a radiologist to interpret the images built up to a certain level, the reports coordinators were instructed to remove some of the cases and upload them to the AccuRead folder. After the cases were uploaded from Intergy, Sharma accessed the cases and electronically sent the EMRs to AccuRead personnel located outside the United States. The diagnostic images were sent via AZ-Tech's NovaPacs main server, which was located at the Mesa-Women's Center.
- 127. After AccuRead received the diagnostic images from NovaPacs and the electronic case files from Sharma, AZ-Tech typically received a radiologist report the next day. These radiology reports were prepared by radiologists not licensed to practice medicine in the United States, and the services were not reimbursable by federal health care programs. Despite knowing that offshore radiologists could not interpret the images, AZ-Tech submitted claims to federal health care programs for these diagnostic services.
- 128. The images for the vast majority, if not all, of AZ-Tech's patients referred by chiropractor J.S. were uploaded and sent to AccuRead for interpretation.
- 129. Multiple text messages confirm Defendants' scheme. For example, on June 16, 2017, Director of Operations Caterina Rhodes sent a text message to Relator stating: "Just talked to [N.W.] she is sending everything to Accuread. They are putting it in the accuread folder so that they can begin the read over the weekend."
- 130. On June 19, 2017, Osborn CT technician N.W. sent Relator a text message confirming that AZ-Tech Patient B had his/her images read by AccuRead.
- 131. On July 5, 2017, in text messages between Narang, Rhodes, and Relator, Narang asked how long it takes to send images to AccuRead and "if they can process it without [the] system crashing."
- 132. On August 29, 2017, in a text message between Gilbert site manager T.W., Regional Manager S.K., Rhodes, and Relator, Rhodes referenced instructing Sharma to have the AccuRead radiologists dictate the dates of service into their reports. This text demonstrates that AccuRead was generating reports and that Sharma was instructing

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AccuRead radiologists on how to do so.

- 133. On September 29, 2017, S.K. sent a text message to Relator confirming that AZ-Tech Patient C had his/her images read by AccuRead.
- 134. On October 19, 2017, Rhodes sent a text message asking Relator to ensure that technologists were not sending tasks (internal messages inside Intergy) to SRAD, which is a reference to S.M., the Centralized Reports Coordinator. Rather, Rhodes asked that the paperwork be provided to the Reports Coordinator to send all tasks and to "take care of paperwork if AccuRead."
- 135. On November 24, 2017, in a text conversation between Narang, the Tempe site manager, CT Technician S.B., and Relator, Narang asked if a sample report could be provided to AccuRead. The reason for this request was AccuRead's need for a report for comparison purposes to better understand what information was needed in reports AccuRead prepared for AZ-Tech. In the text exchange, Relator stated that A.R. would forward three sample cases to AccuRead, and Narang instructed Relator to inform Sharma that the reports were sent to AccuRead.
- 136. On December 12, 2017, AZ-Tech's Assistant Director of Operations, L.A., sent text messages to Relator regarding AZ-Tech Patient C's images being referred and sent to AccuRead for interpretation.

#### D. Defendants Violated the FCA.

- 137. Defendants knowingly administered contrast dye/media to beneficiaries of federal health care programs in preparation for MRI and CT diagnostic studies when there were no physicians on site to provide the required direct supervision. Furthermore, Defendants fraudulently billed the government for services provided by radiologists located outside the United States, and such billings are not reimbursable under Medicare. Defendants' misconduct renders them liable under the FCA.
- 138. In order to submit claims for payment to federal health care programs, providers must first be approved in the particular government program. The enrollment process, in relevant part, consists of submitting a provider enrollment application and

entering into a provider agreement. While these documents may vary, they include language placing the provider on notice, and obtaining the provider's assurance, that it will provide true, accurate, and complete claims data as a condition of participation in the program and as a condition of receiving reimbursement from the program.

- 139. For example, on Medicare Enrollment Applications (CMS Forms 855-B and 855-I), an applicant-provider:
  - a. agrees to abide by the Medicare laws, regulations and program instructions that apply to the provider;
  - b. certifies that the provider understands that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions and on the provider's compliance with all applicable conditions of participation in Medicare;
  - c. is notified of the applicability of the FCA and other laws to statements the provider makes to the government; and
  - d. agrees the provider will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.<sup>8</sup>
  - 140. In addition, on the claim form, CMS Form 1500, the provider certifies that:
    - a. the provider is submitting a claim for payment from federal funds;
    - b. all the information on the form is true, accurate, and complete;
    - c. the provider is familiar with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor;
    - d. the provider has provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision;

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf (last visited July 1, 2020).

- e. the claim complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment; and
- f. the services on the form were medically necessary and personally furnished by the provider or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE.<sup>9</sup>
- 141. Billing a federal health care program in violation of statutes and regulations governing reimbursement, the Medicare Claims Processing Manual, the Medicare Benefit Policy Manual, or other applicable billing requirements, after agreeing not to do so and certifying not to have done so, triggers liability under the FCA.
- 142. Thus, Defendants violated the FCA each time they knowingly billed federal health care programs for (1) administering contrast dye/media in preparation for MRI and CT diagnostic studies when there were no physicians on site to provide the required direct supervision and (2) services provided by radiologists located outside the United States. Each such billing constitutes an actionable false or fraudulent claim for payment and an actionable false or fraudulent record or statement.

#### VI. COUNTS

# FCA: Presentation of False Claims (31 U.S.C. § 3729(a)(1)(A))

- 143. Relator realleges and incorporates by reference the allegations in the preceding paragraphs.
  - 144. This is a claim for treble damages and penalties under the FCA.
- 145. Through the acts described above and otherwise, Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented or caused to be presented to the Government materially false or fraudulent claims for payment or

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last visited July 1, 2020).

approval in violation of 31 U.S.C. § 3729(a)(1)(A).

- 146. The Government was unaware of the falsity or fraudulence of the records, statements, and claims made or presented by Defendants, their agents, and employees.
- 147. The false and fraudulent representations and claims Defendants knowingly made to the Government were material to the Government's decisions to make payments to Defendants.
- 148. Given the false and fraudulent nature of Defendants' representations and claims, the Government was prohibited by law from making corresponding payments to Defendants.
- 149. Defendants knew, both in fact and within the meaning of the FCA, that through the acts described above, they would be violating the FCA by getting false or fraudulent claims submitted or caused to be submitted by Defendants allowed or paid by the Government.
- 150. By reason of the Defendants' acts, the Government has been damaged, and continues to be damaged, in a substantial amount yet to be determined.
- 151. The Government is also entitled to the maximum penalty under 31 U.S.C. § 3729(a)(1)(A) for each and every violation alleged herein.

# FCA: Using False Statements to Get False Claims Paid (31 U.S.C. § 3729(a)(1)(B))

- 152. Relator realleges and incorporates by reference the allegations in the preceding paragraphs.
- 153. Through the acts described above, Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, made, used, or caused to be made or used false records or statements material to the payment of false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).
- 154. Defendants' false certifications and representations were made for the purpose of ensuring that the Government paid the false or fraudulent claims, which was a

reasonable and foreseeable consequence of Defendants' statements and actions.

- 155. The Government was unaware of the falsity of the records, claims, or statements made or used by Defendants, their agents, and employees.
- 156. The false and fraudulent representations and claims Defendants knowingly made to the Government were material to the Government's decisions to make payments to Defendants.
- 157. Given the false and fraudulent nature of Defendants' representations and claims, the Government was prohibited by law from making corresponding payments to Defendants.
- 158. Defendants knew, both in fact and within the meaning of the FCA, that through the acts described above, they would be violating the FCA by making or using false statements or records material to false or fraudulent claims submitted by Defendants.
- 159. By reason of the Defendants' acts, the Government has been damaged, and continues to be damaged, in a substantial amount yet to be determined.
- 160. The Government is also entitled to the maximum penalty under 31 U.S.C. § 3729(a)(1)(B) for each and every violation alleged herein.

# FCA: False Record Material to Obligation to Pay (31 U.S.C. § 3729(a)(1)(G))

- 161. Relator realleges and incorporates by reference the allegations in the preceding paragraphs.
- 162. Through the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to an obligation to pay or transmit money to the Government and knowingly and improperly concealed, avoided, or decreased an obligation to pay or transmit money to the Government in violation of 31 U.S.C. § 3729(a)(1)(G).
- 163. The Government was unaware of the falsity of the records, statements, and claims made or submitted by Defendants.

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- 164. The false and fraudulent representations and claims Defendants knowingly made to the Government were material to the Government's decisions to make payments to Defendants and deprived the Government of money Defendants were obligated to pay to the Government.
- 165. Defendants knew, both in fact and within the meaning of the FCA, that through the acts described above, they would be violating the FCA by making or using false statement or records material to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.
- 166. By reason of the Defendants' acts, the Government has been damaged, and continues to be damaged, in a substantial amount yet to be determined.
- 167. The Government is also entitled to the maximum penalty under 31 U.S.C. § 3729(a)(1)(G) for each and every violation alleged herein.

#### VII. PRAYER

WHEREFORE, Relator prays for judgment against Defendants as follows:

- 1. that Defendants cease and desist from violating 31 U.S.C. §§ 3729, et seq.;
- 2. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Government has sustained because of Defendants' actions, plus a civil penalty for each violation of 31 U.S.C. § 3729, as provided in 31 U.S.C. § 3729 and adjusted for inflation, 28 C.F.R. § 85;
- 3. that Relator be awarded the maximum amounts allowed pursuant to 31 U.S.C. § 3730(d);
- 4. that Relator be awarded all costs of this action, including attorneys' fees and expenses;
- 5. that Relator be awarded interest on money judgments, as provided by law; and
- 6. that the Government and Relator recover such other relief as the Court deems just and proper.

VIII. REQUEST FOR TRIAL BY JURY Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury. Dated: July 1, 2020 Lon R. Leavitt HALUNEN LAW PLLC Nathaniel F. Smith\* HALUNEN LAW PLLC Timothy J. Granitz\* MAHANY LAW Attorneys for Plaintiff/Relator (\* pro hac vice applications to be filed)