IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

)
) Case No.: 3:17-cv-00902
)) JUDGE CAMPBELL
) MAGISTRATE JUDGE HOLMES
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)))

COMPLAINT IN INTERVENTION

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INTRODUCTION

1. The United States of America brings this action under the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), against defendants Methodist Le Bonheur Healthcare ("MLH") and Methodist Healthcare-Memphis Hospitals ("MHMH") (collectively, "Methodist" or "Defendants") to recover hundreds of millions of dollars in damages to Medicare as a result of Defendants' violations of the Anti-Kickback Statute ("AKS") and the FCA.

2. The unlawful kickbacks at issue here were disguised through a sophisticated business integration, wherein Methodist purchased substantially all of the outpatient locations of the largest oncology practice in the Memphis area, owned by non-party, West Clinic, P.C. n/k/a The West Clinic, PLLC ("West"). At the time of the arrangement, Methodist lacked a comprehensive cancer treatment center. The multi-agreement transaction purported to be a lawful way to allow West's patients to be treated at Methodist locations by West-employed physicians for outpatient and inpatient services, with West providing management services to Methodist's adult oncology service line. In return, Methodist would receive the Medicare reimbursements relating to the cancer care. Methodist and West described it as a "joint partnership" along with the participation of the University of Tennessee Health Science Center ("UTHSC"). The stated goal was to create a comprehensive cancer center "without walls" where patients in the mid-South could go for all their cancer-related care at what ultimately was called the West Cancer Center. However, Methodist and West never created any legal partnership, as to do so likely would have run afoul of regulatory requirements for participation in federal health care programs.

3. The multi-year deal involved an Asset Purchase Agreement ("APA"), Leased Employee and Administrative Services Agreement ("LEA"), a Professional Services Agreement ("PSA"), and a Management Services/Performance Improvement Agreement ("MSA"). Methodist also agreed to an Unwind Agreement through which West could terminate the entire deal and essentially buy back its assets at any time after the first six months. As the diagram Methodist provided shows, the deal documents are all inter-related:



4. As part of Methodist's business combination with West, Methodist made a separate for-profit \$7 million investment in ACORN Research, LLC ("ACORN"), an entity in which West and its Medical Director and shareholder, Dr. Lee Schwartzberg, had a personal financial interest.

5. Through the deal, Methodist provided an immediate influx of millions of dollars in cash to West with its purchase of certain assets and the ACORN investment that resulted in a repayment of \$3.5 million in debt owed to West and Dr. Schwartzberg. Kickbacks for the revenues Methodist generated from the West referrals, however, were disguised as payments Methodist

made during the course of the deal, and expressly for certain services that were supposed to be – but were not – provided under the MSA, as discussed in detail below.

6. From the patient's viewpoint, their cancer care remained with West, as the physicians continued to treat their patients at the same outpatient locations Methodist purchased. But the financial reality of the situation was very different. As a result of the transaction, Methodist, which prior to the deal had essentially no outpatient cancer treatment, was able to establish a new stream of income through reimbursements for outpatient treatment. Methodist also realized a huge increase in referrals for inpatient services from West, which previously referred the bulk of its patients to Methodist's competitors, including Baptist Memorial Hospital ("Baptist").

7. By purchasing the West outpatient location, Methodist was able to bill Medicare not only for the facility and professional components of outpatient treatment but also for the chemotherapy and other drugs provided, for which Methodist could recoup a staggering discount in costs through the 340B Drug Pricing Program ("340B Program") resulting in \$50 million in profit to Methodist in one year alone.

8. Methodist knew that it would be a violation of the AKS to compensate West in exchange for the volume or value of referrals to Methodist. Yet, as the referrals to Methodist increased over the seven years of the deal, so did Methodist's payments to West under the MSA.

9. Methodist also knew that West had not been providing all the management services at all the locations required by the MSA. For the management services West was performing, Methodist often was double-paying West, as it was paying separately for these services pursuant to other agreements.

10. In sum, Methodist knowingly agreed to pay West millions of dollars for the revenues Methodist expected to – and ultimately did – realize from West's referrals. The unlawful arrangement lasted from January 1, 2012 through December 31, 2018 – and continued even after Methodist knew that the United States was investigating its conduct following the filing of a whistleblower lawsuit.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 31 U.S.C. §§ 3730(a) and 3732, 28 U.S.C. §§ 1331 and 1345.

12. Venue is proper in the Middle District of Tennessee pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), because all Defendants reside in or operate in Tennessee and because a substantial part of the events and omissions giving rise to the claims alleged occurred in this District.

PARTIES

13. The United States is intervening in this *qui tam* action brought by co-Relators pursuant to the FCA to assert claims on behalf of the United States Department of Health and Human Services ("HHS"), which administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act ("SSA"), 42 U.S.C. §§ 1395 et seq. ("Medicare"), and the Centers for Medicare & Medicaid Services ("CMS"), which administers Medicare for HHS.

14. Defendant MLH is a Tennessee nonprofit hospital corporation. MLH's principal place of business is in Memphis, Tennessee. At all relevant times, MLH operated Fayette Hospital, a Tennessee nonprofit corporation ("Fayette") and Methodist Extended Care Hospital, a Tennessee nonprofit corporation ("Extended Care").

15. Defendant MHMH is a Tennessee nonprofit corporation. MHMH's principal place of business is in Memphis, Tennessee. MLH is the sole member of MHMH. At the time of the transaction with West, MHMH owned and operated four acute care hospitals in the Memphis area: Methodist University ("University"), Methodist Le Bonheur Germantown ("Germantown"), Methodist North Hospital ("North"), and Methodist South Hospital ("South"). Le Bonheur Children's Hospital ("Le Bonheur"), a pediatric acute care hospital facility, which also was a part of MHMH, was expressly excluded from the transaction with West.

16. At all relevant times, non-party West was a Tennessee professional corporation. Prior to executing the APA, West had oncology outpatient clinic locations in Corinth, MS; Southaven, MS; Collierville, TN; Brighton, TN; Humphreys Boulevard in Memphis, TN, and Union Avenue in Memphis, TN. From December 26, 2011 through February 23, 2019, West and Methodist had a contractual relationship whereby West was required to provide professional and management services across the adult oncology service line of Methodist.

17. West presently is a Tennessee professional limited liability corporation with oncology outpatient clinics across three states. It has locations in West Memphis, AR; Jonesboro, AR; Corinth, MS; Southaven, MS; Dyersburg, TN; Collierville, TN; Brighton, TN; Paris, TN; a Midtown Campus on Union Avenue in Memphis, TN, and the Margaret West Comprehensive Breast Center and East Campus at 7945 Wolf River Boulevard in Germantown, TN.

West has been holding itself out to the public and doing business as West Cancer
 Center since 2012.

19. Relator Jeffrey H. Liebman is an individual currently residing in Boston, Massachusetts and was the Chief Executive Officer of University from February 2014 through early May 2017, when he became President of University, a position which he held until he resigned in August 2017. He filed the initial *qui tam* complaint in this action on May 30, 2017.

20. Relator David M. Stern, M.D. is an individual currently residing in Asheville, North Carolina. Dr. Stern was the Executive Dean and Vice Chancellor at the UTHSC during the relevant time period. Dr. Stern served on the Board of Directors of MLH from 2011 to 2017 and was a member of the Executive Cancer Council and the Steering Committee for the West Cancer Center. Dr. Stern became a co-Relator in this action as of December 2019.

LEGAL AND REGULATORY FRAMEWORK

A. <u>The False Claims Act</u>

21. The FCA provides for the award of treble damages and civil penalties for knowingly presenting or causing to be presented false or fraudulent claims for payment to the United States and for knowingly making or using false records or statements material to false or fraudulent claims paid by the United States. 31 U.S.C. §§ 3729(a)(1), (2); 31 U.S.C. §§ 3729(a)(1), (a)(1)(B) (as amended).

22. FCA penalties are regularly adjusted for inflation, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. 28 U.S.C. § 2461 note. For violations occurring between September 28, 1999 and November 2, 2015, the civil penalty amounts range from a minimum of \$5,500 to a maximum of \$11,000. 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, 47103 (1999). For violations occurring after November 2, 2015, the civil penalty amounts currently range from a minimum of \$11,803 to a maximum of \$23,607. 28 C.F.R. § 85.5.

23. For purposes of the FCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of

the truth or falsity of the information. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

24. Under the FCA, a "claim" includes direct requests to the United States for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs, such as Medicare. 31 U.S.C. § 3729(b)(2)(A).

25. For purposes of the FCA, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

26. The standard of proof under the FCA is a preponderance of the evidence. 31 U.S.C.§ 3731(d).

B. <u>The Anti-Kickback Statute</u>

27. The AKS, 42 U.S.C. § 1320a-7b(b), is a federal criminal statute that prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by federal health care programs. The AKS covers both those who pay kickbacks as well as those who solicit or receive remuneration.

28. The AKS arose out of congressional concern that payoffs and kickbacks in federal health care programs would result in goods and services being provided that are excessively costly, medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the kickback gives rise to overutilization, poor quality of care, or patient harm. In particular, when determining what conduct to prohibit, Congress determined that the inducements at issue would "contribute

significantly to the cost" of federal health care programs absent federal penalties as a deterrent. H.R. Rep. No. 95-393, at 53 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3056.

29. First enacted in 1972, Congress strengthened the AKS in 1977, 1987, and 2010, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148. In adopting and repeatedly strengthening the AKS, Congress sought to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs." H.R. Rep. No. 95- 393, at 1 (1977).

30. In pertinent part, the AKS provides:

(b) Illegal remuneration . . .

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

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

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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

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

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

31. "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h).

32. "Remuneration" under the AKS is broadly construed to mean anything of value.

33. If just one purpose for Methodist to provide remuneration to West was to induce referrals for which it would obtain reimbursement from the federal health care programs, the AKS has been violated. Just because the remuneration may have had other purposes, that does not insulate it from violating the AKS.

34. Although Congress has enacted safe harbors that protect certain prohibited payment and business arrangements that could otherwise implicate the AKS, safe harbors are affirmative defenses that are inapplicable here.

35. Compliance with the AKS is material to payment by the Medicare program and can subject the perpetrator to exclusion from participation in federal health care programs and civil monetary penalties. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

36. The AKS further provides that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the AKS are *per se* false or fraudulent within the meaning of 31 U.S.C. § 3729(a).

37. A person violates the FCA when that person knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

38. As this District has noted: "Some AKS violations are obvious; for example, if a hospital CEO 'paid kickbacks to physicians who referred Medicare and Medicaid patients to' his hospital, then he probably violated the AKS." *U.S. ex rel. Goodman v. Arriva Medical, LLC*, 471 F. Supp. 3d 830, 833 (M.D. Tenn. 2020) (Trauger, J.) (citation omitted).

C. <u>Medicare</u>

39. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as Medicare, to pay for the costs of certain health care services for people age 65 or older and for people with certain disabilities or afflictions. Title XVIII of the SSA, 42 U.S.C. § 1395 *et seq.*; 42 U.S.C. §§ 426-426.1.

40. HHS is responsible for administration and supervision of Medicare. CMS, an agency within HHS, is directly responsible for administering Medicare. At all times relevant to this complaint, CMS contracted with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

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

42. For a health care provider to seek reimbursement from Medicare, the provider must obtain a National Provider Identifier ("NPI") from CMS. The provider also must submit an enrollment application.

43. To obtain reimbursement from Medicare, providers submit a claim form, which typically is done electronically.

44. To enroll in the Medicare program, institutional providers such as hospitals must submit a Medicare Enrollment Application, Form CMS-855A. These providers also must complete Form CMS-855A to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

45. Form CMS 855A requires, among other things, signatories to certify:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider.... I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal antikickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

* * *

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

46. An authorized official must sign the "Certification Section" in Section 15 of Form

CMS-855A, which "legally and financially binds [the] provider to the laws, regulations, and

program instructions of the Medicare program."

47. In addition, within five months of the end of the cost reporting period, hospitals are

required to submit to CMS annual reports known as "cost reports" on Form CMS-2552, see 42

C.F.R. §§ 413.20(b), 413.24(f)(2).

48. Part II of Form CMS-2552 and 42 C.F.R. § 413.24(f)(4)(iv)(B) require a mandatory

certification, which includes the following certification statement:

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND OR IMPRISONMENT MAY RESULT. 49. Form CMS-2552 and 42 C.F.R. § 413.24(f)(4)(iv)(B) require a chief financial officer or administrator of the hospital to certify that "I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by [Provider Name(s) and Number(s)] for the cost reporting period beginning [date] and ending [date] and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted."

50. Form CMS-2552 and 42 C.F.R. § 413.24(f)(4)(iv)(B) also require a chief financial officer or administrator of the hospital to certify that "I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations."

51. To enroll in Medicare, physicians must submit a Medicare Enrollment Application, Form CMS-855I. These providers also must complete Form CMS-855I to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

52. Form CMS-855I requires, among other things, signatories to certify:

I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 4A of this application. The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act)).

* * *

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity. 53. The provider must sign the "Certification Section" in Section 15 of Form CMS-855I, and in doing so, is "attesting to meeting and maintaining the Medicare requirements" excerpted above, among others.

54. At all times relevant to this Complaint, CMS contracted with MACs to perform various administrative functions on its behalf, including reviewing and paying claims submitted by healthcare providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. MACs generally act on behalf of CMS to process and pay Medicare claims and perform administrative functions on a regional level. 42 U.S.C. § 1395ff(f)(2).

55. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1). In submitting claims for payment to Medicare, providers must certify that the information on the claim form accurately describes the services rendered and that the services were reasonable and medically necessary for the patient.

56. To obtain Medicare reimbursement, healthcare providers submit claims using paper forms or their electronic equivalents. Providers identify by code on the appropriate form, among other things, the principal diagnosis of the patient and the procedures and services rendered.

57. Among the information the provider includes on the form are certain five-digit codes, including Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Chapter 23, § 20.7 *et seq.* CMS assigns reimbursement amounts to CPT and HCPCS codes.

58. The Medicare program consists of four parts: A, B, C, and D. The United States is not pursuing any damages under Part C.

59. Medicare Part A covers, in relevant part, inpatient hospital care, including cancer treatments while an inpatient, some clinical research studies while an inpatient, and certain breast prostheses.

60. Under Medicare Part A, the hospital, also called a "provider," is authorized to bill Medicare for that treatment. During the relevant time period, CMS reimbursed hospitals for inpatient Part A services through MACs.

61. Since 2007, to get paid, a hospital must complete and submit to the MAC a claim for payment on a Form UB-04 (also known as CMS-1450) or its electronic equivalent. 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 on the accuracy and truthfulness of the UB-04 Forms to determine whether the service is payable and the amounts, if any, the hospital is owed or has been overpaid.

62. In addition, as noted, hospitals are required to submit to the MAC an annual report known as a Medicare "cost report" on Form CMS-2552, which identifies any 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. Failure to submit a cost report can result in all interim payments made since the beginning of the cost reporting period being deemed overpayments. The Medicare program relies on the accuracy and truthfulness of the cost report to determine the amounts, if any, the hospital is owed or has been overpaid during the year.

63. Medicare Part B is a federally subsidized, voluntary insurance program that pays for various medical and other health services and supplies, including laboratory testing, hospital

outpatient services, physician services, and physical, occupational, and speech therapy services. 42 U.S.C. §§ 1395j to 1395w-5. This encompasses medically necessary cancer-related treatment, such as chemotherapy and radiation treatments, diagnostic tools, procedures, and medical supplies, including breast prostheses after a mastectomy, mental health services and some costs of clinical research studies while an outpatient, as well as other items.

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

65. CMS provides reimbursement for Medicare Part B claims from the Medicare Trust Fund. To assist in the administration of Medicare Part B, CMS contracts with MACs. 42 U.S.C. § 1395u. MACs perform various administrative functions for CMS, including processing the payment of Medicare Part B claims to providers.

66. From 2011 to February 25, 2018, Cahaba Government Benefit Administrators, LLC ("Cahaba") was the MAC that administered Medicare Part A and B claims in Tennessee. As of February 26, 2018, Palmetto Government Benefit Administrator, LLC ("Palmetto") became the MAC for Tennessee.

67. To obtain Medicare reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form or its electronic equivalent, known as the 837P format. When a CMS-1500 claim is submitted, the provider

certifies that he or she is knowledgeable of Medicare's requirements and that the services for which payment is sought were "medically indicated and necessary for the health of the patient."

68. Providers wishing to submit an electronic or hard-copy CMS-1500 claim must first seek to enroll in the Medicare program by submitting a provider enrollment form. During the Medicare enrollment process, providers must certify that the claims they submit will be "accurate, complete, and truthful."

69. When submitting claims on the CMS-1500 to Medicare, providers certify, among other things, that: (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information in the claim is "true, accurate, and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." After a February 2012 revision to the CMS-1500, providers further certify that their claims comply "with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law)." CMS-1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties." *See, e.g., Cahaba Medicare Part B EDI Application* (09/2013 v2.51); *Interactive EDI Agreement for Palmetto.*

70. When enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful." When a provider submits an electronic

claim, the provider's identification number and password serve as the provider's signature, just as if the provider physically signed the claim form.

71. Medicare Part D covers some chemotherapy treatments and other drugs prescribed for cancer treatment, as well as prostheses, which includes rebates for prescriptions filled at the 340B Program pharmacies.

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

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

74. Because it is not feasible for Medicare or its MACs to review medical records corresponding to each of the millions of claims for payment received from providers, Medicare relies on providers to comply with Medicare requirements and to submit truthful and accurate certifications and claims.

75. Generally, once a provider submits a claim form for payment to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

76. During the relevant time period, West submitted claims to Medicare under NPI 1447276605.

77. During the relevant time period, Methodist submitted claims to Medicare under NPI 1558365890. Approximately half of Methodist's adult oncology patients during the relevant time period were Medicare patients.

FACTUAL BACKGROUND AND ALLEGATIONS OF FRAUD

78. Methodist describes itself as a mission-driven, not-for-profit, faith-based health system serving the greater Memphis community for over 100 years. Methodist states that it provides inpatient and outpatient services, regardless of a patient's ability to pay.

79. As a result of its status as a non-profit hospital providing care to indigent patients, including in particular those at University, North and South, Methodist was able to participate in the 340B Program, which is discussed in more detail below.

80. As of 2011, Methodist lacked a dedicated inpatient cancer unit and did not have any outpatient cancer locations. Some oncology inpatient services were provided at University.

81. The primary focus of Methodist's cancer care prior to the deal was on the blood and marrow transplant program which it initiated in conjunction with UT. The program received Foundation for the Accreditation of Cellular Therapy (FACT) accreditation in 2005, which it had until the fall of 2011 when the clinical program moved from Methodist to Baptist.

82. At all relevant times, Methodist also had an ongoing affiliation with UTHSC. As part of Methodist's deal with West, UTHSC was brought in to provide opportunities for clinical research and education, which would be necessary to achieve National Cancer Institute (NCI) designation.

83. West was originally formed in 1979. Dr. Kurt Tauer joined West in 1985. Dr. Lee Schwartzberg joined West in July 1987. During the relevant time period, both were shareholders of West and on its Board of Directors. Dr. Schwartzberg served as the Medical Director for West, and Dr. Tauer was the Chief of Staff.

84. At the time of the deal, West controlled the largest market share of cancer patients in the Memphis area. West had sixteen medical oncologists, four gynecological oncologists, four breast surgeons, and four radiologists/interventional radiologists. West had an American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative Certification (QOPI). In 2011, West had \$130 million in revenue and had 600-800 patient encounters per day in the five sites that became a part of the deal. Over 60% of West's net revenue was from chemotherapy and related drugs.

85. West did not have radiation oncology, surgical oncology (apart from breast surgeons) or pathology, which a partnership with Methodist could provide. Historically, West was aligned with Baptist for pathology needs.

86. West advised the United States that, before the deal with Methodist, its providers referred patients to Baptist because Methodist lacked sufficient inpatient cancer care.

87. At the time of the deal, West also needed a cash influx to protect or increase physician compensation, as insurer reimbursements were decreasing, and it was expanding with considerable overhead.

88. Like Methodist, West had visions of becoming a nationally accredited program, which required participation of a research entity (such as UTHSC), clinical trials, and the ability to provide inpatient treatment, which Methodist could provide. A deal with Methodist also could provide West with the cash influx and continued funding it needed to expand.

19

I. METHODIST PARTNERS WITH WEST TO FORM THE WEST CANCER CENTER

89. Beginning in 2010, West contacted the law firm of Foley & Lardner LLP ("Foley") to discuss a strategic partnership with a Memphis-area hospital to expand the services offered by its outpatient cancer facilities and develop a comprehensive cancer center, as well as a partner for the cardiology practice group it had acquired.¹

90. West used Foley because Foley had marketed the profitability of physicianprovider integration models and its prior success in structuring such a deal. In one of its many presentations on the physician-hospital alignment, Foley noted the importance of ensuring that the structure of the deal did not run afoul of the Stark Law, 42 U.S.C. § 1395nn, or the AKS.

91. The main structure Foley proposed involved a co-management agreement, with a base fee and an incentive component, a professional services agreement, a leased employee agreement, an asset purchase agreement, and an unwind mechanism. Foley emphasized the need for fair market value ("FMV") opinions to support the amount of compensation under the arrangement. Foley also noted that aggregate compensation should be set in advance. Total compensation, of course, could not be tied to the volume or value of referrals, and performance measures should not reward revenue increases, which would run afoul of the AKS.

92. Foley highlighted the attractiveness of the arrangement for certain qualifying hospitals, such as Methodist, which would benefit from a collaboration with a physician practice group by obtaining a discount on drugs utilized by the outpatient facilities through the 340B Program, which allows covered hospitals to purchase drugs, including chemotherapy drugs, at a discounted rate.

¹ West also owned a cardiology practice that referred most of its patients to Baptist, which was divested shortly after the deal.

93. The 340B Program, which was created pursuant to Section 340B of the Public Health Act, requires drug manufacturers that participate in the Medicaid drug rebate program to extend discounts on drugs administered in the outpatient setting, including physician-administered infusion drugs, such as those used to treat cancer. The typical discount ranges from 30% to 50% off the drug's list price. For hospitals to qualify for the 340B Program, they must meet certain requirements. 42 U.S.C. § 256b(a)(4)(L)(i). "Off-site outpatient facilities and clinics (child sites) not located at the same physical address as the parent hospital covered entity will be listed on the public 340B database, and are able to purchase and use 340B drugs for eligible patients, if the hospital covered entity provides its most recently filed Medicare cost report demonstrating that: (1) each of the facilities or clinics is listed on a line of the cost report that is reimbursable under Medicare; and (2) the services provided at each of the facilities or clinics have associated outpatient Medicare costs and charges." Federal Register, Vol. 80, No. 167, p. 52302 (August 28, 2015).

94. Foley noted the rising cost of drugs and decreasing amount of reimbursement to physicians provided financial motivations for a physician group, such as West, to partner with hospitals, such as Methodist.

95. Foley identified "irreducible AKS risk" in the physician-hospital integration structure, which was intended to induce referrals from physician groups to hospitals. Nonetheless, Foley characterized it as a "win-win" for all parties.

96. Following some preliminary discussions between West and Methodist, in the fall of 2010, West sent a Request For Proposal ("RFP") to Methodist to determine its interest in a business combination. West also sent an RFP to Baptist, as well as other Memphis-area hospitals, to determine their interest. Of the recipients of West's RFP, Methodist and Baptist expressed the most interest. 97. As discussions with West progressed, Methodist engaged PricewaterhouseCoopers LLP ("PwC") as a consultant to perform a baseline assessment of the adult oncology service line to evaluate the development of the MSA.

98. PwC noted that Baptist had the largest share of the market at 36%, with Methodist at a close second with 33%. At that time, Baptist also had plans to collaborate with Memphis-area oncologists to develop a comprehensive cancer center.

99. West was clear from the outset that it wanted to maintain control of the outpatient locations and was unwilling to have its physicians become hospital employees.

100. West required an "out" for the deal so that if the parties did not maintain the same vision, it could unwind the transaction.

101. Both West and its shareholder and Medical Director Dr. Lee Schwartzberg personally had made substantial investments in ACORN, which was a separate entity affiliated with West that, among other things, provided assistance to West with clinical trials. As of February 2011, Methodist understood that West expected an investment in ACORN to part be of the deal.

102. West was fully aware that covered hospitals would be positioned to obtain substantial discounts for outpatient drugs through the 340B Program. West has advised the United States that "West management concluded that partnering with a major healthcare institution in Memphis, such as Methodist, and accessing increased reimbursement through the 340B program, would allow additional investment in research programs, recruitment of researchers, and participation in value-based care models with Medicare."

103. As a hospital in the downtown Memphis area, serving the Medicaid and indigent population, Methodist was eligible to participate in the 340B Program for outpatient sites that were within 35 miles of the main hospital location.

104. Chris McLean, Methodist's CFO at the time of the negotiation, knew that Baptist was not able to participate in the 340B Program.

105. Methodist's internal documents show that it expected revenues to increase from\$1.25 billion to \$1.45 billion with the West transaction.

106. Only Methodist moved forward in any substantive discussions with West following the initial RFP response, as only Methodist was willing to agree to an unwind after six months.

107. On June 3, 2011, Methodist and West entered into a Letter of Intent, which included the investment in ACORN.

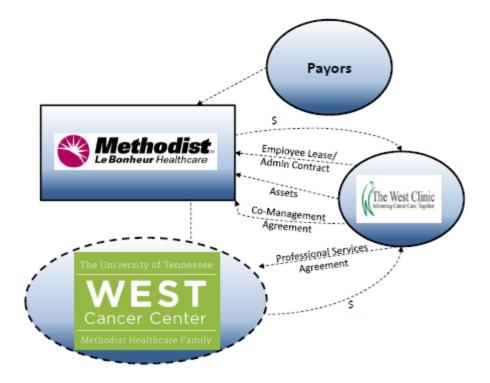
108. In accordance with Foley's outline for the structure, Methodist and West obtained FMV opinions for the amounts to be paid for the assets under the APA, physician compensation under the PSA, the management services under the MSA, and the ACORN investment.

109. Le Bonheur, the pediatric hospital, was expressly excluded from the deal.

110. West had an idea of the overall compensation and fees it expected to realize from the deal, which Methodist's Gary Shorb and Chris McLean had committed to pay. When Methodist obtained a preliminary estimate of the management fee at \$3.362 million in September 2011, Chris McLean noted that it was \$1 million too low. Mr. McLean and Mr. Mounce then worked together to ensure that West would receive the total amount to which Methodist agreed.

111. Given that prior to the deal, West sent most of its patients to Baptist, one purpose of the deal was to induce West to refer its patients to Methodist.

112. As the below diagram that Methodist provided to the United States (which mirrors the one in Foley's presentation) shows, the deal included payments made between Methodist and West through four inter-related agreements (the APA, LEA, PSA, and MSA), with the payments coming into West.



113. West had a unilateral right to terminate the arrangement after six months, and essentially buy back all the assets it sold to Methodist.

114. There was also a separate for-profit investment in ACORN and an agreement establishing collaboration among Methodist, West and the University of Tennessee, for which West received additional compensation.

115. There was never any formal agreement between Methodist and West that documented a legal partnership. The only reference to the vision the documents were intended to achieve was in an attachment to the PSA, which included an anticipated commitment of "between \$60 and \$75 million over the next seven years" to develop a comprehensive cancer center.

116. The terms of the transaction documents are discussed in more detail below.

A. Methodist Purchases West's Outpatient Cancer Sites That Remain Staffed By West

117. Pursuant to the APA, dated December 26, 2011, Methodist purchased certain tangible and intangible assets of West, including substantially all equipment, inventory and offices (through Methodist's assumption of West's leases) in all of West's outpatient cancer treatment locations in Tennessee and one in Mississippi. In accordance with the deal terms, these outpatient facilities became part of Methodist, effective January 1, 2012. The deal included West's principal place of business at 100 Humphreys Boulevard in Memphis; its location at 1588 Union Avenue in Memphis, which was near University; locations in Brighton and Collierville, Tennessee; and one location in Southaven, Mississippi (the "Cancer Center Sites"). West's Corinth space was the only West outpatient cancer location excluded from the deal.

118. Following the deal, the Cancer Center Sites were operated as outpatient departments of Methodist. The APA allowed for Methodist to bill professional services performed at the Cancer Center Sites as hospital clinic sites and not provider-based locations.

119. Patient files were not included in the acquisition but would be provided as needed to effectuate the overall transaction. The APA was signed by Dr. Tauer on behalf of West and Chris McLean on behalf of Methodist.

120. The APA also allowed Methodist to obtain the benefits of the 340B Program.

121. The APA states that the purchase price was determined in accordance with FMV and does not take into account the volume or value of referrals.

122. Methodist obtained an FMV opinion for the APA in October 2011.

123. Through the APA, Methodist was able to bill Medicare for outpatient oncology services, which West providers would perform. As discussed below, despite the terms of the APA, Methodist and West largely ignored that West had formally sold substantially all of its assets.

124. Pursuant to the APA, Methodist paid West \$10,537,397.49. Specifically, MHMH paid \$6,657,397.49 in cash to West and executed a promissory note in favor of West in the amount of \$3.88 million for the remainder of purchase price under the APA. West demanded payment of this note on December 17, 2012. The principal amount of the note plus accrued interest of \$8,308.53 was paid on December 18, 2012.

125. With the LEA, Methodist leased West's 193 non-physician employees, such as nurse practitioners, management and administrative staff, including Erich Mounce, West's Chief Executive Officer during the relevant time period. Under the LEA, Methodist paid West the same rate that West compensated these leased employees based on their full salaries on a pass-through basis. West then would pay its employees directly. No physicians were part of the LEA, as they were compensated by Methodist through the PSA.

126. The LEA was entered into on January 1, 2012 and terminated December 31, 2018.

127. The LEA was signed by Dr. Tauer for West and Chris McLean for Methodist.

128. During the course of the deal, Methodist paid West over \$100 million under the LEA.²

129. The PSA was entered into between MLH, MHMH and West, and was effective December 26, 2011. Although Methodist and West both acknowledged that no services were provided before 2012, Chris McLean indicated that the deal needed to be effective in December 2011 for him to submit the Cost Report to Medicare to capture the discounts for the 340B Program.

130. West physicians who provided professional services at Methodist, whether inpatient or outpatient, were compensated under the PSA, which included adult oncology services

² Methodist and West provided the United States with differing amounts that Methodist paid West under the LEA for 2012 and for 2015 through 2018.

at University, Germantown, North, South, Fayette and Extended Care and outpatient services at the Cancer Center Sites. Only physicians were compensated under the PSA.

131. Unlike the LEA, which resulted in Methodist paying West the same amount that West paid its salaried employee who were leased full-time to Methodist, Methodist agreed to pay West for the professional services of its physicians under the PSA in accordance with work Relative Value Units ("wRVUs") as defined by CMS. The wRVU rates represented a combination of the level of time, skill, training, and intensity required of a physician to provide a given service. Methodist and West agreed on the amount of wRVUs per specialty.

132. Under the PSA terms, West was to submit bimonthly invoices to Methodist based on the wRVUs that physicians worked. In addition, Methodist would cover benefits for the West physicians and malpractice insurance, as well as other items that were part of West's overhead.

133. The PSA required West to cooperate in the administration of the MSA. The term of the PSA ran through December 31, 2018, but it could be terminated without cause after six months. The PSA was signed by Dr. Tauer for West and Chris McLean for Methodist.

134. An initial FMV opinion was obtained in early October 2011 to determine the rates per wRVUs based on physician specialty and group level. At that time, 28 physicians were covered by the agreement. As West physicians were added over time, the total amount of compensation changed. The opinion does not include any reference to the cost of benefits that Methodist paid under the PSA. The opinion also notes that there may be a need for a new opinion in 2014 to cover changes to the practice. A new opinion, however, was not obtained until 2016.

135. West physicians could not submit wRVUs under the PSA for the duties they performed under the MSA, which were not considered to be professional services. (Foley 2018 and contracts)

136. The aggregate compensation to West under the PSA was not set in advance.

137. Under the PSA, from 2012 through December 31, 2018, Methodist paid West over\$280 million.

B. West Is Contracted To Provide Inpatient and Outpatient Management Services

138. Through the MSA, effective January 1, 2012, Methodist contracted with West for its physicians to provide management services across the entire the adult oncology service line, inpatient and outpatient, at six of Methodist's facilities (University, Germantown, North, South, Fayette, and Extended Care), the Cancer Center Sites, and any other off-campus oncology care sites that Methodist acquired and where West provided services under the PSA.³ The agreement was often referred to by the parties as the "co-management" agreement. Dr. Tauer signed the MSA as Secretary for West and Chris McLean signed for Methodist.

139. The MSA required West to perform the management services in accordance with the directives of Methodist's Board of Directors, the Operating Committee, and the Administrator. Erich Mounce, West's CEO at the time, was the Administrator of the MSA. The FMV opinion obtained for the MSA notes that the Operating Committee was "responsible for *directing* and *overseeing* the performance" of West under the MSA. (Emphasis in FMV opinion.) The FMV opinion also made clear that the "Operating Committee and its participants function *solely* in an oversight capacity, and will not perform (nor be responsible for) any of the Management Services that are the responsibility of the Manager." (Emphasis in FMV opinion.) The Operating Committee consisted of seven members: four West physicians and three individuals appointed by Methodist.

³ In its September 2, 2011 report (the "PwC Report"), PwC did not include Fayette or Extended Care as locations that West would provide management services.

140. Under the Foley model, the overall amount of payment under the MSA was supposed to be tied to a percentage of the revenues of the entire service line that West would be managing under the agreement.

141. West had an expectation that under the MSA it would be paid 2.5% of the revenues, but it ultimately settled for 2.3%.

142. However, Erich Mounce, West's Chief Executive Officer at the time, told the United States that the revenues under consideration focused only on the revenues from West's outpatient and inpatient referrals and <u>not</u> the entire service line. According to Mr. Mounce, Foley identified a percentage of revenue of the service line for the outpatient sites and West's referrals to inpatients that West would be paid under the MSA, and the FMV opinion matched that number.

143. It was clear to West that it would not receive credit for all inpatient admissions even though West was required to provide management services for the full adult oncology service line at Methodist.

144. Revenues from Methodist patients that were not attributed to West were not a factor in the fee calculation, including the two increases to the fees during the seven years of the deal. Methodist's Chief Financial Officer at the time, Chris McLean, also confirmed that only the revenues Methodist generated from West's providers were considered.

145. As of December 22, 2011, Methodist and West had essentially agreed on the material terms regarding the management services to be provided under the MSA. Upon information and belief, the only remaining terms to be finalized in the MSA related to the amount of money Methodist would pay West for base management and performance incentive payments.

146. That amount was finalized after West obtained an FMV opinion from HealthCare Appraisers, Inc. ("HAI"), which according to Methodist was provided on December 20, 2011, just

days before the parties executed the MSA. The HAI opinion discusses the list of obligations under the MSA in detail and states that it is based on the draft agreement West provided. The discussion in HAI's opinion evidences that the draft provided to HAI is ostensibly the same as the version executed. The HAI opinion that Methodist produced in this action continues to be labeled as a draft and is dated February 2012.

147. Using a blending of cost and market approaches,⁴ HAI determined that the FMV for the management services to be provided under the MSA ranged from \$2,316,000 to \$3,255,000 per year. The assumptions underlying HAI's FMV opinion are discussed more fully below. HAI stated that the FMV analysis could be relied upon through February 28, 2014.

148. Under the MSA, Methodist agreed to pay West up to a total of \$3,255,000, which was the top end of the FMV range in HAI's opinion.⁵

149. For Base Management Fees, Methodist would pay West \$1,562,400 per year in monthly installments for inpatient management services at the six Methodist hospitals identified in the MSA and \$390,600 per year for management services at the Cancer Center Sites.

150. In addition, West was entitled to Incentive Compensation if certain delineated quality of service benchmarks, operational efficiency benchmarks, budgetary objectives and new program development benchmarks were attained, with a maximum amount of \$1,302,000.00 for the first term based on its "annual performance." Changes to the Incentive Compensation could be made after the first year of the MSA.

⁴ A cost approach was based on a principle of substitution. The premise was that Methodist would pay no more for the management services than what it would cost Methodist to do the services itself or to otherwise contract with others to provide the services. The market approach is also based on a principle of substitution, but it takes into account what others are paying for similar services.

⁵ HAI assumed that Methodist would "exercise reasonable operational diligence in selecting the appropriate compensation value from within (or below) the FMV range for inclusion" in the MSA.

151. The aggregate payment under the MSA was not set in advance, since there was an incentive component.

152. The parties could also adjust the amount of compensation Methodist would pay West under the MSA after two years.

153. The amount Methodist ultimately paid West under the MSA was based on the volume or value of West's referrals to Methodist.

154. Section 4.5 of the MSA states that it would automatically terminate upon termination of either the PSA or the LEA.

155. Because of restrictions on non-profit hospitals, the bond-financed locations had an initial term under the MSA until December 31, 2016, with an agreement to be renewed in writing by the parties prior to the end of the initial term and each successive term. The MSA remained in effect for the other hospital locations and Cancer Center Sites until December 31, 2018.

156. During the duration of the MSA from January 1, 2012 to December 31, 2018, Methodist paid West over \$27 million, approximately \$13 million of which was for Base Management Fees.

i. West Was Required To Perform Extensive Management Services Under The MSA

157. Sections 1.5 through 1.31 and Exhibit A of the MSA required West to provide a "laundry list" of inpatient management at six Methodist locations and outpatient management at the Cancer Center Sites. The major requirements are set forth below.

158. Section 1.5 of the MSA required West to oversee and manage all clinical staff, including oncology personnel, nursing staff, and hospitalists, involved with the Adult Oncology Service Line. Employees of West, including physicians and those Methodist leased under the LEA, were not included. West could not provide management services through the West employees that Methodist leased or the professional services for which West separately received reimbursement under the PSA. In other words, West could not be paid a management fee to manage itself, and Methodist was not allowed to pay West twice for the same services.

159. Section 1.6 of the MSA required the Operating Committee, with the assistance of West, to develop work plans in the first year for the delivery of general Management Services on Exhibit A, as well as for the performance improvement standards on Exhibit B. The work plan was to include, at a minimum, physicians and staff that would be involved and the documentation to be generated, among other items. The work plans were to be submitted to the Operating Committee for approval, which would periodically review the effectiveness of the plans.

160. Under Section 1.11, West was to provide extensive training and education as set out in the work plans.

161. Section 1.21 required West to assist in preparing monthly and annual reports, including operational and statistical reports, approved by the Operating Committee. These reports were to reflect the work performed, the medical director services provided, and other information.

162. Section 1.29 required West to assist in planning and implementing an electronic health record system ("EMR") so that the Cancer Center Sites and the hospital locations would be able to coordinate with access across the Adult Oncology Service Line.

163. West also was tasked with a number of other tasks, including accreditation, evaluating leases and contracts, negotiating reimbursement rates and fees for third party payors, formulating a quality assurance and utilization review, addressing credentialing issues, designing forms, management and information systems, budgets, billing and collection, evaluating physical facilities, pre-bill review, therapeutic selection, supply chain, review of intensive care services,

evaluations, communications for pre-procedures, case management, and maintaining medical records, as well as other books and records.

164. Exhibit A of the MSA described in more detail some of the management services to be provided with respect to Operational Assistance and included an extensive list of inpatient codes for diagnosis-related groups ("DRGs") and outpatient ICD-9 diagnoses codes that were "subject to the Management Agreement." These inpatient DRG codes and outpatient ICD-9 codes were not intended to be an exhaustive list of the diagnoses and procedures for which West was tasked with providing inpatient and outpatient management services under the MSA.

165. Section 1.4 of the MSA required West to engage medical directors who would be physicians employed by West to perform the duties under the MSA. The MSA required West to compensate all medical directors on the basis of the services they performed, which was to be FMV and not in exchange for referrals.

166. The MSA stated that, in addition to naming Erich Mounce as Administrator, West would initially engage a Medical Director and an Assistant Medical Director for the Adult Oncology Service Line.

ii. The FMV Opinion For The MSA Was Based On The Services The MSA Required

167. As noted above, Methodist and West were clear that to avoid running afoul of the AKS, the amount Methodist would pay West under the MSA needed to be supported by a FMV opinion, which initially was obtained from HAI.

168. HAI provided its FMV opinion based on the information that Methodist and West provided to it, including a draft of the MSA that was final except for the amount of fees.

169. HAI assumed that no aspects of the management services being provided would be performed for wRVUs West submitted under the PSA and noted that Methodist's representatives

on the Operating Committee cannot provide any of the services delegated to West. It also stated that West's physicians would not be compensated for clinical services under the MSA.

170. HAI's opinion also states that it did not otherwise take into account the express terms of the LEA or the PSA or any other arrangements between Methodist and West or its physicians.⁶

171. The FMV opinion assumed that the Administrator (Mr. Mounce), and any medical directors West engaged would be paid as an expense from the Base Management Fee and compensated at a rate consistent with FMV for such services.

172. HAI noted that the determinations of the amount of a physician's time required to provide medical director services depends on a variety of factors, including the number and size of locations, complexity of services provided, and the number of procedures performed. HAI based its calculation first on the projected annual net revenue across the service line, which was estimated at \$146 million. (Note that this number appears to be based on information provided to HAI that reflects only the revenues generated from West's outpatient revenues at the referenced locations and the anticipated West inpatient referrals and not the overall service line revenues.)

173. Given that six Methodist hospital locations were included in the MSA, in addition to the Cancer Center Sites, HAI anticipated that six part-time medical directors or 3.8 full time physician employees would be reasonably required to manage daily operations and perform the oversight of the entire service line. It also assumed that the medical directors would be

⁶ HAI stated that FMV is defined as "the value in arm's-length transactions, consistent with general market value," which is further defined as the compensation "included as a result of *bona fide* bargaining between well informed parties to the agreement who are not otherwise in a position to generate business for the other party."

compensated for a specified and documented number of hours at a rate consistent with FMV. (Note that HAI did not provide a FMV opinion on the medical director positions.)

174. HAI estimated over 6600 hours would be needed to perform these duties. It did not consider what hours would be needed to achieve the incentive payments under the MSA.

175. HAI also referenced the extensive DRGs and ICD-9 codes in the MSA that it was provided, which it considered as part of its determination of the management services associated with those codes.

C. Methodist Allows West An Out Through The Unwind Agreement

176. West was insistent that the arrangement have an out negotiated in advance if West decided to terminate the deal for any reason. Pursuant to the Unwind Agreement, effective January 1, 2012, West could ostensibly "buy back" its assets for FMV if the PSA or MSA were terminated or an option to renew was not taken, as well as for other events triggering an Unwind Event. Essentially, the parties would go back to status quo prior to the deal.

177. The Unwind Agreement was signed by Dr. Tauer for West and Chris McLean for Methodist.

D. Methodist, West And UT Collaborate Through An Affiliation Agreement

178. Simultaneous with the Methodist and West agreements discussed above, West entered into an Affiliation Agreement with the University of Tennessee ("UT"), effective January 1, 2012 (the "Affiliation Agreement"), whereby West, Methodist and UT "agreed to collaborate in the management of MHMH's hospital inpatient and outpatient cancer service lines."

179. Through the Affiliation Agreement, which was executed by Dr. Schwartzberg on behalf of West, West physicians served as UT's "primary faculty group practice for the delivery of academically-related cancer care services," for which West received compensation directly, in addition to compensation that would be provided to West providers who acted as faculty. Pursuant to the Affiliation Agreement, UT, West and MHMH formed a Cancer Council to serve as an Advisory Board for the stated purpose of enhancing the quality of inpatient and outpatient cancer care across MHMH's system-wide cancer service line.

180. The Cancer Council was responsible for, among other duties, the "clinical, research, and educational aspects of the cancer care delivery model throughout the MHMH system."

181. A goal of the Affiliation Agreement was for UT to receive a designation as a National Cancer Institute ("NCI"), which is part of the plan attached to the PSA.

182. The Affiliation Agreement commenced April 1, 2012 with a term that ended on December 31, 2018.

183. The Affiliation Agreement was amended in 2014 to provide additional compensation to West physicians.

E. Methodist Indirectly Pays West Through A For Profit Investment in ACORN

184. As a part of the deal with West, on December 8, 2011, Methodist, through its subsidiary for-profit arm, Ambulatory Operations, Inc., invested \$7 million into ACORN, which Dr. Schwartzberg founded in 2002 and acted as its President and Chief Medical Officer at the time of the transaction. ACORN's affiliation with Methodist and West is noted in the vision for the West Cancer Center set out in the attachment to the PSA.

185. ACORN's focus was to bring community-based oncologists into clinical trials. In 2006, it set up a contract research organization to directly manage industry-sponsored clinical trials. In November 2011, it partnered with AdeptBio, LLC, to expand its ability to obtain biospecimens for targeted populations. In early December 2011, it partnered with Clarient, Inc. to

collaborate around molecular testing of tumor samples. It later announced the divestiture of its ACORN community oncology research network unit to support the research mission of West.

186. Methodist was aware that West was insistent on the deal including a \$7 million investment in ACORN, which Methodist's former CFO characterized as a "start-up" company.

187. Under the terms of the deal, Methodist paid \$3.5 million in cash as a capital contribution, and a \$3.5 million loan.

188. Methodist was aware that \$3.5 million in cash would be used by ACORN to pay back debt owed to Dr. Schwartzberg personally and to West as a company.

189. In October 2011, Methodist and West obtained a valuation opinion relating to the ACORN investment from Michael Choukas, who had previously worked for ACORN and ultimately became its CEO in 2014.

190. Choukas did not have significant experience valuing companies and provided an opinion that lacked accurate financial information, as well as support for business projections.

191. On November 28, 2011, Methodist's Vice President of Legal Services and Compliance identified multiple concerns with the opinion. She recommended "at a minimum" that the valuation be supplemented or revised. No changes were made to address these concerns.

192. Not surprisingly, the ACORN investment failed to turn any profit. In the months before and following Methodist's investment, ACORN sustained ongoing financial losses.

193. When ACORN sought to reduce Methodist's percentage of equity, Chris McLean, Methodist's CFO, was concerned that Methodist's Board might question this investment. In particular, Mr. McLean expressed concerns that Mr. Choukas had previously presented projections that fell far short and might lack credibility.

194. Methodist ultimately extricated itself from the ACORN investment at a loss.

195. The ACORN investment was a means for Methodist to compensate West and Dr. Schwartzberg in particular in exchange for referrals.

* * *

196. The stated goal of the "partnership" was to make the Methodist inpatient facilities seamless with the outpatient sites to form a comprehensive cancer care center without walls. In reality, Methodist agreed to pay West in exchange for referrals and the opportunity to recoup discounts through the 340B Program. As a result of the deal, the West Cancer Center was created.⁷

II. THE MULTI-AGREEMENT STRUCTURE WAS A VEHICLE FOR KICKBACKS

197. Throughout the duration of the relationship, Methodist and West repeatedly referred to the structure and the business of the West Cancer Center as a "partnership" even though West technically sold its assets to Methodist under the APA and was contractually obligated to provide services to Methodist under the PSA, LEA and MSA.

198. The United States is not aware of any formal partnership agreement between Methodist and West. Had a legal partnership been formalized, it likely would have run afoul of HHS guidance as to such arrangements, which may violate the AKS and/or the Stark Law.

199. Through the APA, Methodist purported to legally convert West's Cancer Center Sites to Methodist-owned facilities that Medicare would reimburse at hospital outpatient payment rates and allow Methodist to capitalize on the 340B Program. The LEA and PSA allowed Methodist to staff the Cancer Center Sites with West physicians and employees.

⁷ West officially filed paperwork to do business under the assumed name of West Cancer Center on August 10, 2015. At that time, the Humphreys location West sold to Methodist under the APA was still indicated as its principal place of business. West continued to represent to Medicare that the Humphreys address was a West location until January 2018.

200. However, following the January 1, 2012 effective date of the transaction, West continued to have its principal place of business as a location either that Methodist acquired under the MSA or that Methodist purchased during the course of its relationship with West. Neither Methodist nor West ever advised the United States that West was paying rent to Methodist to operate West business, which included acquiring additional West locations, in which Methodist had no interest.

201. While the PSA and LEA were mechanisms for West providers to treat patients at Methodist-facilities purchased under the APA, the MSA was the only formal agreement through which West and Methodist would take action to achieve the stated vision set forth curiously in the attachment to the PSA. Although the MSA had specific contractual obligations for management services, the parties characterized their relationship as a partnership to improve cancer care and expand cancer treatment in the Mid-South.

202. In viewing and treating the relationship as a "partnership" -- despite that such a formal legal arrangement would run afoul of the Stark Law and the AKS -- much of the "management services" for which Methodist paid West were done to grow the West Cancer Center, which was ostensibly West, and not Methodist.

203. The complicated structure was designed so that physicians and hospitals could align in a manner that would avoid regulatory issues. When, as here, the formalities of the structure are overlooked, Methodist cannot rely on the contracts to insulate it from liability for what in reality were unlawful kickbacks.

A. <u>The MSA Cloaked Methodist's Unlawful Payments To West</u>

204. Sixty percent of the amount Methodist paid West under the MSA was intended to compensate West for base management services. Under the terms set forth in Exhibit B to the

MSA, eighty percent of those Base Management Fees was attributed to inpatient management specifically.

205. Both Methodist and West confirmed to the United States that Methodist paid West \$3,007,620 in management fees under the MSA for 2012, \$3,230,588 in management fees under the MSA for 2013, and \$4,401,750 in management fees under the MSA for 2014. However, Methodist and West provided different numbers to the United States in management fees paid under the MSA for 2015 through 2018. Regardless of the disparities in the numbers provided to the United States in sworn interrogatories, the payments Methodist made to West under the MSA for 2015 through 2018 were in excess of \$16 million.

206. As discussed below, these payments constituted kickbacks as (i) West was not providing all the services at all the locations required under the MSA; (ii) Methodist already was paying for the purported management services under the LEA and through other payments made to West; (iii) Methodist knew and intended for the actions West took under the MSA to induce referrals to Methodist; and (iv) West was primarily continuing to manage itself and grow the business of West, as opposed to managing Methodist.

i. Methodist Never Intended For West To Provide Base Management Services At All The Locations In The MSA

207. The MSA included six Methodist locations for which West was supposed to develop and manage inpatient management services for the adult oncology service line. Despite the inclusion of Fayette, which closed in March 2015, and Extended Care as two of those locations in the MSA, and thus in HAI's FMV analysis, Methodist and West both told the United States that there was no expectation that West would perform any inpatient management services at those locations.

208. Dr. Schwartzberg and Dr. Tauer also confirmed that West did not perform <u>any</u> management services at Fayette or Extended Care during the duration of the MSA.

209. Rather, Methodist and West had an understanding, apparently separate from the language in the MSA, that West would only provide some inpatient management services at University, which was going to be the main location where West would refer its patient.

210. Methodist's former Chief Financial Officer, Chris McLean, acknowledged to the United States that Methodist had inpatient cancer care at University, but it was not fully staffed. Methodist lacked an inpatient cancer unit at Germantown prior to entering into the MSA. PwC also confirmed this.

211. Since the main outpatient locations Methodist purchased from West were in midtown Memphis, Methodist expected to expand the University inpatient unit to meet the needs of the patients it anticipated West would refer. Similarly, Germantown would need an inpatient unit to handle the referrals Methodist and West anticipated from their vision of developing the comprehensive cancer center in Germantown, which is a predominantly white, affluent suburb of Memphis.

212. North and South also lacked any inpatient cancer units, but Methodist and West had no intention of developing inpatient units at North or South when the MSA was executed. Dr. Tauer stated that he "didn't do anything at Methodist South or Methodist North."

213. Both North and South are located in densely populated areas with thousands of cancer patients, as Methodist internal documents confirm. These areas are economically distressed with larger populations of Medicaid and self-pay patients.

214. Dr. Tauer and Dr. Schwartzberg told the United States that if a cancer patient was treated at a Methodist hospital location other than University or Germantown, it was an accident

or emergency, as those locations were not optimal for cancer care because they did not have dedicated oncologists on staff.

215. Consistent with the parties' intentions, Mr. Mounce told the United States that West's referrals to University doubled in the first year of the deal.

216. As of July 15, 2015, internal Methodist documents show that "inpatient business more than doubled" since the inception of the relationship.

217. Although Germantown saw an increase in patient referrals, it was not until 2016 that West added a hospitalist who would be staffed onsite to provide daily oversight to the inpatient cancer care. While West was supposed to oversee hospitalists under the MSA, Methodist was to pay hospitalists for their services under the LEA.

218. Although the parties did not anticipate an impact on the referrals for cancer care to North, because of the increase in West's referrals to University, West patients were sent to North when University reached capacity.

219. As a result, West's referrals to North for cancer patients went from 87 patients in 2011 to 2,000 patients in 2014. In 2016, the average daily census for North was 5.92.

220. Despite the number of cancer patients at North, Mr. Mounce confirmed that West did not provide any significant inpatient management services at North until at least late 2014.

221. Mr. Mounce also acknowledged to the United States that West focused on South only when it realized cancer patients at South were not "being treated correctly." Mr. Mounce stated that eventually West inserted a physician to address both inpatient and outpatient issues.

222. Despite the data that reflects thousands of cancer patients at North and South, Dr. Schwartzberg and Dr. Tauer told the United States that they personally did not provide management services at these locations. They also confirmed that West performed minimal work

at North and South. Dr. Schwartzberg and Dr. Tauer were the only Medical Directors identified and approved by the Operating Committee in accordance with the MSA.

223. When it came to the EMR integration, as of May 2012, the sites of consideration were Germantown, University and West Clinic locations, which included the data at Corinth that was not part of the deal. North and South were not mentioned.

224. Neither Methodist nor West ever conveyed to any of the companies who provided FMV opinions for the MSA that West would not be providing inpatient management to all the locations in the MSA.

225. Even if the census data shows that the majority of cancer patients were treated at the University and Germantown locations, because the four other locations were included in the MSA, the FMV opinions wrongly factored in the need and cost for Medical Directors, as well as the oversight of providers at each location in calculating the FMV range for the management fee.

ii. West Never Provided All The Base Management Services The MSA Required

226. In addition to not providing management services in all the locations required under the MSA, West also had not performed a number of the specific items identified in the MSA as base management and for which Methodist paid West.

227. Dr. Tauer acknowledged to the United States that West had not done inpatient management prior to the deal with Methodist. Given that the MSA essentially required West to develop a plan for inpatient care from scratch, notwithstanding that Methodist never intended for West to cover all six hospital locations, it should have been a massive undertaking for West to even be in a position to begin performing many of the base management services in the MSA. Yet virtually no references to the base management services are contained in the minutes of the Operations Committee, which was tasked with oversight for the MSA.

228. The Operating Committee, which consisted of Drs. Kurt Tauer, Lee Schwartzberg, Sylvia Richey and Brad Somer for West and Gary Shorb, Donna Abney and Chris McLean for Methodist, held an initial meeting on January 12, 2012. It was agreed that the Operating Committee would hold monthly meetings. The MSA responsibilities were discussed. Core management included a "laundry list of items and processes that will have to be integrated into a service line concept." Mr. Mounce indicated that he would present a service line management proposal at the next meeting for review. The Operating Committee was advised that the Cancer Center Council had been created, which would be charged with the development and operations of the Cancer Center over the next three years. Mr. Shorb requested that West present its strategic plan for cancer care at the strategic managers meeting.

229. At a February 2, 2012 Cancer Center Executive Council meeting, the Operating Committee members, structure and responsibilities were discussed, which mirrored the January 12, 2012 Operating Committee minutes. The Cancer Center Executive Council consisted of Drs. Tauer, Somer, Schwartzberg and Richey for West and Gary Shorb, Donna Abney and Chris McLean for Methodist.

230. At the February 9, 2012 meeting of what was then referred to as the MLH and West Management Services Agreement Operations Committee,⁸ the status of 340B approval and savings was the first item discussed. Erich Mounce then advised that the Medical Directors under the MSA would be Dr. Schwartzberg and Dr. Tauer.

231. At this same meeting, the Service Line Management Proposal was discussed as New Business. Mr. Mounce presented a "business plan" for service line management, which was

⁸ The initial members of the MLH and West Operating Committee consisted of Dr. Tauer, Dr. Schwartzberg, Dr. Brad Somer, and Dr. Sylvia Richey for West, and Gary Shorb, Chris McLean and Donna Abney for Methodist.

approved.⁹ Mr. Mounce was tasked with communicating the business plan to each affected MLH hospital. This high-level bullet point presentation, which references forming strategic partnerships and building brand strategy, is the only evidence Methodist identified to the United States the plan for West to begin to provide the extensive requirements for base management in the MSA.

232. Beyond this, there is no substantive mention of "base management" services West provided in the Operating/Operations Committee minutes. The focus, instead, was on the performance incentive items, for which the Steering Committee was tasked with oversight.

233. The United States asked for evidence based on the concrete items in the MSA, which should have been easily identified. In particular, the United States focused on Section 1.21 of the MSA, which required monthly and annual reports that would detail the management services.

234. Although West filed annual reports for 2012 and 2013 in connection with its corporate filings, as it had in prior years, it did not provide Methodist with any annual report for 2012 or 2013 relating to the management services under the MSA.

235. In 2015, West distributed the 2014 West Cancer Center Annual Report, which was a marketing tool for West, as it continued to grow its business separate from Methodist. Methodist referred the United States to this report and West Cancer Center's Annual Reports for 2015 and 2016 as evidence of the annual reports that the MSA required.

236. However, none of these annual reports makes any reference to the MSA. They also include information relating to West locations that were not a part of the MSA and services unrelated to Methodist.

⁹ Although the meeting minutes indicated that the proposal should be attached, it was not in Methodist's production of documents and not provided by Methodist prior to the United States' express request for the referenced attachment in June 2021.

237. Interestingly, Methodist did not identify the 2017 West Cancer Center Annual Report, in which only the front-page logo references Methodist, or the 2018 West Cancer Center Annual Report, which makes no mention of Methodist at all. Yet, Methodist paid West for management services under the MSA for the entirety of 2017 and 2018, and Methodist was reimbursed by Medicare for claims based on the outpatient clinics being hospital owned during this time period.

238. It is not surprising that no annual reports were identified for 2012 or 2013 given that Methodist and West acknowledged to the United States that much of the management services required under the MSA did not occur in the first two years, including the EMR integration required by Section 1.21 of the MSA.

239. At a March 19, 2016 meeting of the West Cancer Center Executive Council, which Methodist's Gary Shorb and Donna Abney attended, it was noted that West had finally "started the [EMR] integration piece which is going to be very complicated." Even though West had not performed this base management item fully in over four years, Methodist paid West a performance incentive fee relating to the EMR.

240. In a May 2016 internal West business plan prepared by Mr. Mounce, West would begin to direct efforts into the co-management responsibility for inpatient care for the West Cancer Center oncology program. West included pursuing a hospitalist program, which it was simultaneously planning to implement at other hospitals where West referred patients.

241. In terms of the MSA's requirements for training and education, much of the work to provide training overlapped with the Affiliation Agreement, for which West was separately compensated. The individuals West tasked to develop training and education were paid by Methodist under the LEA. Mr. Mounce also noted that training largely was done for West physicians, and Methodist's physicians could attend.

242. Training also was not provided in all the Methodist hospital locations. Methodist's Donna Abney noted in an internal Methodist presentation that inpatient nursing education was only launched in Germantown in 2013/2014. There is no mention that any West medical director was involved with launching that education.

243. Methodist also confirmed that West was not managing surgical oncology and that it had no expectation that West would do so on a daily basis.

244. Further, when the United States asked for evidence of base management, Methodist largely referred to performance incentive items that Methodist was supposed to have paid extra for once the day-to-day management activities were achieved. Methodist pointed specifically to the minutes of the Steering Committee.¹⁰ Yet Methodist should not have paid West an incentive when it failed to meet the base requirements, let alone increased the amount of fees for services not provided for years, as with the EMR integration.

iii. West Kept No Documentation For Its Services As The MSA Required, And Methodist Never Asked For Any Support For The Fees It Paid West

245. During the April 4, 2012 MLH and West Operations Committee meeting, Erich Mounce presented the first invoice for payment of base management services, noting that under the MSA, payment was technically due each month. Chris McLean reviewed the base management invoice and asked for formal approval. Mr. McLean stated that "the management fee would be paid monthly from here on out." The group agreed to the arrangement, and payment was authorized to be processed. (Note that there is no mention that West members on the Operations

¹⁰ Methodist identified Foley as being counsel to the Steering Committee.

Committee recused themselves from this approval.). Thereafter, Methodist paid West monthly without question and by the end of 2012 agreed to dispense with the need for invoices.

246. Methodist never reviewed any of the base management items in the MSA to confirm what West had performed during the seven years the MSA was in effect. Methodist's former CFO, Chris McLean, confirmed that Methodist never asked West for any documentation or time records.¹¹ Mr. McLean stated that the MSA was not about time and materials.

247. Yet Section 1.4 of the MSA required West to "maintain documentation that demonstrates the time, efforts and completion of the tasks assigned by Manager to the medical directors, which documentation shall be made available to MLH and MHMH upon request." The MSA also set forth an exhibit which was supposed to be a form of agreement that would set forth the duties and responsibilities of the Medical Directors. None was ever created.

248. Despite HAI's expectation that West would have six part-time medical directors (presumably to handle the management services at the six Methodist locations in the MSA), the only two West providers ever formally identified by West as serving as Medical Directors under the MSA were Dr. Lee Schwartzberg and Dr. Kurt Tauer, both of whom were West shareholders, with significant other West responsibilities, in addition to treating patients and participating in clinical trials and research.

249. Neither Dr. Schwartzberg nor Dr. Tauer, the only two Medical Directors West appointed under the MSA, had any real knowledge of who performed all the base management activities at all the locations required by the MSA. The same is true for Methodist's former President and Chief Executive Officer, Gary Shorb, and former Chief Financial Officer, Chris McLean, who were members of the Operating Committee charged with oversight for the MSA.

¹¹ PwC also noted its expectation that time records would be kept.

250. Although Dr. Tauer signed all the deal documents with Methodist on behalf of West, he was unaware that he was the Medical Director under the MSA, and he had no idea who served as Methodist's Medical Director. As part of performing the base inpatient management services under the MSA and being on the Operating Committee, Dr. Tauer necessarily should have needed to interact with the Medical Director of Methodist over the course of the seven years that West was contracted to provide management services for Methodist.

251. The only individual with any information about base management was Mr. Mounce, the Administrator. Mr. Mounce told the United States that he spent only 5-10% of his time on inpatient matters and often worked with Methodist staff to address many of the items West was to perform under the MSA. Mr. Mounce also told the United States that nurse practitioners provided some of the management services under the MSA, but he acknowledged that, like Mr. Mounce, they were paid by Methodist under the LEA.

252. West also was required to "maintain documentation of the payment or distribution of the Base Management Fees and Incentive Compensation to the participants and members" of West. West's former CEO, Mr. Mounce, represented to the United States that West did not provide any direct compensation to anyone under the MSA, including any Medical Directors. Mr. Mounce also was responsible for determining the amount of compensation West provided to its physicians, even though he was an employee leased to Methodist.

253. Despite being a leased employee to Methodist, Mr. Mounce had significant duties for West. Mr. Mounce's entire base salary was paid by Methodist through the LEA, with his bonus paid and determined by West. He was not and could not be paid under the MSA.

254. While West employees leased to Methodist may have provided *some* of the services required under the MSA, West was not entitled to receive compensation for their services under the MSA. West also could not be compensated under the PSA for the MSA services.¹²

255. Although Section 5.1 of the MSA gave Methodist a right to audit West's activities under the MSA, Methodist never did so.

256. If Methodist (or its auditors) had requested any support for the millions Methodist paid West under the MSA, West would not have been able to provide any, as West told the United States that it did not keep any such documentation.

257. Indeed, West confirmed that it has no documentation of what was done or by who to substantiate the Base Management Fees paid under the MSA for each of the hospital locations and the Cancer Center Sites, including the Medical Director duties and compensation.

258. Because West did not possess the requisite support under the MSA, neither West nor Methodist was able to provide the United States with answers as to what work was done and by whom at West that should have explained the basis for the Base Management Fees. That the parties did not even provide the same answers to the United States as to the total amount of fees Methodist paid to West under the MSA from 2015 to 2018 is telling.

iv. Methodist Knew West Did Not Provide All The Services The MSA Required, And That The Assumptions Underlying The FMV Opinions Were Invalid, Yet <u>Methodist Increased Payments To West Under The MSA As Referrals Increased</u>

259. Not only did Methodist pay West the full amount of base management fees for 2012 and 2013, despite knowing it had never performed all the services required by the MSA, let alone

¹² To the extent West received payment from Methodist under the PSA for wRVUs relating to work West physicians, including Dr. Ballo, performed doing management services under the MSA, such payment would be wholly improper under the PSA.

at all the locations required by the MSA, when West sought an increase in the amount of overall fees for 2014 based on the increased revenues to Methodist from its referrals, Methodist agreed.

260. To increase the amount of fees, West needed to obtain an updated FMV opinion that would be used to support the increase West wanted. West again engaged HAI, but it also retained a second firm, Altegra. West provided both with financial information, and copied Chris McLean from Methodist on the email.

261. In the revenue information provided, West included Fayette and Extended Care, where Methodist acknowledged West did not provide any inpatient management, as well as the North and South locations where Methodist knew West spent minimal efforts.

262. The financials provided also included a line for professional fees collected that was deducted from the revenues. Both Methodist and West told the United States that these numbers do not reflect the professional collections for the entire adult oncology service line that West was paid to manage under the MSA. Rather, professional collections were limited to the clinical services that West physicians personally performed at the "partnership" locations.

263. The minutes from the June 4, 2014 meeting of the Operations Committee state that HAI's preliminary analysis valued the total management services in 2014 as between \$2,768,000 to \$3,763,000. Altegra came in with an initial estimate that was between \$4.3 million and \$4.85 million -- over one million more than that of HAI.

264. HAI had done a more in-depth analysis than Altegra and was fully familiar with the MSA requirements from the extensive work it performed to provide the initial FMV opinion. HAI also expressed concerns about the amount for incentives and requested that the benchmarks be more defined. It noted that it would lower the FMV range if this was not done.

265. When the two valuations were put forward, Methodist never expressed any concerns about the disparity and did not debate the increase in the fees. Instead, Methodist accepted Altegra's higher valuation. Altegra's FMV opinion had a range of \$4.32 million to \$4.87 million in fees and could be relied on through December 31, 2016.

266. Methodist and West also agreed on new performance incentives beginning in 2014. Some of these items were part of the base management that were not initially performed, such as the EMR integration. Most everything related to outpatient care.

267. Ultimately, Methodist paid West over \$4 million in fees under the MSA for 2014.

268. Again in 2016, West sought an additional increase in the payment under the MSA.

269. West engaged only one company, Pinnacle, whose staff previously worked for Altegra.

270. As with the 2014 valuation, the revenues reported to Pinnacle include Methodist hospitals not part of the MSA, as well as amounts for professional collections that appear to be incomplete, which results in a higher total revenue, and thus a higher range of fees.

271. The revenues provided to Pinnacle also included Le Bonheur, Methodist's pediatric hospital, which was expressly excluded from the MSA.

272. West expressly confirmed to Pinnacle that the correct revenue amount was \$242 million, which included the locations Methodist and West admitted West did not provide management services and Le Bonheur.

273. West pushed for a higher amount based on the higher revenues, but Pinnacle indicated concerns with increasing the amount. Pinnacle noted that the documentation provided did not support the expectations it had in providing the prior valuation. Specifically, West

provided an estimate of hours that physicians worked which was less than what was previously estimated.¹³

274. Following this communication, West did not push back further and accepted Pinnacle's valuation of \$3.4 million to \$4.74 million. For 2016, Methodist paid West over \$4 million in fees under the MSA.

275. West obtained another valuation from Pinnacle for 2017, which provided a range of \$3.68 million to \$5.09 million.

276. Methodist was aware that the financial information West provided to obtain the 2014, 2016 and 2017 FMV opinions was flawed not just in the revenue information but in the numbers for professional collections, which were deducted from the revenues.

277. Essentially, West provided inflated revenues numbers for locations that it did not manage, and then deducted professional collections based only on the locations where it had provided services based on its referrals. This resulted in a higher revenue amount that would be used to determine the amount of fees.

278. Although Methodist provided amounts for the professional collections in response to the interrogatories Relators served in this action, Methodist and West both told the United States that they could not be certain as to the accuracy of the amount of professional collections. In any event, these figures Methodist provided are tens of millions higher in total than what was provided to obtain the FMV opinions that supported the increases in MSA payments.

279. The amounts of professional collections provided to the valuators were millions less than what Methodist paid West under the PSA.

¹³West never identified to the United States the documentation given to Pinnacle as evidence of the hours spent on management.

280. In addition, to the extent the valuators relied on the inpatient DRGs identified in determining revenues and inpatient services to be managed by West, many of the DRGs have nothing whatsoever to do with oncology. In fact, when the United States asked how the specific DRGs came to be in the MSA, no one from West or Methodist had any understanding of what the purpose was, other than that Foley must have used the same ones they had from another deal it structured.

281. For the reasons stated above, Methodist was aware that the assumptions underlying the initial valuation were in line with the MSA terms, but not with the parties' true intentions.

282. Methodist also was aware that the assumptions underlying the 2014 and 2016 FMV opinions to support the increases in management fees West sought under the MSA were false, including the locations managed, the number of medical directors, the base management items that had not been provided, and that the individuals West purportedly tasked with performing management services were being paid by Methodist under the LEA.

283. Methodist has never identified, and the United States is not aware of, any formal amendment to the MSA.

284. In sum, the failure of Methodist and West to comply with the express terms of the MSA are indicia of a sham agreement, and the payments Methodist made to West thereunder are unlawful.

B. <u>The Deal Documents Were A Means To Disguise The Fraudulent Relationship</u>

285. Under the APA, Methodist purchased the Cancer Center Sites from West. Methodist either directly employed or leased West's non-physician employees under the LEA. The Cancer Center Sites and the dedicated Methodist hospital inpatient locations made up what the parties referred to as the West Cancer Center. During the "partnership," the West Cancer Center grew to include the Margaret West Comprehensive Breast Center. Methodist should have been paying West under the MSA for management services, including Medical Directors, at the West Cancer Center. Under the structure, the West Cancer Center should have been owned and staffed by **Methodist**, except for the physicians who provided professional services there and that were employees of West or UT.

286. Notwithstanding the contracts and the requirements therein that purported to provide a lawful way for Methodist to pay West in exchange for referrals, the conduct of Methodist and West show that those agreements were largely meaningless paper.

287. Following the APA, West never changed its Medicare enrollment forms to reflect that these locations had been sold to Methodist.

288. In numerous email communications to Methodist, West employees, who were leased to Methodist, kept their signature blocks as working for West, located at the Humphreys location Methodist purchased until West moved its principal place of business to the Margaret West Comprehensive Breast Center in 2015, which was a location owned by Methodist at that time. In 2015, West also submitted an enrollment form to Medicare reflecting 7945 Wolf River Boulevard as the primary West location. West began listing a suite at 7945 Wolf River as a West location in January 2013. Upon information and belief, West did not own or even lease space at the 7945 Wolf River location until 2019.

289. In formal communications to third parties, Mr. Mounce, who was a full-time leased employee to Methodist, repeatedly held himself out as acting on behalf of West directly. For example, in the proposal sent to St. Bernards, on which Methodist was copied, despite having his entire base salary paid by Methodist, Mr. Mounce communicates on letterhead on behalf of West specifically. Simultaneously, this related to work Methodist considers as being done in furtherance of the MSA.

290. Three months into the deal, at the April 4, 2012 MLH and West Operations Committee meeting, Dr. Tauer advised that Methodist was "looking to provide a full time position stationed within the West Clinic to help coordinate care and transitions of care for the Hospice." It is unclear where that would be, given that the only remaining West Clinic physical location was in Corinth, MS, which was excluded from the transaction.

291. Despite their supposed roles as Medical Directors for Methodist from 2012 through 2018 under the MSA, as of June 2021, neither Dr. Schwartzberg nor Dr. Tauer considered themselves as acting as Medical Directors for Methodist.

292. Dr. Tauer told the United States that he was never a Medical Director at Methodist. West's counsel told the United States this was supposedly a truthful statement because Dr. Tauer viewed his role as a Medical Director at the West Cancer Center and not Methodist.

293. Neither Dr. Schwartzberg nor Dr. Tauer had any reference to work for Methodist on their curriculum vitaes. Dr. Schwartzberg, who was also a Medical Director at West, indicated that he acted as a Medical Director for the West Cancer Center from 2000 to present; Dr. Tauer does not mention being a Medical Director, including with West.

294. The MSA, however, required the Medical Director to perform inpatient management services at **Methodist** hospital locations. And Methodist's former CFO, Chris McLean, was very clear that Methodist owned the West outpatient locations.

295. Regardless, Methodist and West continued to view the previously owned West locations as still being West, despite the over \$10 million Methodist paid for these locations under the APA. The West employees leased full-time to Methodist also continued to provide services to

West, including human resources and financial services, such as determining compensation to West employees and growing West's business that was unrelated to Methodist.

296. When the United States asked for evidence of the inpatient base management, Methodist instead pointed to its investments to improve cancer care during the deal, including a 123,000 square foot facility in Germantown, which now is the Margaret West Comprehensive Breast Center/East Campus of West, for which Methodist paid West performance incentive fees under the MSA. Yet, West used this location in its corporate filings before West purchased it from Methodist when the relationship ended in 2019.

297. Not once has Methodist indicated that West was paying rent for the space that it occupied that Methodist owned or leased.

298. West also continued to grow its own practice and opened new locations. West could have located itself for corporate purposes in a location that West operated or acquired during the course of the arrangement that were not affiliated with Methodist, including Corinth, MS, Jonesboro, AK, Jackson, TN, or Paris, TN. It did not.

299. West focused its efforts on the breast cancer part of its practice, including hiring several breast surgeons in 2012. West initially opened a Germantown, TN, location referred to as the West Breast Center, while the West Cancer Center/Margaret West Breast Center, named for the mother of West's founder, was being constructed. In an August 14, 2013 meeting of the West, Methodist and UT Cancer Center Executive Council, Erich Mounce noted that the capital expenditures for the downtown cancer sites were expected to be around \$40 million, which largely came from Methodist's budget for construction and renovation of the Wolf River building (now

West's Margaret West Comprehensive Breast Center/East Campus).¹⁴ Methodist contributed millions to construct this facility, which was a source of West inpatient referrals to Methodist during the course of the deal. West purchased the Wolf River building from Methodist when the deal ended in 2019.

300. In 2013 and 2014, nine radiation oncologists joined West Cancer Center, including Dr. Mathew T. Ballo, who was hired by West and UTHSC in October 2, 2013 to be the Medical Director of Radiation Oncology for West, the Director of Radiation Oncology for the UT WEST Cancer Center, and a professor at UTHSC. The offer letter was signed by Dr. Schwartzberg as Chair of the Executive Cancer Council, which consisted of MLH, West and UTHSC, as well as Dr. Stern, on behalf of UTHSC. Members of the Executive Cancer Council, which included Methodist's Gary Shorb, received a copy of the executed Offer Letter.

301. Dr. Ballo's salary for the positions with West and the UT WEST Cancer Center was paid for through Cancer Mission Support Funds that were managed by the Executive Cancer Council. Dr. Ballo was responsible for the "general oversight" of the MLH Radiation Oncology Program, which his offer letter states "delineated responsibility" to West under the MSA. He was also responsible for developing a Quality Management Program that tracked the quality outcome measures for West, for which West could attain payment under the performance incentive component of the MSA. His duties included developing multidisciplinary clinics and recruiting. His clinical work was measured in wRVUs, with an expected floor of no less than 7000 annually.

¹⁴ The 2015 West Cancer Center Annual Report touted the new \$60.5 million East Campus location that was opened officially in November 2015. This funding is consistent with the attachment to the PSA setting forth the vision of the "partnership" that Methodist and West created through the transaction documents.

302. Dr. Ballo expressly was hired to provide services to Methodist under the MSA but was not paid by West under the MSA for such services, whether as a Medical Director or otherwise. Rather, his salary for this came directly from Cancer Mission Support Funds that upon information and belief were provided by Methodist and sourced from the discounts Methodist realized from the 340B Programs.¹⁵

303. Thus, Methodist was paying West for "management" in multiple ways, including under the Affiliation Agreement, which focused on education and research, and with Cancer Mission Support Funds to provide the management services Dr. Ballo provided.

304. Methodist also knew that Dr. Schwartzberg and Dr. Tauer, the only West physicians who were officially acting as Medical Directors under the MSA, and other West physicians, including Dr. Ballo, were simultaneously providing services to UT, for which they were separately compensated, in addition to the professional services for which they would submit wRVUs under the PSA.

305. In sum, West continued to view itself as running the business of West and held itself out to the public as acting on behalf of West, even when it was supposed to be acting on behalf of Methodist. Methodist was aware of this and allowed it to continue, including by allowing West to use Methodist outpatient locations to conduct the business of West that had nothing to do with Methodist.

306. That West continued to operate out of the locations it was supposed to sell for corporate purposes and never viewed itself as providing management services to Methodist demonstrates the structure existed in paper only. Consistent with the parties' conduct, Methodist's

¹⁵ As a result of Dr. Ballo's efforts, West now provides radiation oncology treatment, which it had not done prior to the deal with Methodist. In February 2021, Dr. Ballo became an ownership partner of West.

counsel told the United States that the specific terms of the agreements were not important, as this was not an action asserting claims for breach of contract.

307. Yet, the contracts are key to Methodist being able to bill Medicare for the outpatient services and obtain the 340B Program discounts. If the contracts are a fiction, Medicare should not have reimbursed Methodist for the outpatient claims, and Methodist never would have been able to realize the profits from the 340B Program. If the contracts were real, then Methodist gave West rent-free space and paid for the salaries of West's employees to perform work to further the business of West.

III. METHODIST KNEW THAT IT WAS PAYING WEST TO INDUCE REFERRALS

308. As Methodist's former CEO confirmed, inherent in the parties' stated intention to create a cancer center without walls was the premise that West's patients would be referred to Methodist for any inpatient needs. This was exactly in line with what Foley had marketed.

309. Prior to the deal, West referred the majority of the 35 to 60 inpatients it typically managed on a daily basis to Baptist.

310. Chris McLean was clear that after the deal virtually all of West's patients instead were referred to Methodist.

311. In fact, the West referrals started almost immediately after the deal was done, even though West had concerns about the inpatient care that Methodist could provide its patients, which Methodist's own consultant, PwC also noted should be addressed before inpatient care transitioned.

312. For example, on October 6, 2011, West began treating a new patient, A.R., for cervical cancer. A.R. was referred by West to Baptist for inpatient treatment from November 14 to 16, 2011, for which Medicare reimbursed Baptist. In January 2012, immediately following the

deal, West continued to treat A.R., but with claims being submitted as Methodist-outpatient facilities, and for which Medicare reimbursed Methodist. West referred A.R. to Methodist for inpatient treatment that occurred January 11 to 12, 2012. Medicare reimbursed Methodist \$8,038 for West's referral, which was paid on February 2, 2012. Medicare also reimbursed Methodist for West's outpatient treat of A.R. from June 11 to 14, 2012, in the amount of \$3,944, which was paid on August 1, 2012. Medicare also reimbursed Methodist \$4,818 for West's outpatient treatment of A.R. from September 28 to October 16, 2012, which was paid on November 19, 2012. Medicare continued to reimburse Methodist for West's outpatient treatment of A.R. for West's outpatient treatment of A.R. for West's network of the remainder of 2012 and until February 2013, when West again referred A.R. to Methodist for inpatient treatment received from February 19 to 28, 2013. A.R. passed away in March of 2013.

313. West also had been treating P.H., an established patient throughout 2011. West referred P.H. to Baptist, where she was treated as an inpatient from November 11 to 12, 2011, for which Medicare reimbursed Baptist. In January of 2012, West continued to treat P.H. as an outpatient at Methodist-owned facilities, for which Medicare reimbursed Methodist \$2,573, which was paid on October 15, 2012. West continued to treat P.H. as an outpatient in February, March, May and June of 2012, for which Medicare reimbursed Methodist each time. On June 30, 2012, Methodist again treated P.H. for inpatient care, for which Medicare reimbursed Methodist \$4,340 on July 25, 2012, with a West provider as the referring physician. P.H. continued to be treated as an outpatient by West in July 2012, for which Medicare reimbursed Methodist. West then referred P.H. to Methodist for inpatient care on August 16, 2012. P.H. remained in the care of Methodist until August 19, 2012, when she died. Medicare reimbursed Methodist for this inpatient referral in the amount of \$37,196, which was paid on September 27, 2012.

314. To ensure that West would receive credit for its referrals, such as with A.R. and P.H., Methodist and West tracked the amount of referrals from West to Methodist for both inpatient and ancillary services throughout the course of their relationship.¹⁶

315. In a February 21, 2012 email from West CEO Erich Mounce to Methodist's CFO Chris McLean and a member of Methodist's Knowledge Management Team, entitled West Clinic Methodist Hospital Census, Mr. Mounce requests daily reports from Methodist of the number of patients at Methodist with a West physician as an Admitting, Attending, Referring or Consulting provider.

316. In the MLH and West Operations Committee April 4, 2012 meeting minutes, Erich Mounce updated the committee members on the status of the inpatient census for the number of inpatients "managed" at the West service line inpatient and some outpatient testing at all MLH hospital. A statistics dashboard also was created that tracked this information.

317. Chris McLean told the United States that the inpatient census was tracked so West could be paid more for the additional work under the MSA. He viewed the increase in inpatients as a positive impact on Methodist's revenues. Of course, an increase in cancer inpatient revenue should have been viewed as a negative in terms of treatment outcomes.

318. With the development of the Methodist Healthcare/West Clinic Genetic Education and Counseling Program, Methodist and West also found new avenues to support referrals,

¹⁶ The claims for which Medicare reimbursed Methodist relating to A.R. and P.H. are illustrative of the unlawful referrals for which the United States seeks to recover damages. Given the seven-year duration of the kickback arrangement, the tainted claims consist of all the unlawful referrals for which Medicare reimbursed Methodist, which are too numerous to include.

including through the genetics program that Methodist touted as an example of the management services provided under the MSA.¹⁷

319. Per a May 2, 2012 Steering Committee Quality Initiative Report, which tracked items for performance incentive compensation, "The West Clinic, in combination with Methodist Healthcare, [would] partner to provide the added dimension of healthcare, to include genetic testing." The draft business plan for the genetic program described the arrangement as follows: "West Clinic physicians may request genetic counseling consults for patients who are admitted [inpatient at University or Germantown] and need genetics services before end-of-life." Thus, there was added incentive to West under the MSA in referring patients to Methodist for genetic testing.

320. The push for West physicians to refer patients to Methodist for ancillary services was so great that by November 2012, West radiologists already were complaining. A West provider stated: "I certainly had no idea how serious it was for us to immediately send biopsies to Duckworth and meet with Methodist Radiology." He later asked for clarification of the relationship with Methodist and their ancillary services and sought to ensure that his compensation was not impacted. (Note that Duckworth was affiliated with Methodist, but West physicians were concerned about sending biopsies to Duckworth, which they believed was inferior to other providers.)

321. The census numbers that West and Methodist tracked support the increase in West's referrals to Methodist, as does the amount Medicare reimbursed Methodist, detailed below.¹⁸

¹⁷ Although this was not base management, Methodist identified this as a "work plan" under the MSA when the United States asked for evidence of the base management services, and in particular inpatient management.

¹⁸ Relators allege that the money to pay West for the referrals came from the 340B Program. Although the United States has not yet had an opportunity to investigate the accuracy of this

322. In other negotiations that were purportedly part of the management services Methodist claims were provided, Methodist made clear that it was willing to compensate physicians in exchange for their referrals.

323. For example, the Operations Committee, which was supposed to be tasked with oversight of the MSA, discussed an April 23, 2012 proposal Mr. Mounce of West, who was leased to Methodist under the LEA, sent to St. Bernards Hospital about the possible implementation of a gynecological oncology program in Jonesboro, AR, whereby St. Bernards would use its "best efforts" to refer patients to Methodist's University location.

324. The proposal was for an arrangement among West, Methodist and St. Bernards, whereby they would "work to develop a cancer service line for Gynecological Oncology ('GYNOnc') while developing a tertiary cancer network referral process that will allow patients to be cared for by West / MLH physicians for higher end surgical and medical oncology treatment not typically provided at St. Bernards Hospital." Separately, West/MLH and St. Bernards would develop an extension of the Breast Center in Jonesboro. Methodist's Gary Shorb and Donna Abney were copied on this proposal, which was signed by Mr. Mounce.

325. The Committee noted "that it would be important to ensure appropriate payment but also appropriate referrals back to the MLH system for surgical oncology cases."

IV. <u>METHODIST PROFITS FROM THE UNLAWFUL PARTNERSHIP</u>

326. Over the entire duration of the financial arrangement between Methodist and West, Methodist paid West, directly through the APA, PSA, and MSA and indirectly through the ACORN investment, over \$300 million. In addition, Methodist made substantial capital

allegation, West confirmed that it expected access to the 340B Program to provide it with funding. Methodist also provided West with information on the status and amount of discounts it obtained through the 340B Program, even though it was managed by a third party and not West.

expenditures and provided funding that allowed West to continue to expand, including constructing the Margaret West Breast Cancer Center, as the PSA attachment contemplated.

327. Methodist had no qualms about exactly how much it was paying West and for what services because Methodist was realizing all the gain in revenues from the outpatient and inpatient referrals, as well as the 340B Program.

328. Methodist's former CFO was quick to advise the United States that Methodist realized \$50 million in 2017 alone from discounts through the 340B Program.

329. Consistent with the parties' expectations, Methodist saw an exponential increase in reimbursements from West referrals in the first year. In 2011, Methodist received approximately \$4 million from Medicare for referrals from West providers for inpatient claims. In 2012, this number went up to almost \$6 million.

330. In 2012, Medicare reimbursed Methodist over \$27 million for outpatient claims performed by West providers.

331. During the entire length of the Methodist and West's contractual relationship, Medicare reimbursed Methodist over \$300 million for outpatient services through West providers and over \$53 million for inpatient claims from West's referrals.¹⁹

332. In contrast, Baptist's inpatient reimbursements from Medicare for West referrals were cut in half. Medicare reimbursed Baptist almost \$6 million in 2011 for inpatient claims relating to West. In contrast, Medicare paid Baptist under \$20 million for the entire seven years of the arrangement, which averages to less than \$3 million a year, and this was despite the considerable growth West saw to its business overall through the funds Methodist contributed.

¹⁹ Note that Medicare patients made up approximately half of the payor mix during the deal. Estimations of profits are based only on Medicare claims data.

333. In over two and a half years since the deal terminated in 2019, Medicare reimbursed Methodist less than \$12 million for outpatient claims tied to West. Medicare also reimbursed Methodist less than \$5 million a year for inpatient claims referred by West providers.

334. Methodist was fully aware of the requirements for participation in Medicare, including compliance with the AKS.

335. Had Medicare known about the unlawful conduct described herein, it would have denied payment for these claims.

V. <u>THE KICKBACK ARRANGEMENT COMES TO AN END</u>

336. Despite the profitability of the Methodist-West deal, it was not sustainable.

337. The parties anticipated a movement to value-based care, which lowered the amount of reimbursement, as well as the deterioration of 340B Program. Both came to fruition.

338. In addition, as with many business relationships, the parties did not always see eye to eye in their vision for growth and governance. In particular, Methodist's radiology group was not interested in being managed by West, which was a challenge throughout the relationship. West also had some disputes with UTHSC management, as West often marketed itself as only the West Cancer Center.

339. As the "partnership" was not formally documented, Methodist, West and UTHSC spent several years discussing a business combination in the form of a "friendly PC" or other documented partnership to no avail.

340. Nevertheless, the informal partnership was able to continue because West trusted Methodist's Gary Shorb and Chris McLean. However, the parties knew that Mr. Shorb was retiring in 2016.

341. West did not have the same relationship with Michael Ugwueke, who succeeded Mr. Shorb as Methodist's CEO.

342. Mr. Ugwueke expressed regulatory concerns and was insistent on West physicians becoming Methodist employees and formally documenting the relationship.

343. In December 2016, Ugwueke advised West that if it did not enter into a Letter of Intent to end the prior agreements, which would include West being dissolved and becoming a part of Methodist officially, he intended to bring the matter to Methodist's Board and seek arbitration and resolution.

344. However, West was always clear that it wanted to retain its autonomy, including its ability to negotiate separate arrangements with other area hospitals.

345. While the negotiations continued, West continued to grow its business and extricate itself from any public affiliation with Methodist, as its 2017 Annual Report shows.

346. In June of 2018, the United States served Methodist with a Civil Investigative Demand seeking information relating to the AKS allegations.

347. On August 10, 2018, West advised Methodist that it was going to unwind the transaction.

348. It took several months for the parties to negotiate the terms of the unwind. Ultimately, West paid \$16 million for the assets and \$51 million for the real estate, which included certain assets that Methodist purchased from West initially and provided financing for during the course of parties' relationship, including the \$60.5 million East Campus/Margaret West Comprehensive Breast Center. The arrangement officially ended as of February 23, 2019.

349. In the meantime, on February 1, 2019, the United States obtained a partial seal lift to advise Methodist of the existence of the *qui tam* action.

350. Methodist also lost the adult outpatient cancer centers and the associated referrals.

351. Meanwhile, West went back to the business of running West, retaining the West Cancer Center name it used during the entirety of its relationship with Methodist.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

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

352. The United States repeats and realleges all preceding paragraphs of this Complaint as if fully set forth herein.

353. Methodist violated the AKS in that it knowingly paid West remuneration through, at a minimum, the payments made under the MSA for a purpose of inducing West's referrals of patients and ancillary services to Methodist, and Methodist received reimbursement for such referrals from the federal health care programs, including Medicare.

354. Methodist also submitted false claims to Medicare, including cost reports, stating that it did not violate the AKS.

355. Violations of the AKS also constitute violations of the FCA.

356. As detailed above, Defendants presented, or caused to be presented, materially false and fraudulent claims for payment or approval to the United States, and claims for reimbursement by Medicare that were false and fraudulent because they were based on illegal referrals in exchange for payments to West.

357. As detailed above, Medicare would not otherwise have paid for these false and fraudulent claims.

358. Defendants presented or caused to be presented these claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

359. Defendants are liable to the United States for treble damages and civil penalties for the tainted claims in an amount to be determined at trial.

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

360. The United States repeats and realleges all preceding paragraphs of this Complaint as if fully set forth herein.

361. As detailed above, Defendants made, used, or caused to be made or used, false records or statements, which included the false certifications and representations on forms CMS 1500, as well as the EDI enrollment and applications, to obtain approval for and payment by the United States for false or fraudulent claims as detailed above.

362. Defendants' false certifications and representations were made for the purpose of ensuring that Medicare paid the false or fraudulent claims, which was a reasonable and foreseeable consequence of Defendants' statements and actions.

363. The false certifications and representations made or caused to be made by Defendants were material to the payment of the false claims by the United States.

364. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

365. Defendants are liable to the United States for treble damages and civil penalties for each false statement in an amount to be determined at trial.

THIRD CAUSE OF ACTION

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

366. The United States repeats and realleges all preceding paragraphs of this Complaint as if fully set forth herein.

367. As detailed above, Defendants made, used, or caused to be made or used, false records or statements material to obligations to pay or transmit money to the United, or concealed, improperly avoided or decreased obligations to pay or transmit money to the United States.

368. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

369. Defendants are liable to the United States for treble damages and civil penalties for each false record in an amount to be determined at trial.

FOURTH CAUSE OF ACTION FCA: Reverse False Claim (31 U.S.C. § 3729(a)(1)(G))

370. The United States repeats and realleges all preceding paragraphs of this Complaint as if fully set forth herein.

371. Even if Methodist initially was not aware that the financial arrangement with West violated the AKS, it became aware of it during the course of the deal. When Methodist agreed to increase the amount it paid West under the MSA in 2014, knowing that West had not performed the services and had provided inaccurate and/or incomplete information to obtain the fair market valuation option that formed the basis for the increased amount, it knew or recklessly disregarded that it was violating the FCA. At the latest, Methodist knew it was violating the FCA when Liebman raised objections to the arrangement with West and questioned why West was not providing management services after he became the CEO of University in 2014.

372. Methodist made or used, or caused to be made or used, false records and statements to conceal, avoid, or decrease an obligation to pay or transmit money to the United States with respect to claims submitted fraudulently in violation of the FCA, including the submission of thousands of claims to Medicare.

373. Said concealment and avoidance was done with actual knowledge of the refund or payment obligations, or with reckless disregard or in deliberate ignorance of these obligations.

374. Because of Methodists' unlawful conduct, the United States is entitled to treble damages and civil penalties for each false record or statement in an amount to be determined at trial.

PRAYER FOR RELIEF

Wherefore, the United States demands that judgment be entered in its favor and against Defendants jointly and severally for each violation of the FCA, with the amount of damages trebled and such civil penalties as required by law, together with all such further relief as may be just and proper.

Respectfully submitted,

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