

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNITED STATES OF AMERICA, *ex rel.*
ROBIN WHITE,

Plaintiff,

v.

ORTHOPAEDIC AND NEURO
IMAGING LLC, and RICHARD
C. PFARR.

Defendants.

Civil Action No. 13-1109-RGA

FILED UNDER SEAL AND EX PARTE

UNITED STATES' COMPLAINT IN INTERVENTION

The UNITED STATES OF AMERICA hereby alleges as follows:

1. This is a civil action under the False Claims Act, 31 U.S.C. §§ 3729-3733, and under the common law of unjust enrichment and payment by mistake. The action was originally filed by *qui tam* relator Robin White, and the United States has intervened in this action pursuant to 31 U.S.C. § 3730(b)(4)(A) and now has primary responsibility for the action.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1345, 1355.

3. Venue is proper in the District of Delaware under 31 U.S.C. § 3732(a), 28 U.S.C. §§ 1391(b) and 1395(a).

THE PARTIES

4. Plaintiffs are the United States of America and *qui tam* relator Robin White.

5. Defendant Orthopaedic and Neuro Imaging LLC ("ONI") is a private limited liability company formed in 2002 under the laws of the State of Delaware. The registered agent for ONI is Defendant Richard C. Pfarr in Lewes, Delaware, within the jurisdiction of this Court.

6. Defendant Richard C. Pfarr (“Pfarr”) is an individual residing in Lewes, Delaware, within the jurisdiction of this Court. Pfarr is the President of ONI. Pfarr and his wife are the sole owners of ONI.

BACKGROUND

Medicare

7. Medicare is a federal health insurance program for people 65 and older and for people under 65 with certain disabilities. *See* 42 U.S.C. § 1395. Medicare is administered through the Centers for Medicare and Medicaid Services (“CMS”), a division of the United States Department of Health and Human Services (“HHS”), and administration is further delegated to administrative and program safeguard contractors. Medicare Part B (Medical Insurance) covers physician services and laboratory tests.

8. In order to bill Medicare for services provided to Medicare beneficiaries, physicians and certain legal entities must apply for enrollment in the Medicare program by submitting an enrollment application. Medicare, through its administrative contractors, evaluates the representations and certifications contained on the enrollment application and determines whether to permit the individual or entity to enroll. Once an individual or entity is approved for enrollment, it is assigned a “Provider Number,” which then permits it to bill Medicare and receive payment.

9. At all times relevant hereto, providers seeking to enroll in the Medicare program were required to sign a certification agreeing to abide by Medicare laws, regulations and program instructions. Providers were also required to certify that the information contained in their enrollment application was “true, correct, and complete,” and agree to notify the Medicare administrative contractor within 90 days of any changes to the information.

10. To obtain payment for services they provide to Medicare beneficiaries, Medicare-enrolled providers file “claims” with the Medicare administrative contractor for their region. The basic requirement for any claim to be payable by Medicare is that the service must be “reasonable and necessary for the diagnosis or treatment of illness or injury.” 42 U.S.C. § 1395y(a)(1)(A). What is “reasonable and necessary” is determined by accepted practices in the medical community, as further defined by statute, by regulation, by National Coverage Determinations issued by CMS, and by Local Coverage Determinations and guidance issued by the Medicare administrative contractor.

11. When submitting claims for payment to Medicare, providers use payment codes corresponding to the services provided. These codes are commonly referred to as “Current Procedural Terminology” or “CPT” codes. By submitting claims for payment using CPT codes, providers represent to Medicare that they have provided the services corresponding to the codes.

Medicare Coverage of Claims Submitted by Independent Diagnostic Testing Facilities

12. Medicare pays for diagnostic radiology tests, but deems those tests to be reasonable and necessary and thus payable only if there is physician supervision of the procedure under the standards established by the Medicare program. By definition, a test performed without the appropriate level of physician supervision is not reasonable and necessary, and therefore not payable by Medicare. 42 C.F.R. § 410.32(b).

13. Different types of diagnostic radiology tests require different levels of physician supervision, depending upon the risk of harm to the patient. All diagnostic radiology tests require at least “general supervision” by a physician to be payable by Medicare. Procedures performed under general supervision require the physician’s overall direction and control but the physician’s presence is not required during the performance of the procedure. 42 C.F.R.

§ 410.32(b)(3)(i). Moreover, the physician providing general supervision has “continuing responsibility” to “train[] the nonphysician personnel who actually perform the diagnostic procedure” and to “mainta[in] the necessary equipment and supplies” for the test. *Id.* Examples of procedures requiring general supervision include standard X-rays, Magnetic Resonance Imaging (“MRI”) procedures without any injection of contrast media to which there could potentially be an allergic reaction, Computerized Tomography (“CT”) scans without contrast media, and nuclear imaging tests that do not involve stress on the heart.

14. For diagnostic tests that involve some inherent risk of harm to the patient (for example, MRI and CT scans involving injection of contrast media to which the patient may have an adverse or allergic reaction), Medicare requires that there be “direct supervision” of the procedure. Direct supervision means that a physician has to be “in the office suite and immediately available to furnish assistance and direction” in the event of an adverse reaction. 42 C.F.R. § 410.32(b)(3)(ii). “In the office suite” means in the office suite of the entity conducting the test. CMS publishes a Medicare Physician Fee Schedule Database that contains a listing of all diagnostic procedures that require direct supervision by a physician.

15. Medicare authorizes providers called “independent diagnostic testing facilities,” or “IDTFs” to perform and bill for diagnostic tests on Medicare beneficiaries. When first created, Medicare defined an IDTF as a “new entity independent of a hospital or physician’s office in which diagnostic tests are performed by licensed, certified, non-physician personnel under appropriate physician supervision.” 62 Fed. Reg. 59048-01, 1997 WL 674391, at *59071 (Oct. 31, 1997); *see* 42 C.F.R. § 410.33(a). IDTFs are eligible for participation in Medicare only if they meet certain requirements more stringent than those typically applicable to other Medicare providers.

16. IDTFs have always been required to have “one or more supervising physicians” providing the “general supervision” set forth in 42 C.F.R. § 410.32(b)(3)(i), which includes quality oversight, proper operation and calibration of the testing equipment, and training and qualification of the technicians.

17. In the case of a diagnostic test requiring “direct supervision” and therefore the physician’s presence in the office suite because of some inherent risk of harm to the patient from the test, as set forth in 42 C.F.R. § 410.32(b)(3)(ii), the regulation makes clear that the “IDTF’s supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location.” 42 C.F.R. § 410.33(b)(2).

18. An IDTF’s compliance with the direct supervision requirement is material to Medicare’s decision to pay claims for contrast MRI procedures.

19. IDTFs have always been required to “evidence proficiency” of all of its supervising physicians to the Medicare contractor “in the performance and interpretation of each type of diagnostic procedure performed by the IDTF.” 42 C.F.R. § 410.33(b)(2). To enroll in the Medicare program and thus be entitled to bill Medicare, an IDTF has always been required to list “all supervising physician(s)” that it intends to use and provide information to Medicare about the proposed physician supervisors’ qualifications. *See, e.g., Medicare Enrollment Application, Clinics/Group Practices and Certain Other Suppliers*, <http://www.cms.hhs.gov/CMSforms/downloads/cms855b.pdf>, at 35, 46-47 (last visited Aug. 7, 2017). Furthermore, each one of the IDTF’s supervising physicians have always been required to “certify” to the Medicare administrative contractor the identity of each of the test types that s/he is going to supervise for the IDTF. *See, e.g., id.* at 46-47. If any changes are made to the

supervisory physician staff, the IDTF certifies that it will notify the Medicare administrative contractor of this change, providing the appropriate certifications and documentation within 30 or 90 days, depending on the type of change. *See, e.g., id.* at 39.

20. IDTFs must also agree in the Medicare enrollment application to comply with all Medicare program instructions. IDTFs must additionally acknowledge that all such instructions are available from the Medicare contractor and that payment is contingent upon compliance with all applicable laws, regulations and program instructions. *See, e.g., id.* at 31.

21. In addition to identifying all supervising physicians to Medicare, identifying each type of test that they are going to supervise, documenting their credentials, obtaining approval from Medicare for all supervising physicians, and informing Medicare when there is a supervising change and obtaining approval for new supervising physicians, IDTFs have always been required to “maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished.” 42 C.F.R. § 410.33(b)(2).

STATUTE OF LIMITATIONS

22. The claims in this matter relate back to the filing of the *qui tam* complaint and are therefore timely under 31 U.S.C. § 3731(b).

FACTUAL ALLEGATIONS

ONI Lewes

23. In 2002, Defendant ONI opened an office at 34435 King St. Row, Suite #2, Lewes, Delaware 19958. Between October 2002 and continuing through July 2014, employees at ONI’s Lewes office injected hundreds of Medicare beneficiaries with contrast material during the performance of contrast MRI procedures. By law, contrast MRI procedures require the direct

supervision of a physician in order to be payable by Medicare. However, except for a short period of time in 2012 (described in Paragraph 30 below), ONI provided no direct physician supervision of contrast MRI procedures performed in its Lewes office. ONI and Defendant Richard Pfarr nevertheless submitted or caused to be submitted claims for those tests to Medicare.

24. In or around August 2002, ONI submitted an application to Medicare to enroll its Lewes office as an IDTF. The application listed Dr. Robert Platenberg as the physician providing “General Supervision.” The application did not list a physician for the provision of “Direct Supervision,” despite the application’s instruction to “include information about all supervising physicians.” Pfarr signed the Medicare enrollment application and required certifications as President and “Authorized Official” of ONI.

25. All Medicare enrollment applications submitted by ONI and Pfarr contained the following certifications:

- A. “I have read the contents of this application.”
- B. “My signature legally and financially binds this supplier to the laws, regulations, and program instructions of the Medicare program.”
- C. “I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations and program instructions are available through the Medicare contractor.”
- D. “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”

E. “I agree to notify the Medicare contractor of any future changes to the information” contained in the application within 90 days (or 30 days for certain types of changes).

F. “I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare”

G. “[I] will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.”

26. Beginning in October 2002, ONI performed contrast MRI scans on Medicare beneficiaries in its Lewes Office. ONI and Pfarr were aware of Medicare’s requirement that contrast MRI procedures be performed under the “direct supervision” by a physician, that is, with a physician “in the office suite” and “immediately available to furnish assistance and direction” in the event of an adverse reaction. However, ONI and Pfarr made no attempt to comply with the requirement until approximately February 2012. Despite knowing that ONI did not provide direct supervision for contrast MRI scans, ONI and Pfarr submitted and caused ONI’s third-party billing service to submit claims for those services to Medicare on behalf of ONI.

27. Relator Robin White (“White”) worked as an MRI technologist at ONI from September 2002 until December 2012, primarily at ONI’s Lewes office. In or around 2007, White asked Pfarr about the direct supervision requirement for contrast MRI procedures. Pfarr told White that Dr. Charles Stanislav, a general practice physician who worked in the suite next door to ONI, was ONI’s supervising physician. However, Dr. Stanislav was never in ONI’s office suite during the provision of contrast MRI procedures to Medicare beneficiaries.

Moreover, Dr. Stanislav did not know that he was supervising contrast MRI procedures for ONI, nor did he in fact provide direct supervision of contrast MRI procedures for ONI.

28. On or about January 5, 2012, Richard Pfarr acknowledged in an e-mail his knowledge and understanding of the Medicare supervision requirements, as well as the fact that ONI was not in compliance with those requirements, stating, “ONI was just informed that we have to revalidate all three facility’s [sic], which means we re-submit all documents . . . A problem we need to address is designating radiologists as Direct Supervision – meaning they must be present in the office suite & immediately available to provide assistance throughout the performance of the procedure”

29. One week later, on January 12, 2012, ONI’s third-party billing service e-mailed Pfarr to notify him that “[t]he government will clearly be reviewing supervision in regards to IDTFs” and that “we should talk about this in the near future.” Pfarr responded that he “may have to punt on removing [Relator] Robin [White] from ONI until we can figure out how best to comply!”

30. Shortly thereafter, on or about February 3, 2012, ONI submitted an application to “revalidate” the enrollment of its Lewes office location in the Medicare program. The application indicated that Dr. Robert Platenberg was responsible for both “General Supervision” and “Direct Supervision” at ONI’s Lewes office. Pfarr signed the enrollment application and required certifications. Between approximately February 2012 and July 2012, Pfarr arranged to have Dr. Platenberg present in ONI’s Lewes office on Thursdays to supervise contrast MRI procedures for Medicare beneficiaries. During this period, ONI scheduled Medicare beneficiaries undergoing contrast MRI procedures at its Lewes office for Thursdays.

31. However, in approximately July 2012, ONI and Pfarr stopped providing direct supervision of contrast MRI procedures at its Lewes office. Despite being required to do so, Pfarr and ONI did not notify Medicare within 90 days that Dr. Platenberg was no longer providing direct supervision at ONI's Lewes office. After July 2012, ONI continued to perform and bill for contrast MRI procedures on Medicare beneficiaries at its Lewes office, but ONI provided no direct physician supervision of those procedures.

32. On or about November 5, 2013, ONI submitted a form to Medicare indicating that ONI had changed its direct supervising physician at the Lewes office from Dr. Robert Platenberg to Dr. Charles Stanislav, effective November 1, 2013. That representation was materially false. In fact, ONI had not provided direct supervision of contrast MRI procedures in its Lewes office since approximately July 2012 and had no intent to use Dr. Stanislav to provide direct supervision of contrast MRI procedures. Pfarr signed the form and the required certifications.

33. At or around the same time, ONI created a written agreement under which Dr. Stanislav would purportedly provide "on-site" supervision of contrast MRI procedures at ONI's Lewes office. Under the agreement, ONI was to provide Dr. Stanislav's Administrator with a schedule of contrast patients each week and would pay Dr. Stanislav a fee of \$20.00 "per patient exam" or \$150.00 "[i]n the event that the supervising physician is needed to evaluate a patient." Pfarr signed the agreement on behalf of ONI.

34. ONI's written agreement with Dr. Stanislav in 2013 was a sham created to conceal the fact that ONI did not provide direct physician supervision of contrast MRI procedures performed at its Lewes office. Dr. Stanislav was never present in ONI's office suite during contrast MRI procedures. ONI never provided Dr. Stanislav or his employees with a schedule of contrast patients as required by the agreement. ONI never paid Dr. Stanislav

pursuant to the agreement. Moreover, Dr. Stanislav was unaware that the supervision agreement with ONI had even commenced, since ONI never notified him that it was giving contrast injections.

35. Between July 2003 and July 2014, ONI performed approximately 1,700 contrast MRI procedures on Medicare beneficiaries at its Lewes office without the required direct supervision of a physician, resulting in a payment to ONI of over \$1 million. ONI and Pfarr knew that (except for the period in 2012 described in Paragraph 30) no physician was in ONI's Lewes office suite during the performance of contrast MRI procedures. ONI and Pfarr also knew that claims that were not properly supervised were not entitled to payment from Medicare. Nevertheless, ONI and Pfarr submitted or caused to be submitted claims for payment for those services to Medicare.

36. For example, ONI and Pfarr knew that no physician was in ONI's office suite during the following contrast MRI procedures on Medicare beneficiaries, yet they submitted or caused to be submitted a claim for payment for these services to Medicare knowing that they were not entitled to be paid:

- a. Patient 1 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on July 25, 2003;
- b. Patient 2 received an MRI with contrast, CPT code 72158, at ONI's Lewes office on September 3, 2003;
- c. Patient 3 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on June 8, 2004;
- d. Patient 4 received an MRI with contrast, CPT code 72156, at ONI's Lewes office on December 6, 2004;
- e. Patient 5 received an MRI with contrast, CPT code 74183, at ONI's Lewes office on May 25, 2005;
- f. Patient 6 received an MRI with contrast, CPT code 72158, at ONI's Lewes office on December 1, 2005;

- g. Patient 7 received an MRI with contrast, CPT code 70549, at ONI's Lewes office on May 17, 2006;
- h. Patient 8 received an MRI with contrast, CPT code 72158, at ONI's Lewes office on November 10, 2006;
- i. Patient 9 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on March 2, 2007;
- j. Patient 10 received an MRI with contrast, CPT code 72158, at ONI's Lewes office on October 30, 2007
- k. Patient 11 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on May 9, 2008;
- l. Patient 12 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on September 17, 2009;
- m. Patient 13 received an MRI with contrast, CPT code 70549, at ONI's Lewes office on June 8, 2010
- n. Patient 14 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on December 29, 2010;
- o. Patient 15 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on February 2, 2011;
- p. Patient 16 received an MRI with contrast, CPT code 74183, at ONI's Lewes office on August 3, 2011;
- q. Patient 17 received an MRI with contrast, CPT code 74183, at ONI's Lewes office on December 12, 2011;
- r. Patient 18 received an MRI with contrast, CPT code 72156, at ONI's Lewes office on January 13, 2012;
- s. Patient 19 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on September 5, 2012;
- t. Patient 20 received an MRI with contrast, CPT code 74183, at ONI's Lewes office on February 6, 2013;
- u. Patient 21 received an MRI with contrast, CPT code 70553, at ONI's Lewes office on October 17, 2013;
- v. Patient 22 received an MRI with contrast, CPT code 72158, at ONI's Lewes office on January 21, 2014; and

- w. Patient 23 received an MRI with contrast, CPT code 72158, at ONI's Lewes office on June 25, 2014.

ONI Seaford

37. In or around January 2005, Defendant ONI opened an office at 1350 Middleford Rd., Suite 503, Seaford, Delaware 19973. Beginning in January 2005 and continuing through July 2014, employees at ONI's Seaford office injected hundreds of Medicare beneficiaries with contrast material during the performance of contrast MRI procedures. However, except for a short period of time in 2012, ONI provided no direct physician supervision of contrast MRI procedures performed in its Seaford Office. ONI and Richard Pfarr nevertheless submitted or caused to be submitted claims for those tests to Medicare.

38. In or around November 2004, ONI submitted an application to Medicare to enroll its Seaford office. However, until 2008, ONI continued to bill for services performed at its Seaford office as though they were performed at its Lewes office.

39. In or around March 2009, ONI submitted an application to Medicare to "reactivate" its enrollment for its Seaford office. The application listed Dr. Robert Platenberg as the physician providing "General Supervision." The application did not list a physician for provision of "Direct Supervision." The Medicare administrative contractor informed ONI that, in order to complete processing of the enrollment application, ONI needed to identify a supervising physician "with the appropriate Supervision" for the type of tests it proposed to perform "or a correction to the type of Supervision" to be performed by ONI's supervising physician. On or about April 28, 2009, ONI submitted amended enrollment paperwork indicating that Dr. Robert Platenberg would also provide "Direct Supervision" at ONI's Seaford office. That representation was materially false. In fact, ONI had never provided supervision of contrast MRI procedures in its Seaford office and had no intent at that time to use Dr. Platenberg

to provide direct supervision of contrast MRI procedures. Pfarr signed the enrollment application and required certifications for ONI's Seaford office.

40. On or about the same day, Pfarr sent the Medicare administrative contractor a schedule of dates "assigned" in May 2009 for Dr. Platenberg to directly supervise contrast scans in ONI's Seaford office. Pfarr's letter contained material misrepresentations, as Dr. Platenberg did not provide direct supervision at ONI's Seaford office in 2009, nor was he "assigned" to do so by ONI or Pfarr.

41. In or around February 2012, shortly after being notified that the government was investigating IDTF compliance with supervision requirements (*see* Paragraph 29 above), ONI submitted an application to Medicare to "revalidate" the enrollment of its Seaford office location in the Medicare program. The application indicated that Dr. Robert Platenberg would provide both "General Supervision" and "Direct Supervision" at the Seaford office. Pfarr signed the enrollment application and required certifications. Between approximately February 2012 and July 2012, Pfarr arranged to have Dr. Platenberg present in ONI's Seaford office on Fridays to supervise contrast MRI procedures for Medicare beneficiaries. During this period, ONI scheduled Medicare beneficiaries undergoing contrast MRI procedures at its Seaford office for Fridays.

42. However, in approximately July 2012, ONI and Pfarr stopped providing direct supervision at ONI's Seaford office. Despite being required to do so, ONI and Pfarr did not notify Medicare within 90 days that Dr. Platenberg was no longer providing direct supervision at ONI's Seaford office. After July 2012, ONI continued to perform and bill for contrast MRI procedures on Medicare beneficiaries, but ONI provided no direct physician supervision of those procedures.

43. On or about November 5, 2013, ONI submitted a form indicating that ONI had changed its direct supervising physician from Dr. Robert Platenberg to Dr. Ivonne Herrera, effective November 1, 2013. That representation was materially false. In fact, ONI had not provided direct supervision of contrast MRI procedures in its Seaford office since approximately July 2012 and had no intent to use Dr. Herrera to provide direct supervision of contrast MRI procedures. Pfarr signed the form and the required certifications.

44. At or around the same time, ONI created a written agreement under which Dr. Herrera would purportedly provide “on-site” supervision of contrast MRI procedures at ONI’s Seaford office. Under the agreement, ONI would provide Dr. Herrera a fee of \$20.00 “per patient exam” or \$150.00 “[i]n the event that the supervising physician is needed to evaluate a patient.” Pfarr signed the agreement on behalf of ONI.

45. ONI’s written agreement with Dr. Herrera in 2013 was a sham created to conceal the fact that ONI did not provide direct physician supervision of contrast MRI procedures performed at its Seaford office. Dr. Herrera was never present in ONI’s office suite during contrast MRI procedures. Moreover, ONI never paid Dr. Herrera pursuant to the agreement.

46. Between January 2005 and July 2014, ONI performed over 300 contrast MRI procedures on Medicare beneficiaries at its Seaford office without the required direct supervision of a physician, resulting in a payment to ONI of approximately \$200,000. ONI and Pfarr knew that (except for a period in 2012 described above in Paragraph 41) no physician was in ONI’s Seaford office suite during the performance of contrast MRI procedures. ONI and Pfarr also knew that claims that were not properly supervised were not entitled to payment from Medicare. Nevertheless, ONI and Pfarr submitted or caused to be submitted claims for payment for those services to Medicare.

47. For example, ONI and Pfarr knew that no physician was in ONI's office suite during the following contrast MRI procedures on Medicare beneficiaries, yet they submitted or caused to be submitted a claim for payment for these services to Medicare knowing that they were not entitled to be paid:

- a. Patient 24 received an MRI with contrast, CPT code 70548, at ONI's Seaford office on January 27, 2005;
- b. Patient 25 received an MRI with contrast, CPT code 70543, at ONI's Seaford office on August 16, 2005;
- c. Patient 26 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on August 15, 2006;
- d. Patient 27 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on May 2, 2007;
- e. Patient 28 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on February 14, 2008;
- f. Patient 29 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on May 27, 2008;
- g. Patient 30 received an MRI with contrast, CPT code 74183, at ONI's Seaford office on December 3, 2008;
- h. Patient 31 received an MRI with contrast, CPT code 72158, at ONI's Seaford office on May 13, 2009;
- i. Patient 32 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on December 22, 2009;
- j. Patient 33 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on May 20, 2010;
- k. Patient 34 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on October 11, 2010;
- l. Patient 35 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on April 5, 2011;
- m. Patient 36 received an MRI with contrast, CPT code 72157, at ONI's Seaford office on January 4, 2012;

- n. Patient 37 received an MRI with contrast, CPT code 72156, at ONI's Seaford office on September 27, 2012;
- o. Patient 38 received an MRI with contrast, CPT code 70553, at ONI's Seaford office on January 7, 2013;
- p. Patient 39 received an MRI with contrast, CPT code 73720, at ONI's Seaford office on October 8, 2013;
- q. Patient 40 received an MRI with contrast, CPT code 72156, at ONI's Seaford office on May 20, 2014.

ONI Millsboro

48. In 2008, Defendant ONI opened an office at 26744 John J. Williams Highway, Suite 2, Millsboro, Delaware 19966. Beginning in October 2008 and continuing through July 2014, employees at ONI's Millsboro office injected hundreds of Medicare beneficiaries with contrast material during the performance of contrast MRI procedures. However, ONI generally provided no direct physician supervision of contrast MRI procedures performed in its Millsboro Office. ONI and Richard Pfarr nevertheless submitted or caused to be submitted claims for those procedures to Medicare.

49. In or around November 2008, ONI submitted an application to Medicare to enroll its Millsboro office. The application listed Joseph Inzinna as the physician providing "General Supervision." The application did not list a physician for provision of "Direct Supervision." On or about December 1, 2008, the Medicare administrative contractor informed ONI that, in order to process its enrollment application, ONI needed to identify a supervising physician "with the appropriate Supervision" for the type of tests it proposed to perform "or a correction to the type of Supervision" to be performed by ONI's supervising physician. On or about December 15, 2008, ONI submitted amended enrollment paperwork indicating that Joseph Inzinna would provide both "General Supervision" and "Direct Supervision." That representation was materially false. In fact, ONI had no intent to use Dr. Inzinna to provide direct supervision of

contrast MRI procedures. Pfarr signed the enrollment application and required certifications for ONI's Millsboro office.

50. Dr. Inzinna did not provide direct supervision at ONI's Millsboro office, nor has he ever visited that office. Despite that fact, ONI continued to perform and bill for contrast MRI scans from October 2008 until February 2012.

51. In or around February 2012, shortly after being notified that the government was investigating IDTF compliance with supervision requirements (*see* Paragraph 29 above), ONI generally stopped performing contrast MRI procedures to Medicare beneficiaries at its Millsboro office.

52. In early 2014, ONI resumed providing and billing for contrast MRI procedures to Medicare beneficiaries at its Millsboro office. ONI did not provide the required direct supervision of those procedures.

53. In or around November 2013, ONI created a written agreement under which Dr. Fadi Damouni would purportedly provide "on-site" supervision of contrast MRI procedures at ONI's Millsboro office. Under the agreement, ONI was to provide Dr. Damouni's Administrator with a schedule of contrast patients each week and would pay Dr. Damouni a fee of \$20.00 "per patient exam" or \$150.00 "[i]n the event that the supervising physician is needed to evaluate a patient." Pfarr signed the agreement on behalf of ONI.

54. ONI's written agreement with Dr. Damouni in 2013 was a sham created to conceal the fact that ONI did not provide direct physician supervision of contrast MRI procedures performed at its Millsboro office. Dr. Damouni was never present in ONI's office suite during contrast MRI procedures. ONI never provided Dr. Damouni or his employees with a schedule of contrast patients as required by the agreement. ONI never paid Dr. Damouni

pursuant to the agreement. Moreover, Dr. Damouni was unaware that the supervision agreement with ONI had commenced until one of his own patients underwent a contrast MRI procedure in or around July 2014. ONI and Pfarr never updated ONI's Medicare enrollment to indicate that Dr. Damouni was responsible for direct supervision at the Millsboro office.

55. Between 2008 and July 2014, ONI performed over 200 contrast MRI procedures on Medicare beneficiaries at its Millsboro office without the required direct supervision of a physician, resulting in a payment to ONI of over \$100,000. ONI and Pfarr knew that no physician was in ONI's Millsboro office suite during the performance of contrast MRI procedures. ONI and Pfarr also knew that claims that were not properly supervised were not entitled to payment from Medicare. Nevertheless, ONI and Pfarr submitted or caused to be submitted claims for payment for those services to Medicare.

56. For example, ONI and Pfarr knew that no physician was in ONI's office suite during the following contrast MRI procedures on Medicare beneficiaries, yet they submitted or caused to be submitted a claim for payment for these services to Medicare knowing that they were not entitled to be paid:

- a. Patient 41 received an MRI with contrast, CPT code 70553, at ONI's Millsboro office on October 16, 2008;
- b. Patient 42 received an MRI with contrast, CPT code 70552, at ONI's Millsboro office on May 12, 2009;
- c. Patient 43 received an MRI with contrast, CPT code 74183, at ONI's Millsboro office on December 7, 2009;
- d. Patient 44 received an MRI with contrast, CPT code 72157, at ONI's Millsboro office on August 17, 2010;
- e. Patient 45 received an MRI with contrast, CPT code 70553, at ONI's Millsboro office on June 30, 2011;
- f. Patient 46 received an MRI with contrast, CPT code 70553, at ONI's Millsboro office on January 11, 2012;

- g. Patient 47 received an MRI with contrast, CPT code 70553, at ONI's Millsboro office on January 13, 2014; and
- h. Patient 48 received an MRI with contrast, CPT code 74183, at ONI's Millsboro office on July 7, 2014.

ONI Salisbury

57. In 2012, Defendant ONI opened an office at 400 Eastern Shore Drive, Suite 104, Salisbury, Maryland 21804. Beginning in June 2012 and continuing through July 2014, employees at ONI's Salisbury office injected Medicare beneficiaries with contrast material during the performance of contrast MRI procedures. However, ONI generally provided no direct physician supervision of contrast MRI procedures performed in its Salisbury Office. ONI and Richard Pfarr nevertheless submitted or caused to be submitted claims for those tests to Medicare.

58. In or around July 2012, ONI submitted an application to Medicare to enroll its Salisbury office. The application listed Dr. Donald Wood as the physician providing "Direct Supervision." That representation was materially false. In fact, ONI had no intent to use Dr. Wood to provide direct supervision of contrast MRI procedures. Richard Pfarr signed the enrollment application and required certifications.

59. On or about August 2, 2012, ONI created a written agreement under which Dr. Wood's practice, Peninsula Cardiology Associates, P.A., would purportedly provide "on-site" supervision of contrast MRI procedures at ONI's Salisbury office. Under the agreement, ONI was to pay Peninsula Cardiology Associates a fee of \$20.00 "per patient exam" or \$150.00 "[i]n the event that the supervising physician is needed to evaluate a patient." Pfarr signed the agreement on behalf of ONI.

60. ONI's written agreement with Peninsula Cardiology Associates in 2012 was a sham created to conceal the fact that ONI generally did not provide direct physician supervision of contrast MRI procedures at its Salisbury office. Upon information and belief, ONI never paid Peninsula Cardiology Associates pursuant to the agreement.

61. Between June 2012 and July 2014, ONI performed approximately 80 contrast MRI procedures on Medicare beneficiaries at its Salisbury office, resulting in a payment to ONI of over \$25,000. ONI generally did not provide the required direct physician supervision for those procedures. ONI and Pfarr knew that no physician was in ONI's Salisbury office suite during the performance of contrast MRI procedures. ONI and Pfarr also knew that claims that were not properly supervised were not entitled to payment from Medicare. Nevertheless, ONI and Pfarr submitted or caused to be submitted claims for payment for those services to Medicare.

Failure to maintain records

62. In order to ensure that patient health and safety is appropriately protected, the Medicare regulations applicable to IDTFs require them to "maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished." 42 C.F.R. § 410.33(b)(2). When the government subpoenaed ONI for those records, no documentation showing supervision of tests requiring physician presence in the office suite was produced. On information and belief, ONI did not maintain such documentation.

CLAIMS FOR RELIEF

COUNT ONE

63. This is a claim under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) (formerly 31 U.S.C. § 3729(a)(1)).

64. The United States realleges and incorporates by reference each and every allegation contained in paragraphs 1 through 62 of this complaint.

65. Defendants ONI and Pfarr knowingly (as defined by 31 U.S.C. § 3729(b)) presented or caused to be presented false or fraudulent claims for payment or approval by the United States in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) (formerly 31 U.S.C. § 3729(a)(1)).

66. Defendants ONI and Pfarr are therefore liable to the United States, jointly and severally, for civil penalties and damages as provided in the False Claims Act, 31 U.S.C. § 3729(a).

COUNT TWO

67. This is a claim under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (formerly 31 U.S.C. § 3729(a)(2)).

68. The United States realleges and incorporates by reference each and every allegation contained in paragraphs 1 through 62 of this complaint.

69. Defendants ONI and Pfarr knowingly (as defined by 31 U.S.C. § 3729(b)) made, used, or caused to be made or used a record to get a false or fraudulent claim paid or approved by the United States in violation of the False Claims Act, 31 U.S.C. § 3729(a)(2) (2008), and/or knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (2010).

70. Defendants ONI and Pfarr are therefore jointly and severally liable to the United States for civil penalties and damages as provided in the False Claims Act, 31 U.S.C. § 3729(a).

COUNT THREE

71. This is a claim at common law for unjust enrichment.

72. The United States realleges and incorporates by reference each and every allegation contained in paragraphs 1 through 62 of this complaint.

73. By virtue of the acts described above, Defendants were unjustly enriched at the expense of the United States through the false claims submitted to Medicare during the relevant period.

74. Defendants are therefore liable to the United States for actual damages, interest and the costs associated with the investigation, prosecution and collection of the debt in this matter.

COUNT FOUR

75. This is a claim at common law for payment by mistake.

76. The United States realleges and incorporates by reference each and every allegation contained in paragraphs 1 through 62 of this complaint.

77. By virtue of the acts described above, Defendants ONI and Pfarr caused the United States to make payments by mistake for claims submitted to Medicare during the relevant period and, as a result, the United States has suffered actual damages.

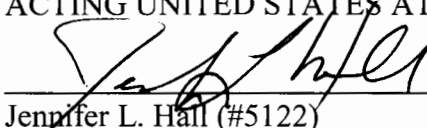
WHEREFORE, plaintiff United States of America respectfully requests that:

1. Judgment be entered against defendants in the amount of civil penalties, damages (trebled as required by law), pre- and post-judgment interest and investigative costs as allowed by law; and
2. The Court grant such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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