

**THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
WAYCROSS DIVISION**

UNITED STATES OF AMERICA)	
<i>ex rel.</i> LANA ROGERS,)	
)	Civil Action No. CV507-92
Plaintiff,)	
)	
v.)	
)	
NAJAM AZMAT, M.D., AND)	
SATILLA HEALTH SERVICES, INC., d/b/a)	
SATILLA REGIONAL MEDICAL CENTER)	
)	
Defendants.)	
_____)	

UNITED STATES' COMPLAINT

Plaintiff, the United States of America, by and through its undersigned counsel, brings this cause of action against the defendants, Satilla Health Services, Inc. d/b/a Satilla Regional Medical Center (Satilla) and Najam Azmat, M.D. (Azmat), and for its causes of action alleges as follows:

NATURE OF ACTION

1. This is an action brought by the United States to recover damages and civil penalties under the False Claims Act (FCA), 31 U.S.C. §§ 3729-33, and to recover all available damages and other monetary relief for common law or equitable causes of action for payment under mistake of fact and unjust enrichment. Each of these claims arises out of a scheme by the defendants to knowingly submit claims to federal health care programs for services that were not reasonable and necessary, were incompatible with standards of acceptable medical practice, and were worthless and of no medical value.

In the Spring of 2005, Satilla recruited Azmat, a general surgeon by training, to relocate from Kentucky to Waycross, Georgia, to set up his own practice and to join Satilla's medical staff. In August of 2005, Satilla granted Azmat general and vascular surgery privileges. Satilla recruited Azmat and allowed him to join its staff even though Satilla knew that Azmat had a history of medical competence issues. Satilla knew that at one of the hospitals where Azmat previously worked, the Medical Executive Committee, responding to an unacceptably high intra-operative and post-operative complication rate and to concern regarding the appropriateness of his procedures, restricted Azmat's privileges by requiring him to obtain a written second opinion on all of his elective procedures and to have a second surgeon participate on all of his major surgical cases. Satilla knew that the restrictions imposed by the Medical Executive Committee lasted almost three years. Satilla also knew that Azmat had been named as a defendant in three malpractice cases, at least one of which resulted in his paying a monetary settlement.

Shortly after he joined Satilla's staff, Satilla allowed Azmat to perform endovascular procedures - highly specialized operative procedures that require formal training - in Satilla's Heart Center cath lab. Azmat did so despite the fact that he lacked training to perform such procedures, was not qualified or competent to perform such procedures, had never performed such procedures before at any of the hospitals where he was on staff, and did not even have privileges at Satilla to perform such procedures.

From the very first endovascular procedures he performed in Satilla's cath lab, it was obvious to the cath lab nursing staff that Azmat was not qualified or competent to perform endovascular procedures. The nurses noted that Azmat did not know the names of the catheters, did not know the proper procedure for introducing the catheters, was not proficient at manipulating the catheters and wires, lacked knowledge regarding medications used to sedate

patients during procedures, and was not able to recognize and treat complications when they arose. The nurses repeatedly voiced their concerns to Satilla's management, but Satilla took no action for five months, during which patients were seriously injured and one died from hemorrhagic shock after Azmat had perforated her renal artery. Not only did Satilla ignore its nurses' complaints, but Satilla also performed no formal oversight of Azmat, categorically excluding all of his endovascular procedures from Satilla's peer review process.

Satilla could have suspended Azmat's privileges at any time, as its bylaws provide that the President of the Medical Staff and Chief Executive Officer have the authority to suspend all or any portion of the clinical privileges of a medical staff member who may pose a danger to patients. Suspending Azmat's privileges, however, was not in Satilla's financial interest, as Satilla counted on Azmat's endovascular procedures to help offset the drop in cath lab revenues that had occurred in September 2004, when a cardiology group that had an exclusive contract with Satilla to provide cardiology services, terminated its contract.

When it finally did take action, in January of 2006, Satilla entered into an agreement with Azmat pursuant to which he would refrain from performing endovascular procedures until he was able to demonstrate the appropriate proficiency to perform such procedures. In the agreement, both Satilla and Azmat expressly agreed that neither would report the restriction on his privileges to either the National Practitioner Data Bank (NPDB) or to the Georgia Composite Medical Board (GCMB), as was required under federal and state law respectively. And neither did ever report the restriction to either the NPDB or the GCMB.

Although Satilla categorically excluded Azmat's endovascular procedures from its peer review process, in June of 2006, well after Azmat had agreed to stop performing endovascular procedures and well after Azmat had seriously injured several patients, Satilla retained an outside

consultant to conduct a retrospective review of Azmat's endovascular cases. In the review, the consultant concluded that he had "overall concerns with Dr. Azmat's ability to adequately and safely perform endovascular procedures."

In sum, (1) Azmat was not qualified or competent to perform endovascular procedures, (2) Azmat had never, before applying for privileges at Satilla, performed any endovascular procedures of any kind on any living patients, (3) Azmat did not have privileges at Satilla to perform endovascular procedures, and (4) Satilla performed no peer review of Azmat's endovascular procedures. Accordingly, the endovascular procedures performed by Azmat at Satilla, as well as the related hospital services provided by Satilla, were not reasonable and necessary, were incompatible with standards of acceptable medical practice, and were worthless and of no medical value. In addition, federal health care program beneficiaries who underwent an endovascular procedure by Azmat at Satilla did not know of any of the aforementioned facts; had they known, they would not have consented to undergo an endovascular procedure performed by Azmat and Satilla, and no federal health care program payments would ever have been made to Azmat or Satilla for those procedures and related hospital services.

This is an action to recover the federal health care program dollars billed by and paid to Azmat and Satilla for those worthless services.

JURISDICTION

2. This action arises under the FCA and under the common law.
3. The Court has subject matter jurisdiction over this action under 28 U.S.C. § 1345 because the United States is the Plaintiff. In addition, the Court has subject matter jurisdiction over the FCA cause of action under 28 U.S.C. § 1331 and supplemental jurisdiction to entertain

the common law and equitable causes of action under 28 U.S.C. § 1367(a). The Court may exercise personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a).

VENUE

4. Venue is proper in the Southern District of Georgia under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because the defendants resided in this district during the operative period, and a substantial part of the events and omissions giving rise to these claims occurred in this district.

PARTIES

5. Plaintiff is the United States of America (hereinafter United States or Government). The United States brings this action on behalf of (a) the United States Department of Health and Human Services (HHS), including its component, the Centers for Medicare and Medicaid Services (CMS), which administers the Medicare and Medicaid Programs, and (b) the United States Department of Defense, including its component, Tricare Management Activity, which administers the TRICARE Program.

6. The Relator, Lana Rogers, is a resident and citizen of Ware County, Georgia. The Relator is a registered nurse who worked in Satilla's Heart Center cath lab from June 2002 to January 2006. As a nurse in the Heart Center, Ms. Rogers worked directly with defendant Azmat when he performed endovascular procedures. On November 13, 2007, Ms. Rogers filed a *qui tam* complaint with this Court captioned, *United States ex rel. Lana Rogers v. Najam Azmat, M.D., Satilla Health Services, Inc., d/b/a Satilla Regional Medical Center, Robert Trimm, Windell Smith, Harmon Raulerson, Jonathan Abbott, and Gregory Uhl, M.D.*, Case No. CV507-

92 (S.D. Ga.). On April 1, 2010, the United States intervened in part and declined in part in the *qui tam*.

7. Defendant Satilla Health Services, Inc. is a Georgia corporation with its principal place of business in Ware County, Georgia. Satilla operates a public acute care hospital in Ware County, at 410 Darlington Avenue, Waycross, Georgia 31501, known as “Satilla Regional Medical Center.”

8. Defendant Najam Azmat, M.D. is a resident of the state of Georgia. He resides at 707 Confederate Way, Waycross, Georgia 31503.

9. Defendants Satilla and Azmat are enrolled health care providers in Medicare, Medicaid and TRICARE.

FEDERAL HEALTH CARE PROGRAMS

A. MEDICARE

10. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare Program, as part of Title XVIII of the Social Security Act to pay for the costs of certain health care services. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426-1. The regulations implementing the Medicare Program are found at 42 C.F.R. § 409 *et seq.*

11. HHS is responsible for the administration and supervision of the Medicare Program. CMS is an agency of HHS and is directly responsible for the administration of the Medicare Program. For purposes of this action, there are two primary components to the Medicare Program, Part A and Part B. Medicare Part A authorizes payment for institutional care, including hospital, skilled nursing facilities, and home health care. *See* 42 U.S.C. § 1395c-13951i-4. Medicare Part B is a federally subsidized, voluntary insurance program that covers a

percentage of the fee schedule for physician services as well as a variety of “medical and other services.” *See* 42 U.S.C. §§ 1395j-1395w-4.

12. To participate in the Medicare Program, a health care provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the Medicare Program and in order to receive reimbursement from Medicare.

13. Medicare reimburses only services furnished to beneficiaries that are “reasonable and necessary for the diagnosis or treatment of illness or injury” 42 U.S.C. § 1395y(a)(1)(A). In submitting claims for payment to Medicare, providers must certify that the information on the claim form presents an accurate description of the services rendered and that the services were reasonably and medically necessary for the patient.

14. One of the conditions for participation in Medicare for hospitals is that the hospital “must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.” 42 C.F.R. § 482.22. In addition, the medical staff of a hospital participating in Medicare “must examine the credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.” 42 C.F.R. § 482.22(a)(2).

15. HHS has issued Interpretive Guidelines for the regulatory requirements set forth in the Medicare hospital conditions of participation. The Interpretive Guideline for section 482.22(a)(2) provides that “[t]here must be a mechanism established to examine credentials of individual prospective members (new appointments or reappointments) by the medical staff. The individual’s credentials to be examined must include at least:

- A request for privileges;
- Evidence of current licensure;
- Evidence of training and professional education;
- Documented experience; and
- Supporting references of competence

... The medical staff ... must consider all of the above.”

16. Another Medicare condition of participation for hospitals is that the hospital must “develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement [QAPI] program.” 42 C.F.R. § 482.21. As part of its QAPI program, the hospital “must set priorities for its performance improvement activities that (i) focus on high-risk, high-volume, or problem-prone areas; (ii) consider the incidence, prevalence, and severity of problems in those areas; and (iii) affect health outcomes, patient safety, and quality of care.” *Id.* § 482.21(c)(1). Finally, the hospital “must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms[.]” *Id.* § 482.21(c)(2).

1. Medicare Part A

17. Part A of the Medicare program authorizes payment for institutional care, including hospitalization, for eligible patients.

18. Under Medicare Part A, hospitals enter into an agreement with Medicare to provide health care items and services to treat Medicare patients. The hospital, also called a “provider,” is authorized to bill Medicare for that treatment.

19. Most hospitals, including Satilla, derive a substantial portion of their revenue from the Medicare program.

20. During the relevant time period, HHS reimbursed hospitals for inpatient Part A services through Medicare contractors referred to as fiscal intermediaries.

21. Fiscal intermediaries are private insurance companies that are responsible for determining the amount of payments to be made to providers. Under their contracts with HHS, fiscal intermediaries review, approve, and pay Medicare bills, called “claims,” received from hospitals. Those claims are paid with federal funds.

22. In order to get paid, a hospital completes and submits a claim for payment on a Form UB-92. This form contains patient-specific information including the diagnosis and types of services that are assigned or provided to the Medicare patient. The Medicare program relies upon the accuracy and truthfulness of the UB-92 to determine whether and what amounts the hospital is owed.

23. In addition, and at the end of each fiscal year, a hospital submits a form referred to as a “cost report” to the fiscal intermediary which identifies any remaining or outstanding costs that the hospital is claiming for reimbursement for that year. The cost report serves as the final claim for payment that is submitted to Medicare. The Medicare program relies upon the accuracy and truthfulness of the cost report to determine whether and what amounts the hospital is owed, or what has been overpaid during the year.

24. In 1983, Congress established the prospective payment system (PPS) as the system by which hospitals are reimbursed for inpatient hospital costs. Under PPS, the amount Medicare pays a hospital for treating an inpatient Medicare beneficiary is based in large part on the particular illness or condition that led to the patient’s admission, or was the patient’s illness or condition that was principally treated by the hospital.

25. Under PPS, a patient's illness or condition is categorized under a classification system called a diagnostic related group (DRG). In short, the DRG establishes how much the hospital will be paid under Medicare and is based on a weighting factor that reflects the resources the patient's condition or certain procedure typically requires. The fiscal intermediary uses the patient specific information (for example, the diagnosis codes) submitted by the hospital on the UB-92 to determine what DRG is assigned to a certain claim, and hence, what amount will be paid.

26. Hospital outpatient procedures are reimbursed on a fee-for-service basis under the outpatient prospective payment system. 42 C.F.R. § 419 *et seq.* Medicare reimburses hospitals for outpatient procedures based on which ambulatory payment classification the procedures falls under. *Id.* § 419.31. The payment classifications are set forth at 65 Fed. Reg. 18,434 (Apr. 7, 2000).

2. Medicare Part B

27. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. Eligible individuals who are 65 or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums as established by HHS. However, payments under Medicare Part B are often made directly to service providers, such as physicians, rather than to the patient/beneficiary. This occurs when the provider accepts assignment of the right to payment from the patient/beneficiary. In that case, the provider bills the Medicare Program directly.

28. The United States provides reimbursement for Medicare claims from the Medicare Trust Fund through CMS. To assist in the administration of the Medicare Part B Program, CMS contracts with carriers. 42 U.S.C. § 1395u. Carriers, typically insurance

companies, are responsible for processing the payment of Medicare Part B claims to providers on behalf of CMS.

29. In order to bill Medicare, a provider must submit an electronic or hard-copy claim form called a CMS 1500 form to the carrier. When the CMS 1500 is submitted, the provider certifies that the services for which payment is sought were “medically indicated and necessary for the health of the patient.” Providers wishing to submit the CMS 1500 electronically must first submit a provider enrollment form.

30. For a CMS 1500 claim to be paid by the Medicare Part B Program, the claims must identify each service rendered to the patient/beneficiary by the provider by a corresponding code for such services listed in the American Medical Association (AMA) publication called the Current Procedural Terminology (CPT) Manual. The CPT is a systematic listing of codes for procedures and services performed by or at the direction of a physician. Each procedure or service is identified by a five digit CPT numeric code.

31. In addition to the CPT Manual, the AMA publishes the International Classification of Diseases (ICD-9) Manual, which assigns a unique numeric identifier to each medical condition. In order to be payable by Medicare, the CMS 1500 claim form must identify (a) the CPT code the provider is billing for and (b) the corresponding ICD-9 code that identifies the patient’s medical condition that renders the procedure or service medically necessary.

B. MEDICAID

32. The Medicaid Program, as enacted under Title XIX of the Social Security Act of 1965, 42 U.S.C. § 1396-96v, is a system of medical assistance for indigent individuals. Though federally created, the Medicaid Program is a joint federal-state program in which the United

States provides a significant share of funding. The Medicaid Program in the state of Georgia covers, among other things, the cost of hospital and physician services.

33. CMS administers Medicaid on the federal level. Within broad federal rules, however, each state decides who is eligible for Medicaid, the services covered, payment levels, and administrative and operation procedures. The state pays healthcare providers directly with the state obtaining the federal share of the payment from accounts that draw on funds from the United States Treasury. 42 C.F.R. §§ 430.0-430.30. The Secretary of HHS determines each state's federal share of most healthcare costs using a formula based on average state per capita income compared to the national U.S. average. These matching rates are updated every year to reflect changes in average income. The federal assistance percentage for the state of Georgia in 2005 and 2006 was approximately 60 percent.

34. The state of Georgia administers its Medicaid Program through the Georgia Department of Community Health, Division of Medical Assistance.

35. The Georgia Medicaid Program has promulgated the Georgia Medicaid State Plan (State Plan). The State Plan specifically excludes from coverage "services and supplies which are inappropriate or medically unnecessary as determined by" the authorized state agencies. State Plan, attachment 3.1-A, p. 1c, under "non covered services and procedures," ¶ 1.

36. In its provider manuals, the Georgia Department of Community Health, Division of Medical Assistance sets forth the conditions under which it will pay for health care services. As a continued condition for accepting Medicaid, providers agree to "[b]ill the Division only for those covered services that are medically necessary and within accepted professional standards of practice." Georgia Dep't of Community Health, Div. of Medical Assistance, Part I Policies and Procedures for Medicaid/PeachCare for Kids, Sec. 106(k). The term "medically necessary"

is defined as “medical services” that are “compatible with the standards of accepted medical practice.” *Id.* Definition 19.

37. Additionally, to participate in Medicaid, the provider must sign a Medicaid participation agreement.

38. Under that agreement, the provider agrees that “[b]y submitting claims for reimbursement, [the] Provider certifies that Covered Services were medically necessary”

Id. App. H, Sec. 2.

C. TRICARE

39. TRICARE, formerly known as CHAMPUS, is a federal health benefits program, established by 10 U.S.C. §§ 1071-1110, that offers a triple option benefit plan: an HMO option; a PPO option; and a fee for service option. TRICARE is administered by the Secretary of Defense. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

40. The regulatory authority establishing the TRICARE program provides reimbursement to individual health care providers applying the same reimbursement scheme and coding parameters that the Medicare program applies. 10 U.S.C. §§ 1079(j)(2) (institutional providers), (h)(1)(individual health care professional) (citing 42 U.S.C. 1395, *et seq.*).

41. TRICARE will pay only for “medically necessary services and supplies required in the diagnosis and treatment of illness or injury.” 32 C.F.R. § 199.4(a)(1)(i).

42. With respect to “professional services,” including services provided by a physician, services must be “provided in accordance with good medical practice and established standards of quality.” 32 C.F.R. § 199.4(c)(1). In addition, covered professional services “must

be rendered in connection with and directly related to a covered diagnosis or definitive set of symptoms requiring medically necessary treatment.” 32 C.F.R. § 199.4(c)(1)(ii).

43. Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness or injury are specifically excluded from coverage. 32 C.F.R. § 199.4(g)(1).

44. TRICARE prohibits practices such as submitting claims for services which are not medically necessary, consistently furnishing medical services that do not meet accepted standards of care, and failing to maintain adequate medical records. 32 C.F.R. §§ 199.9(b)(3)-(b)(5). Such practices are deemed abusive and cause financial loss to the United States. 32 C.F.R. §§ 199.9(b).

FACTS

A. ENDOVASCULAR PROCEDURES

45. Endovascular procedures are invasive procedures that are performed within arteries and veins. These procedures are performed through a small puncture in the skin, as opposed to traditional “open” procedures, which are performed through an incision in the skin and typically require longer recuperation time.

46. The basic technique involves introducing a catheter percutaneously - through the skin - to access the inside of arteries or veins. Typically, the catheter is introduced near the groin in the femoral artery or vein. Endovascular procedures performed on coronary, carotid, cerebral and renal arteries, for example, can be done by percutaneously accessing the femoral artery.

47. The technique by which the catheter is percutaneously introduced in a vessel is known as the Seldinger Technique, which was originally described in 1953.

- First, a needle is inserted into the femoral artery.

- A guide wire is then inserted into the lumen of the needle and advanced into the artery.
- The needle is then removed over the wire, while the guide wire is held securely in place to maintain access to the inside of the artery.
- A sheath with a dilator in it is then advanced over the wire and rotated back and forth. The dilator opens up the insertion site and facilitates the introduction of the catheter. The dilator is then removed, but the sheath is left in place.
- The catheter is inserted over the guide wire, but inside the sheath, and into the artery.
- Finally, the guide wire is removed, with the catheter held securely in place in the artery.

48. Endovascular procedures were originally developed for diagnostic purposes. The catheter through which the inside of the arteries or veins is accessed is injected with a radio-opaque contrast that can be seen on a live real-time X-ray (fluoroscopy) and can be permanently archived digitally or on film. (This medical imaging technique is known as angiography or arteriography.) As the contrast courses through the vessels, the resulting images seen can assist in the diagnosis of diseases such as atherosclerosis (the process by which plaque builds up in arteries, narrowing the artery and causing stenosis), vascular trauma, or aneurysms (an abnormal widening or ballooning of an artery due to injury or weakness in the artery wall that renders the artery susceptible to rupture).

49. More recently, endovascular procedures came to be performed for therapeutic, as well as diagnostic, purposes. For example, blockages detected in arteries and veins may be

treated by balloon angioplasty (explained below), placement of stents (explained below), and thrombolysis (the use of clot dissolving drugs).

50. With balloon angioplasty, a deflated balloon catheter is threaded through the vascular tree and advanced until it is positioned at the site of narrowing. Once there, the balloon is inflated, pushing outward against the wall of the artery, thereby widening the artery and improving or restoring blood flow through it.

51. Stents are small fine wire devices that are sometimes used in conjunction with balloon angioplasty. Stents are placed inside an artery or vein and act as a scaffold to hold the vessel open, after a balloon angioplasty is performed to widen the vessel. A balloon may be inflated adequately but the artery may not remain open due to elastic recoil; in these cases, a stent may be placed to serve as a scaffold that holds the artery open.

52. Angiography, balloon angioplasty, stenting and/or thrombolysis may be performed as part of either an endovascular procedure or an open peripheral vascular bypass procedure. What differentiates an endovascular procedure from an open vascular procedure is that in an endovascular procedure the inside of the vessels is accessed percutaneously, through a puncture in the skin, whereas in an open vascular procedure the vessels are accessed through an open surgical incision. Moreover, in an open vascular procedure, there is direct visualization of the surgical field whereas in an endovascular procedure visualization is indirect and through the use of x-ray or fluoroscopy.

B. AZMAT - PRE-SATILLA

1. Education and Training

53. Azmat graduated from Khyber Medical College, of the University of Peshawar, in Pakistan, in 1982.

54. Azmat completed a two year internship at D.C. General Hospital in June of 1989.

55. Azmat completed a second internship at Brookdale Hospital Medical Center, in Brooklyn, New York, in June of 1990.

56. In June of 1995, Azmat completed a five year residency in general surgery at Catholic Medical Center, in Jamaica, Queens, New York.

57. During his residency at Catholic Medical Center, Azmat did not receive formal endovascular training and did not perform endovascular procedures.

58. In June of 1996, he completed a one-year unaccredited vascular surgery fellowship at St. Vincent Medical Center (SVMC), in Toledo, Ohio.

59. During that year at SVMC, Azmat did not receive endovascular training and did not perform endovascular procedures.

2. Hardin Memorial Hospital - Elizabethtown, Kentucky

60. In October of 1996, Azmat joined the staff of Hardin Memorial Hospital (Hardin), in Elizabethtown, Kentucky, where he had privileges to perform general and vascular surgery procedures.

61. By letter dated October 29, 1997, approximately one year after joining Hardin's staff, Azmat was notified that his privileges were being restricted.

62. As part of Hardin's quality review process, the Medical Executive Committee had determined that 23 percent of Azmat's surgeries had either an intra-operative or post-operative complication.

63. Based on that high complication rate, the Medical Executive Committee required that (1) all of Azmat's elective procedures have a second opinion obtained and attached to the patient chart before the procedure could be scheduled; and (2) for all major surgical cases, a list

of which is enumerated on the October 29, 1997 letter, Azmat have a second physician assisting with the case.

64. As it was required to do by law, Hardin filed an Adverse Action Report (Report) with the National Practitioner Data Bank (NPDB) regarding the restriction on Azmat's privileges.

65. The Report cites a "concerning rate of intraoperative and post operative complications and concern with appropriateness of procedures" and states that Hardin required a second opinion for all elective surgical cases and a second assistant surgeon for all vascular surgery cases and some major general surgery cases.

66. Azmat's privileges remained restricted at Hardin until April 17, 2000.

67. While he practiced at Hardin, Azmat did not have privileges to perform, and did not perform, endovascular procedures.

3. Trover Clinic - Madisonville, Kentucky

68. Azmat left Hardin in July of 2002.

69. In August of 2002, Azmat joined the staff of the Trover Clinic (Trover), in Madisonville, Kentucky. Azmat had privileges at Trover to perform general and vascular surgery procedures.

70. While he practiced at Trover, Azmat did not have privileges to perform, and did not perform, endovascular procedures.

71. Azmat left Trover in September of 2004.

4. *Locum Tenens* Positions in Louisiana and Maine

72. Azmat did not hold a full-time staff position again until he joined the staff of Satilla in July of 2005.

73. Between Trover and Satilla, Azmat worked as a *locum tenens* physician, first at the Veterans Administration Medical Center (VAMC) in Alexandria, Louisiana, and then at Central Maine Medical Center (CMMC) in Lewiston, Maine. As a *locum tenens* physician, Azmat held temporary staff privileges at these hospitals.

74. At the VAMC, where Azmat worked from November of 2004 through March of 2005, Azmat had temporary privileges to perform general surgery procedures.

75. While Azmat was temporarily on staff at the VAMC, he did not have privileges to perform, and did not perform, endovascular procedures.

76. At CMMC, where Azmat worked from April through July of 2005, Azmat had privileges to perform general surgery procedures.

77. While he was temporarily on staff at CMMC, he did not have privileges to perform, and did not perform, endovascular procedures.

78. When it granted Azmat temporary privileges, the CMMC Medical Board considered whether to grant Azmat privileges to perform endovascular procedures and vascular surgery procedures.

79. As it was required to do under section 482.22(a)(2) of the Medicare conditions of participation for hospitals, the CMMC Medical Board reviewed the documentation supporting Azmat's privilege application. The CMMC Medical Board found no documentation to support granting Azmat privileges to perform endovascular procedures and no adequate documentation to support granting Azmat privileges to perform advanced vascular surgery procedures. Azmat then withdrew his request for privileges to perform endovascular and advanced vascular procedures at CMMC.

C. SATILLA LOOKS TO OFFSET A DROP IN ITS HEART CENTER REVENUES AS TWO CARDIOLOGISTS RELOCATE

80. In 2001, Satilla entered into a contract with South Georgia Cardiology Associates, P.C. (SGCA), a professional corporation formed by two cardiologists, Drs. Willie Bell and Joel Ferree, who had held privileges to practice cardiology at Satilla since 1989.

81. Under the contract, SGCA would be the “exclusive provider of Cardiovascular Services” at Satilla.

82. In September of 2004, Drs. Bell and Ferree notified Satilla that SGCA was terminating its contract with Satilla but that Drs. Bell and Ferree planned to continue practicing at Satilla in their personal capacities pursuant to the privileges that had been granted to them and renewed on an ongoing basis since 1989.

83. In response, Satilla notified Drs. Bell and Ferree that their privileges were being automatically terminated and that they would no longer be permitted to practice cardiology at all at Satilla.

84. On January 28, 2005, Satilla entered into a contract with a new physician group under which the new group would become the new exclusive provider of cardiovascular services at Satilla.

85. On January 31, 2005, Drs. Bell and Ferree filed a complaint in the Georgia Superior Court, Ware County, seeking, among other things, a permanent injunction prohibiting Satilla from limiting Drs. Bell and Ferree’s ability to exercise their clinical privileges to practice cardiology at Satilla.

86. On February 15, 2005, after holding an evidentiary hearing, the trial court granted the preliminary injunction in favor of Drs. Bell and Ferree.

87. Satilla appealed, but the Court of Appeals of Georgia affirmed the trial court's decision.

88. Although Drs. Bell and Ferree prevailed in their suit to retain their privileges at Satilla, after SGCA terminated its contract with Satilla, Drs. Bell and Ferree relocated their practice and began to perform many procedures that they previously performed at Satilla at their new practice location.

89. After SGCA terminated its contract with Satilla, and Drs. Bell and Ferree relocated to a different practice setting, Satilla experienced a 25 percent decrease in its cath lab volume, a 39 percent decrease in its nuclear studies volume, and a 50 percent decrease in its Holter procedure volume.

90. After SGCA terminated its contract with Satilla, and Drs. Bell and Ferree relocated to a different practice setting, Satilla experienced a drop of 35 percent or more in volume of procedures performed in its Heart Center.

91. After SGCA terminated its contract with Satilla, and Drs. Bell and Ferree relocated to a different practice setting, Satilla experienced a drop in revenues from its Heart Center.

92. Satilla expected that Azmat's performance of endovascular procedures in the cath lab would help to offset the drop in procedure volume and revenues following the relocation of Drs. Bell and Ferree.

D. AZMAT APPLIES FOR AND RECEIVES ONLY GENERAL AND VASCULAR SURGERY PRIVILEGES AT SATILLA

1. Summer 2004 Interview with Dr. Travis Paul

93. Azmat first considered joining the Satilla staff in the summer months of 2004, when he was working at Trover.

94. In the summer of 2004, Azmat responded to an advertisement by a group of surgeons, including Dr. Travis Paul, who practiced at Satilla and were looking to add a member to the group.

95. At that time, Dr. Paul was a member of Satilla's medical staff and held the position of Chairman of the Department of Surgery of Satilla.

96. In the summer of 2004, Azmat interviewed with Dr. Paul and his group, but was not extended an offer to join the group.

2. Spring 2005 Application for Privileges at Satilla

97. Approximately one year later, in the Spring of 2005, Azmat began negotiating with the management of Satilla to join its staff and set up his own surgical practice in Waycross, Georgia.

98. Satilla's credentialing policy states that "[e]valuation of the applicant for privileges requested shall be based upon the applicant's education, training, experience, references, demonstrated clinical competencies including clinical judgment, technical skills and ability and utilization patterns and other relevant information."

99. Satilla's Medical Staff Bylaws provide that "[p]rivileges will be granted . . . only after applicant meets the criteria related to current licensure, relevant training and experience, demonstrated competence and the ability to perform the requested privileges."

100. On June 18, 2005, Azmat submitted to Satilla a pre-application form for privileges. On that form, Azmat indicated that his specialties were general and vascular surgery.

101. Azmat did not list endovascular procedures as a specialty on the pre-application form he submitted to Satilla.

102. On June 18, 2005, Azmat also submitted a Credentialing Application form to Satilla.

103. Azmat's Credentialing Application form refers to the NPDB Report filed by Hardin Hospital.

104. The Credentialing Application also lists three medical malpractice cases that had been filed against Azmat in the past, one of which was settled out of court with a monetary payment by Azmat.

105. In support of his Credentialing Application form, Azmat had seven physicians each complete a Confidential Evaluation form on his behalf and submit that form to Satilla.

106. The Confidential Evaluation forms list the procedures for which Azmat was seeking privileges at Satilla.

107. The procedures for which Azmat was applying for privileges at Satilla were general and vascular surgery procedures as well as three special procedures: advanced laparoscopic procedures, ventilator management, and carotid endarterectomy.

108. The list of procedures on the Confidential Evaluation forms does not include endovascular procedures.

109. The word "endovascular" does not even appear on the Confidential Evaluation forms.

110. The procedures for which Azmat was applying for privileges at Satilla did not include endovascular procedures.

111. At the time that Azmat submitted his application for privileges at Satilla in June of 2005, he had never before performed an endovascular procedure of any kind on a living patient.

112. The seven physicians who completed the Confidential Evaluation forms on behalf of Azmat each recommended that he be granted privileges to perform the procedures that were listed on those forms, with the following three exceptions: (1) Dr. Patrick Murray, the Chair of the Department of Surgery at VAMC, noted that Azmat did not perform vascular procedures at VAMC; (2) Dr. Larry Hopperstead, the Chief Medical Officer of CMMC, did not recommend without reservation that Azmat be granted privileges to perform advanced laparoscopy, carotid endarterectomy or moderate sedation procedures; and (3) Dr. Cora Veza, the President of Hardin's Medical Staff, made no recommendation at all on the form, and attached a separate letter describing the restrictions that Hardin had placed on Azmat's privileges.

113. Because the procedures listed on the Confidential Evaluation forms did not include, or even make any reference to, endovascular procedures, when the physicians who completed these forms on Azmat's behalf recommended on these forms that Azmat be granted privileges at Satilla, the physicians were not recommending and did not recommend that Azmat be granted privileges to perform endovascular procedures at Satilla.

114. On or about August 8, 2005, Satilla granted Azmat privileges to perform general and vascular surgery procedures, as well as three special procedures: advanced laparoscopic procedures, ventilator management, and carotid endarterectomy.

115. The procedures for which Satilla granted Azmat privileges were the same procedures that were listed on the Confidential Evaluation forms that the seven physicians with whom Azmat had previously worked had completed on his behalf.

116. The word "endovascular" does not appear on the list of procedures for which Azmat was granted privileges by Satilla.

117. The privileges that Satilla granted to Azmat on or about August 8, 2005 do not include endovascular procedures.

118. In between June 18, 2005, the date that Azmat submitted his application to Satilla for privileges, and August 8, 2005, the date that Satilla granted privileges to Azmat, no one at Satilla, including any Satilla administrator or anyone on Satilla's Credentialing Committee, ever asked Azmat a single question about his training, experience or competence to perform endovascular procedures.

3. Azmat's Application for Privileges Bypassed Dr. Paul

119. When Satilla was considering whether to bring Azmat onto its staff, Dr. Paul, who had interviewed Azmat a year earlier for a position in Dr. Paul's group, and was the Chairman of the Department of Surgery, told Robert Trimm, Satilla's Chief Executive Officer (CEO), that Satilla should investigate very carefully why Azmat was so anxious to leave Kentucky and why he had been unable to find a full-time position after leaving Trover.

120. Under Section VIII of Satilla's Credentialing Policy, the Chairman of the Department of Surgery in which the applicant seeks privileges is supposed to review the application and supporting documentation and to transmit a written recommendation to the Medical Executive Committee.

121. Despite the fact that Dr. Paul was the Chairman of the Department Surgery when Azmat submitted his application for privileges to Satilla, Dr. Paul was not given - and indeed never saw - Azmat's application for privileges or supporting documentation.

122. Azmat's privileges application and supporting documentation were reviewed, and a written recommendation was prepared by an Acting Chairman, when Dr. Paul was on a short and rare family vacation.

4. The Recruitment Agreement

123. On June 27, 2005, Satilla and Azmat entered into a Recruitment Agreement, pursuant to which Satilla agreed to pay Azmat a signing bonus of \$25,000, pay for Azmat's reasonable moving expenses, and guarantee Azmat a salary of \$600,000 for his first year at Satilla.

124. At the time that the Recruitment Agreement was executed, thereby obligating Satilla to pay Azmat a signing bonus and moving expenses, and to guarantee his salary, Azmat was not even on Satilla's staff.

125. In fact, at the time the Recruitment Agreement was executed, the only information that Satilla had regarding Azmat was his application for privileges and the NPDB Report.

126. At the time that the Recruitment Agreement was executed, none of the seven physician Confidential Evaluation forms had been provided to Satilla.

E. WHEN IT GRANTED AZMAT GENERAL AND VASCULAR SURGERY PRIVILEGES, SATILLA DID NOT HAVE ANY DOCUMENTS INDICATING THAT AZMAT WAS TRAINED OR HAD EXPERIENCE IN PERFORMING ENDOVASCULAR PROCEDURES

127. When it granted Azmat privileges, Satilla did not have any documentation indicating that Azmat was trained or had experience in performing endovascular procedures.

128. When it granted Azmat privileges, Satilla did not have any documentation indicating that Azmat had previously been granted privileges to perform endovascular procedures.

129. The only pertinent training that Azmat had, in fact, received in endovascular procedures before joining the staff at Satilla was a two day course, on June 29 and 30, 2005, at the Terrebonne General Medical Center, in Houma, Louisiana.

130. Satilla, however, did not even know about Azmat's participation in the Terrebonne course when, in August of 2005, it granted Azmat privileges and when, in September of 2005, it allowed Azmat to begin to perform endovascular procedures in Satilla's cath lab.

131. Satilla only learned that Azmat had attended the two day course at Terrebonne on October 23, 2005, well after (1) Satilla had already permitted Azmat to perform endovascular procedures in the cath lab; (2) nurses in the cath lab had already raised concerns with Satilla's management regarding Azmat's incompetence; and (3) Azmat already had put patients who underwent endovascular procedures at serious risk of injury and death.

132. On his application for the Terrebonne course, which was completed before Azmat applied for privileges at Satilla, Azmat indicated that his reason for attending the course was that he was going to be starting an endovascular program at his new location.

133. Azmat knew that he would be performing endovascular procedures at Satilla even before he applied for and received privileges at Satilla and despite the fact that the privileges for which he applied and were granted did not include endovascular procedures.

134. Satilla also knew, even before Azmat applied for privileges at Satilla, that Azmat planned on performing endovascular procedures when he joined the Satilla staff.

F. SATILLA'S PEER REVIEW PROGRAM

135. Under Satilla's Medical Staff Bylaws, all medical staff members must participate in and be subject to the peer review program.

136. In addition, under Satilla's Medical Staff Bylaws, the responsibilities of the department chairperson include monitoring and evaluating the quality and appropriateness of care and conducting peer review of all members within that department.

137. It is the policy of the medical staff at Satilla to provide an effective process for peer review.

138. Satilla's peer review program is supposed to be timely and supposed to continuously improve the quality of care provided to Satilla's patients.

139. Under Satilla's peer review program, there are 24 peer review criteria.

140. If a case meets any one of these criteria, then a peer review is supposed to be initiated.

141. Included in the 24 criteria that are supposed to trigger a peer review at Satilla are the following:

- Death (Satilla peer review criteria code A91001);
- Clinical indication for surgery not met (A91006);
- Repair of laceration, tear or puncture of an organ subsequent to surgical or invasive procedure (A91012);
- Unplanned removal, injury or harm to tissue (A91013); and
- Documented complaints (by patient, nurse, physician, support staff, family) attributed to physician (A91030).

142. Under Satilla's peer review program, a physician within the relevant department reviews the case that met one or more of the peer review criteria and submits a report to the department chairperson.

143. The department chairperson then evaluates the report and determines if the care was deficient and should be reviewed by the entire department at a monthly department-wide meeting.

144. The department will then review the case and determine the severity level, remedial action plan, and follow up plan.

G. AZMAT BEGINS PRACTICING AT SATILLA, AND SATILLA ALLOWS HIM TO PERFORM ENDOVASCULAR PROCEDURES

145. On or about August 8, 2005, Azmat received privileges to practice at Satilla.

146. The privileges applied for by Azmat and granted by Satilla did not include endovascular procedures.

147. On or about September 16, 2005, Azmat began to perform endovascular procedures at Satilla.

148. Azmat performed endovascular procedures at Satilla from September of 2005 until December of 2006.

149. Satilla did not do any peer review of any of the endovascular procedures performed by Azmat, including procedures that met one or more of the 24 peer review criteria in Satilla's peer review program.

150. Azmat performed endovascular procedures at Satilla despite the fact that he was not qualified or competent to perform endovascular procedures and that he did not have privileges to perform endovascular procedures.

151. Satilla permitted Azmat to perform endovascular procedures even though Azmat was not qualified or competent to perform endovascular procedures and did not have privileges to perform endovascular procedures.

152. The endovascular procedures performed by Azmat at Satilla, and the hospital services provided by Satilla that were related to those endovascular procedures, were not reasonable and/or necessary services, were incompatible with standards of accepted medical

practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid, and TRICARE.

153. Azmat knew that the endovascular procedures he performed at Satilla were not reasonable and/or necessary, were incompatible with standards of accepted medical practice, and not payable by Medicare, Medicaid and TRICARE, and that the hospital services related to those endovascular procedures were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and not payable by Medicare, Medicaid and TRICARE, but Azmat presented and caused to be presented claims for payment to Medicare, Medicaid and TRICARE for those endovascular procedures and related hospital services anyway.

154. Satilla knew that the endovascular procedures Azmat performed at Satilla were not reasonable and/or necessary, were worthless and of no medical value, and not payable by Medicare, Medicaid and TRICARE, and that the hospital services related to those endovascular procedures were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and not payable by Medicare, Medicaid and TRICARE, but Satilla presented and caused to be presented claims for payment to Medicare, Medicaid and TRICARE for those endovascular procedures and related hospital services anyway.

155. Had the federal health care program beneficiaries on whom Azmat performed an endovascular procedure known that Azmat was not competent or qualified and did not have privileges at Satilla to perform such procedures, those beneficiaries would not have consented to undergo the procedure performed by Azmat at Satilla, and federal health care programs would not have made payment for those procedures or the related hospital services.

156. The claims for payment presented and caused to be presented by Azmat for the endovascular procedures he performed at Satilla, and by Satilla for the hospital services it provided that were related to the endovascular procedures performed by Azmat at Satilla, were false and fraudulent because the endovascular procedures and related hospital services were not reasonable and/or necessary, were incompatible with standards of accepted medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid, and/or TRICARE.

157. Azmat presented at least 61 claims for payment to Medicare and Medicaid for the endovascular procedures he performed at Satilla.

158. Azmat received at least \$10,761 from Medicare and \$135 from Medicaid for the endovascular procedures he performed at Satilla.

159. Satilla presented at least 45 claims for payment to Medicare, Medicaid, and TRICARE for hospital services related to the endovascular procedures performed by Azmat at Satilla.

160. Satilla received at least \$180,784 from Medicare, \$43,810 from Medicaid, and \$30,533.72 from TRICARE for the hospital services billed to those programs that were related to the endovascular procedures performed by Azmat at Satilla.

161. Attached hereto, and incorporated herein, is Exhibit 1, which includes some of the false and fraudulent claims for payment presented and/or caused to be presented by Azmat and Satilla for endovascular procedures performed by Azmat at Satilla, and hospital services provided by Satilla that were related to those endovascular procedures. All of the claims for payment on Exhibit 1 are false and fraudulent because the endovascular procedures and hospital services related to those procedures on the claims were not reasonable and/or necessary, were

incompatible with standards of accepted medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid, and/or TRICARE.

162. For each false and fraudulent claim for payment listed thereon, Exhibit 1 contains, among other things, the patient name, HIC number, payer, claim number, procedure performed, related hospital services provided, diagnosis code, date of service, date the claim was submitted, amount claimed, and amount paid. In order to protect the privacy of the patients, Exhibit 1 was filed under seal. A copy of Exhibit 1 was served upon the defendants.

163. By way of example, Azmat and Satilla presented and/or caused to be presented the following false or fraudulent claims for payment for endovascular procedures performed by Azmat at Satilla, and related hospital services provided by Satilla. (The following examples can be found on Exhibit 1 as Patient 32, Patient 9, Patient 2, Patient 11, Patient 25, Patient 6, and Patient 21.)

Patient 32

164. On October 14, 2005, Azmat performed an aortogram with right renal arteriogram, right renal angioplasty and stent placement on patient 32.

165. On the operative report, Azmat indicated that the pre- and postoperative diagnoses were high grade stenosis of the right renal artery.

166. The renal arteriogram did not, in fact, show a significant degree of stenosis. Accordingly, the right renal angioplasty and placement of the stent were not medically necessary.

167. The unnecessary stent placed by Azmat in the patient's right renal artery was too large; the diameter of the stent was larger than the diameter of the renal artery.

168. By placing a stent that was too large, Azmat put the patient at a higher than expected risk for subsequently developing an aneurysm or perforation.

169. Following the procedure, the patient began to bleed from the site where the catheter was inserted in her left femoral artery.

170. Azmat was not able to control the bleeding from the puncture site, and took the patient to the operating room that same day, where the patient was placed under general anesthesia, and Azmat had to make an open incision over the puncture site and surgically repair that patient's femoral artery.

171. Although bleeding from the puncture site may occur, bleeding that is so extensive that it requires operative repair is an extremely rare complication.

172. This case met peer review criteria A91006 because the clinical indication for the right renal angioplasty and placement of the stent was not met.

173. This case met peer review criteria A91012 because Azmat had to repair the patient's left femoral artery following the right renal angioplasty and stent placement.

174. Satilla did not, however, perform peer review of this case.

175. On November 18, 2005, Satilla presented a claim to Medicaid for \$19,364.25 for hospital services it provided to patient 32 that were related to the aortogram, right renal angioplasty and stent placement performed by Azmat on October 14, 2005.

176. Satilla received \$10,872.56 from Medicaid for the hospital services it provided to patient 32 that were related to the aortogram, right renal angioplasty and stent placement performed by Azmat on October 14, 2005.

177. The claim for payment presented by Satilla for the hospital services it provided that were related to endovascular procedures performed by Azmat on patient 32 on October 14,

2005 was false and fraudulent because the endovascular procedures performed by Azmat, and related hospital services provided by Satilla, were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicaid.

Patient 9

178. On November 2, 2005, Azmat attempted to perform a left common iliac artery angioplasty on patient 9 at Satilla.

179. Azmat was not able to perform the angioplasty after multiple attempts.

180. During one of those many attempts, Azmat dissected the patient's left iliac artery with the guide wire and catheter.

181. The dissection of the left iliac artery placed the patient at higher than normal risk for progressive arterial occlusion with limb loss and for developing an aneurysm and rupture of the artery.

182. This case met peer review criteria A91013 because when Azmat dissected the patient's left iliac artery, there was unplanned injury and harm to tissue.

183. Satilla did not, however, perform peer review of this case.

184. On April 10, 2006 and October 30, 2007, Azmat presented claims to Medicare totaling \$3665 for the endovascular procedures he attempted to perform on patient 9 on November 2, 2005.

185. Azmat received \$435.21 from Medicare for the endovascular procedures he attempted to perform on patient 9 on November 2, 2005.

186. On December 28, 2005, Satilla presented a claim to Medicare for \$4697.37 for hospital services it provided to patient 9 that were related to the endovascular procedures attempted by Azmat on November 2, 2005.

187. Satilla received \$821.36 from Medicare for the hospital services it provided to patient 9 that were related to the endovascular procedures attempted by Azmat on November 2, 2005.

188. The claims for payment presented by Azmat and Satilla for the endovascular procedures attempted or performed by Azmat on patient 9 on November 2, 2005 at Satilla, and related hospital services provided by Satilla, were false and fraudulent because the endovascular procedures attempted or performed by Azmat, and related hospital services provided by Satilla, were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicaid.

Patient 2

189. On November 17, 2005, Azmat performed a left renal arteriogram, angioplasty and stent placement on patient 2 at Satilla.

190. The operative report dictated by Azmat states that the patient had high grade stenosis of his left renal artery.

191. The renal arteriogram, which was of poor quality, did not, in fact, show a significant degree of stenosis.

192. Accordingly, the left renal angioplasty and stent placement were not medically necessary.

193. During the procedure, Azmat perforated a branch of the patient's left renal artery.

194. There is no mention in the operative report or medical record that Azmat had perforated a branch of the patient's left renal artery.

195. Azmat did not recognize that he had perforated a branch of the patient's left renal artery.

196. The arterial perforation should have been recognized and treated immediately.

197. The arterial perforation could have been treated by use of coils that occlude the site of the perforation and stop the bleeding.

198. Satilla did not have such coils in its cath lab, and no arrangements were made to transfer the patient urgently to a facility that had such capabilities.

199. In fact, Azmat and Satilla discharged the patient home following the procedure.

200. This case met peer review criteria A91013 because when Azmat perforated the patient's left renal artery, there was unplanned injury and harm to tissue.

201. Satilla did not, however, perform peer review of this case.

202. On April 17, 2006, October 30, 2007, and December 6, 2007, Azmat presented claims to Medicare totaling \$6340 for the endovascular procedures he performed on patient 2 on November 17, 2005.

203. Azmat received \$709.71 from Medicare for the endovascular procedures he performed on patient 2 on November 17, 2005.

204. On February 14, 2006, Satilla presented a claim to Medicare for \$35,023.58 for hospital services it provided to patient 2 that were related to the endovascular procedures performed by Azmat on November 17, 2005.

205. Satilla received \$17,016.21 from Medicare for the hospital services it provided to patient 2 that were related to the endovascular procedures performed by Azmat on November 17, 2005.

206. The claims for payment presented by Azmat and Satilla for the endovascular procedures performed by Azmat on patient 2 on November 17, 2005 at Satilla, and related hospital services provided by Satilla, were false and fraudulent because the endovascular procedures performed by Azmat, and related hospital services provided by Satilla, were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare.

Patient 11

207. On October 31, 2005, Azmat performed an aortogram with peripheral runoff on patient 11 at Satilla.

208. The aortogram and runoff studies showed occlusion of the left superficial femoral artery, but the studies did not show any significant stenosis or disease of the arteries in the patient's right leg.

209. November 17, 2005, Azmat performed a right iliofemoral arteriogram and right femoral angioplasty with cryo-balloon on patient 11.

210. On the operative report, Azmat indicated that the pre- and post-operative diagnoses were occlusive disease of the *left* femoral and popliteal arteries.

211. The operative report incorrectly states the date of procedure as December 19, 2004, when, in fact, the procedure was performed on November 17, 2005.

212. The right iliofemoral arteriogram, right femoral angioplasty, and cryo-balloon that Azmat performed on patient 11 November 17, 2005 were not reasonable and/or medically

necessary because the aortogram and runoff studies that Azmat had performed on those vessels just weeks earlier did not show significant stenosis or disease.

213. This case met peer review criteria A91006 because the clinical indication for the endovascular procedures performed on November 17, 2005 was not met.

214. Satilla did not, however, perform peer review of this case.

215. On April 10, 2006, Azmat presented a claim to Medicaid for \$400 for the endovascular procedures he performed on patient 11 on October 31, 2005.

216. Azmat received \$76.79 from Medicaid for the endovascular procedures he performed on patient 11 on October 31, 2005.

217. On January 16, 2006, Satilla presented a claim to Medicaid for \$7161.15 for hospital services it provided to patient 11 that were related to the endovascular procedures performed by Azmat on October 31, 2005.

218. Satilla received \$1995.64 from Medicaid for the hospital services it provided to patient 11 that were related to the endovascular procedures performed by Azmat on October 31, 2005.

219. On January 20, 2006, Satilla presented a claim to Medicaid for \$13,933.35 for hospital services it provided to patient 11 that were related to the endovascular procedures performed by Azmat on November 17, 2005.

220. Satilla received \$3459.17 from Medicaid for the hospital services it provided to patient 11 that were related to the endovascular procedures performed by Azmat on November 17, 2005.

221. The claims for payment presented by Azmat and Satilla for the endovascular procedures performed by Azmat on patient 11 on October 31, 2005 and November 17, 2005 at

Satilla, and related hospital services provided by Satilla, were false and fraudulent because the endovascular procedures performed by Azmat, and related hospital services provided by Satilla, were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare.

Patient 25

222. On November 30, 2005, Azmat performed bilateral external iliac stenting with right iliac balloon angioplasty on patient 25.

223. During the procedure, Azmat perforated the patient's right superficial femoral artery.

224. The operative report makes no mention of the perforated right superficial femoral artery.

225. Azmat did not recognize that he had perforated the patient's right superficial femoral artery.

226. This case met peer review criteria A91013 because when Azmat perforated the patient's superficial femoral artery, there was unplanned injury and harm to tissue.

227. Satilla did not, however, perform peer review of this case.

228. On November 12, 2007, Azmat presented a claim to Medicare for \$7723 for the endovascular procedures he performed on patient 25 on November 30, 2005.

229. Azmat received \$561.81 from Medicare for the endovascular procedures he performed on patient 25 on November 30, 2005.

230. On February 23, 2006, Satilla presented a claim to Medicare for \$21,015.65 for hospital services it provided to patient 25 that were related to the endovascular procedures performed by Azmat on November 30, 2005.

231. Satilla received \$16,104.21 from Medicare for the hospital services it provided to patient 25 that were related to the endovascular procedures performed by Azmat on November 30, 2005.

232. The claims for payment presented by Azmat and Satilla for the endovascular procedures performed by Azmat on patient 25 on November 30, 2005 at Satilla, and related hospital services provided by Satilla, were false and fraudulent because the endovascular procedures performed by Azmat, and related hospital services provided by Satilla, were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare.

Patient 6

233. On October 24, 2005, Azmat performed a bilateral renal arteriogram on patient 6 at Satilla.

234. The arteriogram performed on October 24, 2005 showed no significant stenosis.

235. On December 29, 2005, Azmat performed a right renal arteriogram on patient 6 at Satilla.

236. According to the operative report from the December 29, 2005 procedure, the indication for the procedure was to determine whether the patient had stenosis of her *left* renal artery.

237. Azmat repeated the right renal arteriogram on December 29, 2005, even though he had performed a right renal arteriogram on patient 6 just two months earlier and that arteriogram showed no stenosis.

238. The operative report from the December 29, 2005 procedure states that Azmat performed a bilateral renal arteriogram, when, in fact, he performed only a right renal arteriogram.

239. The right renal arteriogram performed by Azmat on December 29, 2005 met peer review criteria A91006 because there was no clinical indication for repeating the procedure which had just been performed two months earlier and which showed no stenosis.

240. Satilla did not, however, perform peer review of this case.

241. On June 28, 2006, Azmat presented a claim to Medicaid for \$485 for endovascular procedures he performed on patient 6 on October 24, 2005.

242. Azmat did not receive reimbursement from Medicaid for the endovascular procedures he performed on patient 6 on October 24, 2005.

243. On June 28, 2006, Azmat presented a claim to Medicaid for \$235 for the endovascular procedures he performed on patient 6 on December 29, 2005.

244. Azmat received \$58.66 from Medicaid for the endovascular procedures he performed on patient 6 on December 29, 2005.

245. On December 27, 2005, Satilla presented a claim to Medicaid for \$3141 for hospital services it provided to patient 6 that were related to the endovascular procedures performed by Azmat on October 24, 2005.

246. Satilla received \$868.19 from Medicaid for the hospital services it provided to patient 6 that were related to the endovascular procedures performed by Azmat on October 24, 2005.

247. On January 31, 2006, Satilla presented a claim to Medicaid for \$2981.80 for hospital services it provided to patient 6 that were related to the endovascular procedures performed by Azmat on December 29, 2005.

248. Satilla received \$825 from Medicaid for the hospital services it provided to patient 6 that were related to the endovascular procedures performed by Azmat on December 29, 2005.

249. The claims for payment presented by Azmat and Satilla for the endovascular procedures performed by Azmat on patient 6 on October 24 and December 29, 2005 at Satilla, and related hospital services provided by Satilla, were false and fraudulent because the endovascular procedures performed by Azmat, and related hospital services provided by Satilla, were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicaid.

Patient 21

250. On January 19, 2006, Azmat performed a right renal arteriogram, angioplasty and stent placement on patient 21.

251. During the procedure, one of the cath lab nurses questioned whether Azmat had advanced the guide wire too far risking perforation of the kidney.

252. Azmat continued the procedure, advancing the wire to the point where it formed a circular loop at the end of the wire.

253. There is no vessel in the kidney that makes such a loop, so Azmat should have known that the loop had, at this point, perforated, and was outside of, the renal artery.

254. Even though the wire was outside the renal artery Azmat continued to advance it, not only perforating the renal artery, but tearing it as well, and tearing the kidney tissue.

255. Azmat continued to push the wire until it was outside the body of the kidney.

256. Azmat should have realized that the wire had perforated the renal artery and the kidney and that the patient was bleeding internally and needed immediate treatment.

257. Azmat, however, went ahead and placed a stent in the patient's renal artery.

258. Placing a stent was the wrong thing to do because the stent served to increase the blood flow to the perforated and torn renal artery and kidney, thereby aggravating the patient's internal bleeding.

259. In addition, the stent that Azmat placed in the patient's renal artery was too large.

260. There is no mention in the operative report that Azmat had perforated the patient's renal artery and kidney.

261. Azmat did not recognize that he had perforated the patient's renal artery and kidney.

262. The renal artery and kidney perforation should have been recognized and treated immediately.

263. The renal artery and kidney perforation could have been treated by use of coils that embolize the artery and stop the bleeding.

264. Satilla did not have such coils in its cath lab.

265. Following the procedure, the nurses in the recovery room noted that the patient's blood pressure was low and that her abdomen was distended.

266. In addition, the patient awoke from the procedure complaining of abdominal pain and pain in her right groin where her femoral artery had been accessed for the endovascular procedure.

267. The nurses asked Azmat to order an ultrasound of her abdomen to evaluate the patient's condition.

268. Azmat did not order the ultrasound.

269. The nurses then asked another Satilla physician, Dr. Gregory Uhl, the Medical Director of Satilla's Heart Center, to order the ultrasound.

270. Uhl ordered the ultrasound of the patient's abdomen, which showed a collection of blood around the kidney, and an ultrasound of the patient's right groin, where she was complaining of pain, which showed a hematoma (collection of blood).

271. After obtaining the ultrasound studies, Uhl ordered a CT scan of the patient's abdomen, which showed a "huge" collection of blood around the kidney.

272. The patient's blood pressure and blood counts (hemoglobin and hematocrit) continued to drop indicating that she was in hemorrhagic shock.

273. That evening, the patient was life-flighted to Baptist Medical Center in Jacksonville, Florida, where she underwent emergency embolization of her right renal artery to stop the bleeding caused by the perforation that occurred at Satilla.

274. The patient died of hemorrhagic shock and multi-system organ failure.

275. The operative report was dictated by Azmat on March 16, 2006, approximately two months following the procedure and after the patient had died.

276. The operative report makes no mention of any complications, including the perforation of the patient's renal artery and kidney and right groin hematoma.

277. The operative report states that the patient was transferred to the recovery room in stable condition when, in fact, the patient was internally bleeding from her perforated and torn renal artery and kidney.

278. This case met peer review criteria A91013 because when Azmat perforated the patient's renal artery and kidney, there was unplanned injury and harm to tissue.

279. This case also met peer review criteria A91001 because the patient died.

280. Satilla did not, however, perform peer review of this case.

281. On April 10, 2006, September 12, 2006, and September 25, 2006, Azmat presented claims to Medicaid, each for \$2450, for the endovascular procedures he performed on patient 21 on January 19, 2006.

282. Azmat did not receive reimbursement from Medicaid for the endovascular procedures he performed on patient 21 on January 19, 2006.

283. On March 3, 2006, Satilla presented a claim to Medicaid for \$28,622.36 for hospital services it provided to patient 21 that were related to the endovascular procedures performed by Azmat on January 19, 2006.

284. Satilla received \$10,872.56 from Medicaid for the hospital services it provided to patient 21 that were related to the endovascular procedures performed by Azmat on January 19, 2006.

285. The claims for payment presented by Azmat and Satilla for the endovascular procedures performed by Azmat on patient 21 on January 19, 2006 at Satilla, and related hospital services provided by Satilla, were false and fraudulent because the endovascular procedures performed by Azmat, and related hospital services provided by Satilla, were not reasonable and/or necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicaid.

H. THE CATH LAB NURSING STAFF REPEATEDLY COMPLAINED TO SATILLA MANAGEMENT ABOUT AZMAT'S LACK OF COMPETENCE¹

286. Satilla was aware of the fact that (1) Azmat was not qualified or competent to perform endovascular procedures, (2) Azmat did not have privileges to perform endovascular procedures, and (3) Azmat was endangering the lives of patients who underwent endovascular procedures.

287. For many months, however, Satilla did nothing to correct the situation.

288. When Azmat started to perform endovascular procedures at Satilla in September of 2005, nurses in the cath lab recognized that Azmat was not qualified or competent to perform endovascular procedures and raised those concerns with Satilla's management.

289. On or about September 16, 2005, Lana Rogers, a nurse in Satilla's cath lab, assisted on her first endovascular case performed by Azmat.

290. During that case, it became evident to Rogers that Azmat had no idea what he was doing and had not performed endovascular procedures before.

291. Rogers noticed that Azmat did not know the names of any of the catheters.

292. Rogers noticed that Azmat did not know to remove the dilator before attempting to introduce the catheter over the guide wire.

293. Rogers noticed that Azmat was not proficient at manipulating the catheter and the wire.

294. After scrubbing in on her second endovascular procedure performed by Azmat, also in September of 2005, Rogers went to the office of Harman Raulerson, the Manager of Satilla's Heart Center, to notify him of her concerns regarding Azmat's lack of competence.

¹ For ease of reference, we have included Exhibit 2, which is an index of the Satilla personnel referenced in this section of the Complaint.

295. As Manager of the Heart Center, Raulerson was responsible for, among other things, the safe operation of the Heart Center, including the cath lab, and it was Raulerson's job to know of any significant complications that occurred in the Heart Center.

296. Robert Trimm, Satilla's Chief Executive Officer (CEO), was present in Raulerson's office when Rogers arrived.

297. Rogers told Raulerson and CEO Trimm that it was obvious to her that Azmat had not performed endovascular procedures before.

298. Rogers explained to Raulerson and CEO Trimm that Azmat did not know the names of the catheters, did not know how to manipulate the catheters, and did not know to remove the dilator before introducing the wire and catheter.

299. Raulerson responded by telling Rogers that she should teach Azmat.

300. Cath lab nurse Evan Gourley thought that Azmat's endovascular technique was very poor.

301. Gourley noticed that Azmat had a hard time accessing the femoral artery.

302. Gourley noticed that Azmat knew very little about catheters and would often ask the nurses what kind of catheter should be used.

303. Gourley noticed that Azmat frequently asked for the wrong type of catheter.

304. On one occasion, during a carotid angiogram, Gourley noticed Azmat asked for a particular catheter, a "C3" or "Cobra" catheter, that is not long enough to reach the carotid artery.

305. Gourley told Jonathan Abbott, Products and Technical Coordinator of Satilla's Heart Center, and Raulerson that when he worked with Azmat he did not feel safe for the patients.

306. In mid-October of 2005, nurses from the cath lab approached Abbott, to inquire if Azmat had privileges to perform endovascular stenting procedures at Satilla.

307. Abbott in turn met with Windell Smith, Satilla's Chief Operating Officer (COO), to review Azmat's privileges. Despite the fact that Smith had no medical or clinical training of any kind, did not consult a physician or clinician, and had no role whatsoever in credentialing, COO Smith reviewed the privileges and told Abbott that Azmat did, in fact, have privileges to perform stenting procedures.

308. Abbott then told the cath lab nurses that Azmat did have privileges to perform stenting procedures.

309. In the Fall of 2005, after the mid-October meeting between Abbott and COO Smith, Raulerson and Abbott told COO Smith that the cath lab nursing staff were concerned that Azmat did not know the names of catheters.

310. This did not cause COO Smith to have any concerns regarding Azmat's competence or patient safety.

311. COO Smith did nothing in response to hearing the nurses' concerns regarding Azmat.

312. COO Smith did not convey the nurses' concerns to anyone else at Satilla, including the CEO or any member of the medical staff.

313. The cath lab nurses typed up a two-page document, which is incorporated herein as Exhibit 3, that lists multiple instances where the nurses expressed concern to Satilla's management regarding Azmat's lack of competence and the risk he posed to patients who underwent endovascular procedures. Certain of the instances described in the document are set forth below in paragraphs 314-317, 319, 321-324, 326 and 327.

314. On November 20, 2005, following an arteriogram performed by Azmat, cath lab nurse Marci Johnson told Raulerson and Abbott that Azmat “lack[ed] an overall game plan,” was not familiar with the catheters, and “lack[ed] knowledge regarding medications.”

315. On December 22, 2005, Johnson spoke with Uhl, the Medical Director of Satilla’s Heart Center, about Azmat’s “lack of technique, and lack of medical knowledge” regarding “sedation and treatment of hypertension.”

316. On December 29, 2005, following an endovascular procedure during which Azmat dissected the patient’s aorta, the cath lab nursing staff spoke with Raulerson about the risk that Azmat posed to patient safety.² The nursing staff specifically told Raulerson that Azmat was unable to “recognize” and “treat” complications when they arose.

317. Also on December 29, 2005, Johnson, Gourley, Rogers, and Eric Herrin, another nurse in the cath lab, spoke with COO Smith about the risk that Azmat posed to patient safety, and about the fact that he was unable to detect and treat complications as they arose.

² This was an endovascular procedure performed by Azmat on a patient who was not a federal health care program beneficiary. Azmat attempted to perform a right common iliac angioplasty on the patient. During the procedure, Azmat dissected the patient’s aorta, first with a wire, then with a catheter, and again with a larger pigtail catheter. Azmat did not recognize that he had dissected the patient’s aorta. The images show that he continued to advance the guide wire after it had dissected the aorta. He then advanced an introducer sheath into the dissection. Finally, he even placed a larger pigtail catheter into the dissection, further compromising the integrity of the patient’s aorta. During the procedure, cath lab nurse Gourley told Azmat that the wire appeared to be in the wrong place. Azmat responded that everything was fine and proceeded to further dissect the patient’s aorta with the introducer sheath and pigtail catheter. Before the procedure was over, nurse Gourley threw off his surgical gown in disgust and left the cath lab. During the procedure, the nursing staff contacted another physician in the Heart Center, Dr. Timothy Catchings, who came into the procedure and confirmed that Azmat had dissected the patient’s aorta. Abbott was scrubbed in the procedure, and Raulerson witnessed the procedure from a control booth in the cath lab. Azmat dictated the operative report for the procedure on February 3, 2006, more than one month after the procedure. Azmat never told the patient that he had dissected the aorta. This case met peer review criteria A91013 because when Azmat dissected the patient’s aorta, there was unplanned injury and harm to tissue, and peer review criteria A91030 because there were documented complaints by nurses who were scrubbed in on the case. Satilla did not, however, perform peer review of this case.

318. From August 8, 2005, the date that Azmat joined Satilla's medical staff, through December 29, 2005, the date on which Azmat dissected a patient's aorta during an aortogram, no one from Satilla's management or medical staff ever spoke to Azmat about the complaints and concerns that had been expressed by the cath lab nursing staff.

319. On January 3, 2006, Uhl, Abbott, and Raulerson met with Azmat to discuss the concerns of the nursing staff regarding the risk posed by Azmat to patient safety.

320. After that meeting, Uhl and Raulerson met with the cath lab nursing staff. At that meeting, Uhl and Raulerson told the cath lab nursing staff that Azmat had voluntarily agreed to perform only lower-risk procedures, such as diagnostic arteriograms, going forward and that he would no longer be performing stents, angioplasties and interventional procedures percutaneously.

321. In addition, Uhl and Raulerson told the nursing staff that "either Uhl or another physician would be proctoring Dr. Azmat." Uhl and Raulerson indicated that "furthering [sic] training would be done with Azmat also." Finally, Raulerson and Uhl advised the nursing staff that "if they could see past their conscious [sic] to stay and work with Dr. Azmat, they were welcome - but if not, they would be helped to transfer to another department."

322. On January 4, 2006, members of the cath lab nursing staff met with Raulerson individually to tell him that they would agree to continue to work with Azmat in the cath lab based on Azmat's voluntary agreement to perform only low-risk procedures, as communicated by Uhl and Raulerson to the cath lab nursing staff on January 3, 2006.

323. On January 5, 2006, Johnson spoke with CEO Trimm regarding "Azmat's poor technique, lack of knowledge regarding catheters and equipment, lack of knowledge regarding medications, lack of game plan," and the risk he posed to "overall patient safety."

324. On January 10, 2006, Wendy McClellan, another cath lab nurse, Johnson and Abbott learned that Azmat had scheduled a renal stent placement for January 12, 2006. Because they had been told by Uhl and Raulerson on January 3, 2006 that Azmat had voluntarily agreed to perform only lower-risk procedures, which did not include stenting procedures, McClellan, Johnson and Abbott went to Raulerson for an explanation as to why Azmat had scheduled a renal stent placement.

325. Raulerson then informed COO Smith that Azmat had scheduled a renal stent placement and that the cath lab nurses were concerned that this was not a low-risk procedure. COO Smith told Raulerson that there was no way to enforce Azmat's voluntary agreement to perform only low-risk procedures.

326. Raulerson then went back to the cath lab nurses and "explained that powers higher than within this department stated 'Dr. Azmat is credentialed to do procedures and has full privileges.'"

327. On January 11, 2006, during an aortogram with femoral runoffs, Azmat ordered Johnson to give the patient 4 mg of Versed for sedation. The normal starting dose for moderate sedation for Versed is 1-2 mg. Following the procedures, Johnson spoke with Uhl and asked him to educate Azmat with respect to sedation techniques.

328. On the morning of January 19, 2006, before the procedure on patient 21 during which Azmat perforated her renal artery and kidney, Gourley asked COO Smith: "Is someone going to have to die before we can stop Dr. Azmat?" COO Smith responded "yes" or "probably."

329. On more than one occasion, and before the procedure on patient 21 on January 19, 2006, Uhl expressed concern to Satilla's administrators regarding patient safety if Satilla permitted Azmat to continue to perform endovascular procedures in the cath lab.

330. In December of 2005, Uhl met with CEO Trimm and Dr. Wade Dye, the Chief of the Medical Staff at Satilla, to review the privileges that had been approved by the Medical Executive Committee for Azmat. Uhl reviewed the privileges and told Trimm and Dye that Satilla had been allowing Azmat to perform procedures for which he had not, in fact, been granted privileges.

331. Satilla continued to allow Azmat to perform endovascular procedures even after Uhl reviewed Azmat's credentials and told CEO Trimm and Dye that Azmat did not have privileges to perform such procedures.

I. CONFIDENTIAL AGREEMENT

332. Satilla did not restrict the performance of endovascular procedures by Azmat until February 14, 2006, when Azmat and Satilla entered into a Confidential Agreement (Agreement).

333. Citing concern for "patient safety," the Agreement provided that, effective January 26, 2006, Azmat "will no longer use the catheterization lab to perform endovascular procedures."

334. The Agreement also provided that Azmat would refrain from performing endovascular procedures at Satilla "until such time as either Dr. Azmat is able to satisfactorily demonstrate appropriate proficiency to perform endovascular procedures or when his privileges are due for renewal."

335. Satilla and Azmat agreed in the Agreement to "not report that any adverse actions have been taken against Dr. Azmat's medical staff membership or clinical privileges to the

National Practitioner Data Bank or to the Georgia Composite State Board of Medical Examiners.”

336. Under 42 U.S.C. § 11133(a)(1)(A), a hospital that takes a professional review action that adversely affects the clinical privileges of a physician for longer than 30 days is required to submit an adverse action report to the National Practitioner Data Bank.

337. Under the Georgia Patient Right to Know Act of 2001, a licensed physician is required to provide the Georgia Composite Board of Medical Examiners with “a description of any final revocation or any final disciplinary action resulting in any restriction of hospital privileges, either involuntary or by agreement, for reasons related to competence or character.” Ga. Code. Ann. 31 § 43-34A-3(c)(14).

338. Neither Satilla nor Azmat notified either the National Practitioner Data Bank or the Georgia Composite State Board of Medical Examiners of the restrictions placed on Azmat by Satilla pursuant to the Agreement.

339. Despite the Agreement, Azmat continued to perform endovascular procedures at Satilla, though less frequently, until December of 2006.

J. THE QUALITY MANAGEMENT CONSULTING GROUP, LTD.

340. Satilla did not conduct peer review of any of Azmat’s endovascular cases.

341. The only review conducted of Azmat’s endovascular cases was an entirely retrospective review performed by an outside consultant after Azmat had agreed to stop performing endovascular procedures in Satilla’s cath lab and after Azmat had seriously injured several patients.

342. The retrospective review, which was dated June 12, 2006, was performed by The Quality Management Consulting Group, Ltd. (QMCG), a consultant retained and paid for by Satilla.

343. The retrospective review performed by QMCG consisted of a review of twenty cases performed by Azmat.

344. Of the twenty cases reviewed by QMCG, ten were open vascular surgery cases and ten were endovascular procedures.

345. The QMCG physician reviewer presented his findings to Satilla in a report dated June 12, 2006, which is incorporated by reference herein as Exhibit 4.

346. In his report, the QMCG physician reviewer had “overall concerns with Dr. Azmat’s ability to adequately and safely perform endovascular procedures.”

347. The QMCG physician reviewer’s findings, which are set forth in the report, included:

- “a pattern of consistently poor documentation both in documentation of indications for endovascular procedures, the exact procedure performed, as well as, the patient outcome upon conclusion of the procedure”;
- “Renal artery stenting was done in cases in which indications were not documented”;
- Also with respect to renal artery stenting, “visualization was not adequate to appropriately document the degree of stenosis prior to the decision to stent the stenosis” and “the resulting arterial blood flow was poorer than what would be expected”;

- “an abnormally high number of dissections,” which “when they were not recognized, will result in increased complications”; and
- “Azmat did not pay attention to detail in wire placement.”

348. As part of the retrospective review, the QMCG physician reviewer also reviewed Azmat’s credentialing file, and noted that although Azmat did eventually complete a general surgery residency and one year of training in vascular surgery, “endovascular procedures are a new technology and not every surgeon who has completed surgical training (even in recent years) has had adequate training to justify privileges in endovascular procedures.”

349. The QMCG physician reviewer also noted that “[i]t is highly important that endovascular credentialing include full documentation specifically in endovascular specific education, training and procedures performed, before privileges can be requested (and considered by the Medical Center).”

350. Finally, the QMCG physician reviewer concluded that Satilla’s “process for credentialing and consideration for privileging any surgeon for endovascular procedures, and the ongoing quality monitoring of such procedures, may benefit from careful review and revision.”

K. UNDER ITS BYLAWS, SATILLA HAD AUTHORITY TO SUSPEND THE PRIVILEGES OF ANY MEDICAL STAFF MEMBER WHO POSED A DANGER TO PATIENTS; SATILLA DID NOT, HOWEVER, EXERCISE THAT AUTHORITY WITH RESPECT TO AZMAT

351. Article IX, Section I of Satilla’s Medical Staff Bylaws provides that the President of the Medical Staff and the CEO have the authority to suspend all or any portion of the clinical privileges of the medical staff member that may pose a danger to patients.

352. Satilla did not suspend Azmat under that authority even though Azmat was not qualified or competent to perform endovascular procedures and posed a danger to patients who underwent endovascular procedures.

353. Article IX, Section II of Satilla's Medical Staff Bylaws provide that a physician's privileges may be suspended for failure to complete medical records in a timely fashion.

354. Although Satilla never exercised its authority to suspend Azmat based on the danger he posed to patients who underwent endovascular procedures, Satilla suspended Azmat at least twice for failure to complete his medical records in a timely fashion.

355. Satilla suspended Azmat for failure to complete his medical records in a timely fashion in part because it was Satilla's practice to not bill for services until medical records were complete.

CAUSES OF ACTION

A. FIRST CAUSE OF ACTION - VIOLATIONS OF THE FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)

356. The United States re-alleges and incorporates herein by reference paragraphs 1-355.

357. Azmat knowingly presented false or fraudulent claims to the United States for payment in violation of the FCA, 31 U.S.C. § 3729(a)(1). Specifically, Azmat presented claims for payment to Medicare, Medicaid and TRICARE for endovascular procedures that Azmat performed at Satilla. These claims were false or fraudulent because Azmat was not qualified, competent or credentialed to perform endovascular procedures. Therefore, the endovascular procedures performed by Azmat at Satilla were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were

not payable by Medicare, Medicaid or TRICARE. Azmat knew, recklessly disregarded or deliberately ignored that he was not qualified, competent or credentialed to perform endovascular procedures, and that the procedures were, therefore, not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE, but Azmat presented claims to those programs for the endovascular procedures he performed at Satilla anyway.

358. Azmat also caused Satilla to present false or fraudulent claims to the United States for payment in violation of the FCA, 31 U.S.C. § 3729(a)(1). Specifically, Azmat caused Satilla to present claims for payment to Medicare, Medicaid and TRICARE for hospital services that Satilla provided that were related to endovascular procedures that Azmat performed at Satilla. These claims were false or fraudulent because Azmat was not qualified, competent or credentialed to perform endovascular procedures. Therefore, the endovascular procedures performed by Azmat at Satilla, and related hospital services that Satilla provided, were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE. Azmat knew, recklessly disregarded, or deliberately ignored that he was not qualified, competent or credentialed to perform endovascular procedures, and that the endovascular procedures and related hospital services provided by Satilla were, therefore, not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE, but Azmat caused Satilla to present claims to those programs for hospital services that were related to the endovascular procedures Azmat performed at Satilla anyway.

359. Satilla knowingly presented false or fraudulent claims to the United States for payment, in violation of the FCA, 31 U.S.C. § 3729(a)(1). Specifically, Satilla presented claims for payment to Medicare, Medicaid and TRICARE for hospital services that were related to the endovascular procedures that Azmat performed at Satilla. These claims were false or fraudulent because Azmat was not qualified, competent or credentialed to perform endovascular procedures. Therefore, the endovascular procedures performed by Azmat at Satilla, and related hospital services provided by Satilla, were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE. Satilla knew, recklessly ignored, or deliberately ignored that Azmat was not qualified, competent or credentialed to perform endovascular procedures, and that the endovascular procedures performed by Azmat, and related hospital services provided by Satilla, were, therefore, not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE, but Satilla presented claims to those programs for hospital services related to the endovascular procedures Azmat performed at Satilla anyway.

360. Satilla also caused Azmat to present false or fraudulent claims to the United States for payment in violation of the FCA, 31 U.S.C. § 3729(a)(1). Specifically, Satilla caused Azmat to present claims for payment to Medicare, Medicaid and TRICARE for endovascular procedures that Azmat performed at Satilla. These claims were false or fraudulent because Azmat was not qualified, competent or credentialed to perform endovascular procedures. Therefore, the endovascular procedures performed by Azmat at Satilla were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE. Satilla knew,

recklessly disregarded or deliberately ignored that Azmat was not qualified, competent or credentialed to perform endovascular procedures, and that the endovascular procedures he performed at Satilla were, therefore, not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE, but Satilla caused Azmat to present claims to those programs for the endovascular procedures Azmat performed at Satilla anyway.

361. All of the claims presented by Azmat and Satilla to Medicare, Medicaid, and TRICARE for payment for endovascular procedures performed by Azmat at Satilla and related hospital services provided by Satilla were false claims under the FCA.

362. By virtue of these false or fraudulent claims for payment, the United States suffered damages in an amount to be determined at trial.

B. SECOND CAUSE OF ACTION - VIOLATIONS OF THE FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(2)³

363. The United States re-alleges and incorporates herein by reference paragraphs 1-362.

364. Azmat knowingly made and caused to be made false statements in order to get a false claim paid by the United States for payment, in violation of the FCA, 31 U.S.C. §

³ Section 4 of the Fraud Enforcement and Recovery Act of 2009 (FERA) revised certain provision of the FCA, including section 3729(a)(2), which is now codified at the new section 3729(a)(1)(B). In *Hopper v. Solvay Pharm.*, 588 F.3d 1318,1327 n. 3 (December 4, 2009), the United States Court of Appeals for the Eleventh Circuit concluded that the old section 3729(a)(2), rather than newly created section 3729(a)(1)(B), applies to situations where the claims for payment that are at issue were filed before June 7, 2008, and the newly created section 3729(a)(1)(B) applies where the claims for payment were pending or filed on or after June 7, 2008. Based on *Hopper*, the United States cites here in this Complaint to section 3729(a)(2). The United States, however, respectfully disagrees with the *Hopper* Court's interpretation of FERA. The United States' reading of FERA is that section 3729(a)(2) applies to FCA causes of action that were filed before June 7, 2008, and the newly created section 3729(a)(1)(B) applies to FCA causes of action that were pending or filed on or after June 7, 2008.

3729(a)(2). Specifically, Azmat made and caused to be made false statements in connection with false claims for payment presented to Medicare, Medicaid and TRICARE for endovascular procedures Azmat performed at Satilla and for hospital services provided by Satilla that were related to those endovascular procedures. Azmat was not qualified, competent or credentialed to perform endovascular procedures. Therefore, the endovascular procedures performed by Azmat at Satilla, and related hospital services provided by Satilla, were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE. Azmat knew, recklessly disregarded or deliberately ignored that the endovascular procedures and related hospital services were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE.

365. Satilla knowingly made and caused to be made false statements in order to get a false claim paid by the United States for payment, in violation of the FCA, 31 U.S.C. § 3729(a)(2). Specifically, Satilla made and caused to be made false statements in connection with false claims for payment presented to Medicare, Medicaid and TRICARE for endovascular procedures Azmat performed at Satilla and for hospital services provided by Satilla that were related to those endovascular procedures. Azmat was not qualified, competent or credentialed to perform endovascular procedures. Therefore, the endovascular procedures performed by Azmat at Satilla, and related hospital services provided by Satilla, were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE. Satilla knew, recklessly disregarded or deliberately ignored that the endovascular procedures and related

hospital services were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by Medicare, Medicaid or TRICARE.

366. The false statements knowingly made and caused to be made by Azmat and Satilla described above in paragraphs 364 and 365 were material to false claims paid by the United States and were made for the purpose of getting false claims paid by the United States.

367. All of the claims presented by Azmat and Satilla to Medicare, Medicaid, and TRICARE for endovascular procedures performed by Azmat at Satilla and related hospital services provided by Satilla were false claims under the FCA.

368. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

C. THIRD CAUSE OF ACTION - UNJUST ENRICHMENT

369. The United States re-alleges and incorporates herein by reference paragraphs 1 through 368.

370. From September of 2005 to December of 2006, the United States, including Medicare, Medicaid, and TRICARE, paid for endovascular procedures performed by Azmat at Satilla, and related hospital services provided by Satilla, that were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were worthless and of no medical value, and were not payable by those federal health care programs.

371. The United States is entitled to the return of all payments made by the United States, including payments made by Medicare, Medicaid and TRICARE, to Azmat for the endovascular procedures performed by Azmat at Satilla, and to Satilla for the hospital services it provided that were related to the endovascular procedures performed by Azmat at Satilla.

372. By reason of the payments described above in paragraphs 370 and 371, Azmat and Satilla have received money from Medicare, Medicaid and TRICARE to which they were not entitled. Thus, Azmat and Satilla have been unjustly enriched in an amount to be determined at trial.

D. FOURTH CAUSE OF ACTION - PAYMENT BY MISTAKE OF FACT

373. The United States re-alleges and incorporates herein by reference paragraphs 1 through 372.

374. From September of 2005 to December of 2006, the United States, including Medicare, Medicaid, and TRICARE, paid defendants Azmat and Satilla as a result of mistaken understandings of fact.

375. The false or fraudulent claims that defendants Azmat and Satilla submitted and/or caused to be submitted to the United States, including Medicare, Medicaid and TRICARE, were paid by the United States based upon mistaken or erroneous understandings of materials fact.

376. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of statements, certifications and representations by defendants Azmat and Satilla, paid to defendants Azmat and Satilla money to which Azmat and Satilla were not entitled. Thus, defendants Azmat and Satilla are liable to account and pay such amounts, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

A. AS TO THE FIRST CAUSE OF ACTION

As against defendants Azmat and Satilla, judgment in the amount equal to:

1. FCA statutory treble damages in an amount to be established at trial;

2. civil penalties for each false claim presented or caused to be presented as provided at law;
3. the cost of this action, plus interest, as provided by law; and
4. any other relief that this Court deems appropriate.

B. AS TO THE SECOND CAUSE OF ACTION

As against defendants Azmat and Satilla, judgment in an amount equal to:

1. FCA statutory treble damages in an amount to be established at trial;
2. civil penalties for each false statement made or caused to be made as provided by law;
3. the cost of this action, plus interest, as provided by law; and
4. any other relief that this Court deems appropriate.

C. AS TO THE THIRD CAUSE OF ACTION

As against defendants Azmat and Satilla, judgment in an amount equal to:

1. The money paid by the United States, including Medicare, Medicaid and TRICARE, to, or received by, defendants Azmat and Satilla, plus interest;
2. the cost of this action, plus interest, as provided by law; and
3. any other relief that this Court deems appropriate.

D. AS TO THE FOURTH CAUSE OF ACTION

As against defendants Azmat and Satilla, judgment in an amount equal to:

1. The money paid by the United States, including Medicare, Medicaid and TRICARE, to, or received by, defendants Azmat and Satilla, plus interest;
2. the cost of this action, plus interest, as provided by law; and
3. any other relief that this Court deems appropriate.

JURY DEMAND

The United States requests a trial by jury.

Dated: July 27, 2010

Respectfully submitted,

TONY WEST
Assistant Attorney General

s/ Arthur S. Di Dio
JOYCE R. BRANDA
DANIEL R. ANDERSON
ARTHUR S. DI DIO
D.C. Bar No. 463357
Attorneys, Civil Division
Department of Justice
Post Office Box 261
Ben Franklin Station
Washington, D.C. 20044
Telephone: (202) 307-0275
Facsimile: (202) 307-3852
Email: Arthur.Di.Dio@udoj.gov

EDWARD J. TARVER
United States Attorney

s/ Edgar D. Bueno
EDGAR D. BUENO
Assistant United States Attorney
U.S. Attorney's Office
Post Office Box 8970
Savannah, Georgia 31412
Telephone: (912) 652-4422
Email: Edgar.Bueno@usdoj.gov

CERTIFICATE OF SERVICE

This is to certify that on July 27, 2010, I have served a copy of the foregoing pleading by addressing same to:

John E. Bumgartner, Esq.
Counsel for Lana Rogers
Brown, Readdick, Bumgartner, Carter, Strickland & Watkins, LLP
Post Office Box 220
Brunswick, GA 31521-0220

John R. Ferrelle, Esq.
Counsel for Lana Rogers
777 Gloucester Street, Suite 411
Brunswick, GA 31520

Leonard J. Panzitta, Esq.
Counsel for Satilla Regional Medical Center
Panzitta, LLC
200 E. St. Julian Street, Suite 605
Savannah, GA 31401

Dan M. Mulholland, Esq.
Phil Zarone, Esq.
Counsel for Satilla Regional Medical Center
Horty Springer Mattern, PC
4614 Fifth Avenue, Suite 1
Pittsburgh, PA 15213

Adam Ferrell
Counsel for Najam Azmat, M.D.
Adam Ferrell, P.C.
128 NW Central Avenue
Blackshear, GA 31516

and in accordance with the directives from the Court Notice of Electronic Filing (NEF), which was generated as a result of electronic filing.

s/ Edgar D. Bueno
Edgar D. Bueno
Assistant United States Attorney
Post Office Box 8970
Savannah, GA 31412
(912) 652-4422