IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY

UNDER SEAL, PLAINTIFF[S], v. UNDER SEAL, DEFENDANTS.	CIVIL ACTION NO. 3:17-CV:294-CRS JURY TRIAL DEMANDED **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730**

AMENDED COMPLAINT

SEALED CASE---DO NOT ENTER ON PACER

TABLE OF CONTENTS

I. Introduction 1

II. Jurisdiction and Venue 4

III. Parties 5

IV. Applicable Federal and State Laws and Regulations 6

A. Government Health Insurance Programs 6

B. The Federal False Claims Act 8

C. The Anti-Kickback Laws of the United States and Kentucky 10

D. The Federal Stark Statute 12

E. Required Certifications to Government Health Care Programs 13

F. Claims for Payment Must Conform to Law and Regulation 15

1. Medicare Part B Requires Detailed Written Orders Prior to Billing and Refill Requests Prior to Dispensing Refills 15

2. All Claims Must Reflect Accurate Costs and Not Exceed "Usual and Customary Price" 17

3. Routine Waiver of Co-Pays and Deductibles Results in False Claims and Violates the Anti-Kickback Statute 19

4. In-Kind Services Are Illegal Remuneration under the AKS 20

V. Facts and Allegations 21

A. Summary of Defendants' Unlawful Conduct 21

B. Violation of Detailed Written Order and Refill Request Requirements 23

C. Overcharging the Government 26

D. Illegal Copayment and Deductible Waivers and Write-Offs 27

E. Illegal Kickbacks and Violations of the Stark Law 28

F. Damages 30

1. Damages from Violation of Medicare Part B Requirements 30

2. Damages from Overcharging Usual and Customary Price 30

3. Damages from Copayment and Deductible Waiver False Claims 30

4. Damages from Illegal Kickbacks and Self-Referrals 30

VI. Claims for Relief....31
Count One - Federal False Claims Act – False Claims....31
Count Two - Federal False Claims Act – False Records or Statements....31
Count Three - Federal False Claims Act – Conspiracy....32
Count Four - Federal False Claims Act – Reverse False Claims....33
VII. Prayers for Relief....34

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY

UNITED STATES OF AMERICA *ex rel.* ROBERT STONE, PLAINTIFF, V. JEWISH HOSPITAL & ST. MARY'S HEALTHCARE, INC., KENTUCKYONE HEALTH, INC., AND UNIVERSITY OF LOUISVILLE PHYSICIANS, INC., DEFENDANTS.	Civil Action No. 3:17-CV:294-CRS JURY TRIAL DEMANDED **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730**

AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

I. INTRODUCTION

1. This is an action to recover damages, civil penalties, and other relief on behalf of the United States for false and/or fraudulent statements, records, and claims made and caused to be made, and overpayments retained, by the Defendants and/or their agents and employees and subsidiaries to Government Health Care Programs in violation of the federal False Claims Act, 31 U.S.C. §§ 3729, *et seq*.

2. Defendants Jewish Hospital & St. Mary's Healthcare, Inc. ("Jewish Hospital"), KentuckyOne Health, Inc. ("KentuckyOne"), and University of Louisville Physicians, Inc. ("UL Physicians") have committed and are committing this health care fraud on an ongoing basis.

3. Jewish Hospital and KentuckyOne's fraudulent schemes include submitting false and fraudulent claims to Government Health Care Programs through their Pharmacy Plus and Pharmacy Plus Specialty Departments that:

a. violate Medicare Part B Detailed Written Order ("DWO") and refill request rules;

b. overcharge the government for prescription medications; and

c. seek payment for prescriptions induced through illegally waived co-payments and deductibles and the provision of care coordination staff to prescribing physicians (including transplant physicians and other high value physician groups).

4. Defendant UL Physicians' fraudulent scheme includes accepting kickbacks, including care coordination staff and the promise of waived co-pays and deductibles, in exchange for referrals to Jewish Hospital and KentuckyOne and thereby causing the submission of false and/or fraudulent claims.

5. Defendant UL Physicians also refer patients to Jewish Hospital's Pharmacy Plus and Pharmacy Plus Specialty despite having a financial relationship with Jewish Hospital, in violation of federal prohibitions on self-referral under the Stark Law, 42 U.S.C. § 1395nn.

6. Defendants' conduct alleged herein violates the FCA. The FCA was originally enacted during the Civil War to deal with unscrupulous military contractors. Congress substantially amended the FCA in 1986—and, again, in 2009 and 2010—to enhance the ability of the Government to recover losses sustained as a result of fraud. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to

encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

7. The FCA prohibits, *inter alia*: knowingly presenting (or causing to be presented) a false or fraudulent claim for payment or approval; knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government; knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government; and, conspiring to commit any of these acts. 31 U.S.C. §§ 3729(a)(1)(A), (B), (G), and (C). Any person who violates the FCA is liable for a civil penalty of up to $21,916 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1); 82 Fed. Reg. 9131, 9133 (Feb. 3, 2017).

8. For purposes of the FCA, a person "knows" a claim is false if that person: "(i) has actual knowledge of [the falsity 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." 31 U.S.C. § 3729(b)(1). The FCA does not require proof that the defendant specifically intended to commit fraud. *Id.* Unless otherwise indicated, whenever the words "know," "learn," "discover" or similar words indicating knowledge are used in this Complaint, they mean "knowingly" as defined in the FCA.

9. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal (without service on the defendant during that time) to allow the

Government time to conduct its own investigation and to determine whether to join the suit. The person bringing the action is known under the FCA as the "Relator."

10. Based on the foregoing federal FCA provisions, *qui tam* Plaintiff-Relator seeks, through this action, to recover damages and civil penalties arising from the Defendants' knowing fraud against the United States, including through the Medicare and Medicaid programs. Jewish Hospital has submitted and continues to submit to Government Health Care Programs, including Medicare and Medicaid, claims for reimbursement through its in-house pharmacy, Pharmacy Plus and mail-order pharmacy Pharmacy Plus Specialty, that are false and/or fraudulent under the FCA.

11. The allegations set forth in this Complaint have not been publicly disclosed within the meaning of the FCA, as amended, 31 U.S.C. § 3730(e)(4). In the alternative, if the Court finds that there was a public disclosure of such allegations before the filing of this Complaint, Relator is an "original source" as that term is used in the FCA.

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732, which confers jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

13. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because one or more Defendants can be found in, resides in, and transacts substantial business in this district, including business related to Defendants' misconduct.

14. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1391, and 28 U.S.C. § 1395(a), because Defendants transact business in this District by among other things operating and utilizing the Pharmacies that engage in the misconduct alleged herein.

III. PARTIES

15. Plaintiff the United States of America is the real party in interest with respect to the federal *qui tam* claims herein. Plaintiff-Relator Robert Stone is pursuing causes of action on behalf of the named Plaintiff the United States pursuant to 31 U.S.C. § 3730(b).

16. Relator Robert Stone is a citizen of the United States who is familiar with and has knowledge of the Defendants' business operations and the allegations herein. Relator's identity and additional information regarding Relator's knowledge of Defendants' fraudulent schemes have been and will continue to be provided to the United States.

17. Defendant Jewish Hospital is a Louisville-based subsidiary of KentuckyOne wholly under its control. Jewish Hospital is, among other things, a regional provider of organ transplants, particularly of the heart, lung, kidney, liver and pancreas. Jewish Hospital provides pharmacy services to its employees, patients, and the general public through its Pharmacy Plus and Pharmacy Plus Specialty divisions.

18. Pharmacy Plus is the name of Jewish Hospital's in-house pharmacy. It fills immunosuppressant prescriptions for Jewish Hospital transplant patients upon and after their discharge from the hospital. It provides Care Coordinators to the transplant and oncology physicians to assist their patients in obtaining insurance reimbursement. It also fills prescriptions for hospital employees and patients referred from other specialty groups throughout the KentuckyOne HealthCare network including its oncology practice.

19. Pharmacy Plus Specialty is a mail-order pharmacy located in Louisville off-site from Jewish Hospital. Opened in 2014, Pharmacy Plus Specialty fills scripts for patients after discharge from Jewish Hospital as well as for patients from other hospitals in Kentucky.

20. Defendant KentuckyOne Health, Inc. is a Kentucky corporation with its principal place of business in Louisville, Kentucky. KentuckyOne is part-owned by Catholic Health Initiatives, a non-profit healthcare chain based in Denver, Colorado.

21. Defendant University of Louisville Physicians, Inc. is a Kentucky corporation with its principal place of business in Louisville. It employs around 700 physicians, some number of whom have admitting privileges at Jewish Hospital to provide services including transplant surgery to Jewish Hospital patients and who prescribe medications that are dispensed at Pharmacy Plus and Pharmacy Plus Specialty.

IV. APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS

A. Government Health Insurance Programs

22. The Health Insurance for the Aged and Disabled Program, known as Medicare, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*. ("Medicare"), is a health insurance program administered by the United States Government and funded by taxpayer revenue. The United States Department of Health and Human Services ("HHS"), through its Centers for Medicare and Medicaid Services ("CMS"), oversees Medicare.

23. Medicare was designed to be a health insurance program and to provide for payment of, among other things, medical services and equipment to persons over 65 years of age and certain others who qualify under Medicare's terms and conditions. The Medicare program has four parts: Part A, Part B, Part C, and Part D.

24. Medicare Part A, the Hospital Insurance Benefits for Aged and Disabled, covers the cost of inpatient hospital services and post-hospital nursing facility care. *See* 42 U.S.C. §§ 1395c-1395i-4. Medicare Part B, the Supplementary Medical Insurance Benefits for Aged and Disabled, covers the cost of services performed by physicians and certain other health care providers to Medicare patients. *See* 42 U.S.C. §§ 1395k, 1395l, 1395x(s). Medicare Part B also

covers the cost of certain immunosuppressant and oral chemotherapy drugs under certain circumstances. 42 U.S.C. § 1395x(s); 42 C.F.R. § 414.1001(b). Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

25. The Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("Medicaid"), is a health insurance program administered by the United States Government and the States and is funded jointly by state and federal taxpayer revenue. CMS and HHS oversee Medicaid jointly with agencies in each State, including Kentucky.

26. Medicaid is designed to assist participating States in providing medical services, medical equipment, and prescription drugs to needy individuals. The States and the United States share reimbursement costs. States directly pay providers, and then obtain the federal contribution from accounts drawn on the United States Treasury. 42 C.F.R. §§ 430.0-*et seq*. Federal funding for the Medicaid Program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, co-payments, co-insurance, and deductibles. The Medicare Savings Programs consist of the Qualified Medicare Beneficiary Program, 42 U.S.C. § 1396d(p)(1), the Specified Low-Income Medicare Beneficiary Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals Program, 42 U.S.C. § 1396d(s). Medicaid may serve as the primary insurer, or in some instances as the secondary insurer (e.g., with Medicare or private insurance providing primary coverage). Medicaid sets forth minimum requirements for state Medicaid programs to meet to qualify for federal funding and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program.

27. The Kentucky Medicaid program, also known as Kentucky Health, promulgates regulations that govern a healthcare provider's interactions with the program, including its payment policies with respect to prescription drug reimbursement. *See* 907 Ky Admin. Regs. 1:018.

28. The Civilian Health and Medical Program of the Uniformed Services (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members. TRICARE pays for, among other things, hospital services and covered prescriptions for its beneficiaries.

29. CHAMPVA, administered by the United States Department of Veterans Affairs ("VA"), is a health care program for the families of veterans with 100-percent service-connected disability, or for those who died from a VA-rated-service-connected disability.

30. The Federal Employee Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. Under the FEHBP, the federal employee is covered by private payer health insurance which is in turn subsidized in part by the federal government. As a result, fraud on a patient covered by the FEHBP constitutes fraud on the federal government and the loss of federal funds.

31. Together, the programs described above, and any other government-funded health care programs, are referred to as "Government Health Care Programs."

B. The Federal False Claims Act

32. The Federal FCA creates liability for "any person who," among other things:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

c. "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C).

d. "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

33. The FCA further provides that any person who violates the FCA "is liable to the United States for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. § 2461 note, further increases the civil penalty. 82 Fed. Reg. 9131, 9133 (Feb. 3, 2017).

34. The FCA provides that "the terms 'knowing' and 'knowingly' – (A) 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; and (B) require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1).

35. The FCA provides that "the term 'claim' – (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United

States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2).

36. The FCA provides that "the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment[.]" 31 U.S.C. § 3729(b)(3). Moreover, in the health care context, such as Medicare and Medicaid, an obligation is defined as any "overpayment retained by a person after the deadline for reporting and returning the overpayment" and an overpayment must be reported "by the later of…60 days after the date on which the overpayment was identified…or the date any corresponding cost report is due, if applicable." 42 U.S.C. § 1128J(d); *see also* 42 U.S.C. § 1320a-7k(d) (describing the obligation to report overpayments within 60 days).

37. The FCA provides that "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).

C. The Anti-Kickback Laws of the United States and Kentucky

38. The Medicare and Medicaid Fraud and Abuse Statute (the "Anti-Kickback Statute" or "AKS"), 42 U.S.C. § 1320a-7b(b), prohibits any person or entity from offering or paying or soliciting or receiving "any remuneration" to induce or reward any person for referring, recommending, or arranging for health care services or items for which payment may

be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute's prohibition applies to both sides of an impermissible kickback relationship (i.e., the giver and the recipient of the kickback).

39. Underscoring the breadth of the statutory definition of "remuneration," the HHS Office of Inspector General ("HHS OIG" or "OIG") has defined the term "remuneration" as "anything of value in any form or manner whatsoever." HHS OIG, *OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35958 (July 29, 1991). *See also United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, 2008 WL 5282139, at *6 (S.D. Ohio Dec. 18, 2008) (citing to "anything of value" language in the HHS OIG Anti-Kickback Provisions); HHS OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731, 23734 (May 5, 2003) (similar).

40. Compliance with the AKS is a precondition to participation and to payment as a health care provider under Medicare and Medicaid. *See United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 312 (3d Cir. 2011) (Medicare); *see generally State of New York v. Amgen Inc.*, 652 F.3d 103 (1st Cir. 2011) (Medicaid). The Patient Protection and Affordable Care Act, § 6402(f) provided that violations of the federal AKS can subject the perpetrator to liability under the federal FCA, for causing the submission of false or fraudulent claims or for making a false or fraudulent statement or record material to a false or fraudulent claim. *See* 42 U.S.C. § 1320a-7b(g); *see also id.* at (h) (No "actual knowledge of this section or specific intent to commit a violation of this section" is required).

41. Violation of the AKS subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7).

42. Kentucky also has an anti-kickback statute at Ky. Rev. Stat. Ann. 205.8461, which prohibits providers from knowingly soliciting, receiving, or offering any remuneration for ordering, arranging for or recommending goods for which payment may be made under Medicaid.

D. The Federal Stark Statute

43. Section 1877 of the Social Security Act (42 U.S.C. § 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark Law," prohibits physicians from making referrals for designated health services including, *inter alia*, outpatient physician drugs, to an entity with which they have a financial relationship. 42 U.S.C. § 1395nn (a)(1)(A). It also prohibits entities from billing Government Health Care Programs for services rendered pursuant to a referral by a physician with whom the pharmacy has a prohibited financial relationship. 42 U.S.C. § 1395nn(a)(1)(B). Further, neither Medicare nor Medicaid may pay for any designated health services provided in violation of the Stark Statute. 42 U.S.C. § 1395nn(g)(1); 42 U.S.C. § 1396b(s).

44. If a person collects payments billed in violation of the Stark law, that person must refund those payments on a "timely basis," not to exceed 60 days. *See* 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d); § 1003.101 (defining a "timely basis").

45. The Stark law prohibits referrals to any entity under the referring physician's direct or indirect ownership or investment, whether through equity, debt, or other means, including interest in an entity that holds an ownership or investment interest in the entity performing the designated health service. 42 C.F.R. § 411.354(b). The law likewise prohibits referrals in the case of direct or indirect "compensation arrangements." Direct compensation arrangements exist if there is no intervening person between the referring physician and entity rendering the service. *Id.* at § 411.354(c). Indirect compensation relationships require: (a) an

unbroken chain of ownership or compensation arrangements between the referring physician and the entity; (b) that the referring physicians' compensation varies with volume or value of referrals; and (c) that the entity knows that the compensation varies with the volume or value of referrals. *Id.* at § 411.354(c)(2).

46. The statute's exceptions –also known as safe harbors–identify specific arrangements exempted from its prohibitions. Once the government has demonstrated each element of a violation of the Stark law, the burden shifts to the defendant to establish that defendant's conduct at issue was protected by a safe harbor. Relevant safe harbors include "Rental of office space," "Fair market value compensation" and "Indirect compensation arrangements." 42 C.F.R. § 411.357(a), (l), (p). All three require that the arrangement be "in writing." Thus, if compensation included illegal and/or undocumented remuneration such as waiving documentation requirements or co-payments for patients, or providing care coordinators to physicians, it would not fall under a Stark Law safe harbor. *See id.*

47. Violations of the Stark law may subject the physician and the billing entity to exclusion from participation in Government Health Care Programs and various financial penalties, including: (a) a civil money penalty of up to $15,000 for each service included in a claim for which the entity knew or should have known that the payment should not be made; and (b) an assessment of three times the amount claimed for a service rendered pursuant to a referral the entity knows or should have known was prohibited. *See* 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

E. Required Certifications to Government Health Care Programs

48. Due to congressional and agency experience with largescale fraud in Government Health Care Programs, suppliers and providers, including pharmacies, are required to expressly certify compliance with governing rules and regulations on program enrollment and claim forms.

49. Providers such as Defendants Jewish Hospital and UL Physicians that wish to be eligible to obtain Medicare reimbursement, must certify, *inter alia*, that they agree to comply with the Medicare laws, regulations and program instructions that apply to them, and that they acknowledge, *inter alia*, that payment of claims by Medicare is conditioned upon the claim and the underlying transaction complying with all applicable laws, including without limitation, the federal AKS and the Stark law. *See, e.g.*, Form CMS-855A (for institutional providers); Form CMS-855S, at 24 (for certain suppliers); Form CMS-855I (for physicians and non-physician practitioners).

50. Kentucky Medicaid Provider Enrollment Forms require similar certifications of compliance with Medicaid rules and regulations, as well as the federal AKS. *See* Form MAP-811, 11-12 *available at* http://chfs.ky.gov/NR/rdonlyres/7BCC467D-65C0-4E17-B67A-DE5C97120905/0/Map811EnrollmentRevised2017finalweb.pdf.

51. The federal government provides prescription drug benefits to Medicare Part D beneficiaries through contracts with private insurance plans, known as Part D Product Plan Sponsors ("PPS"). CMS provides for and pays a portion of the plan premiums for Medicare beneficiaries and for expenses using *direct* and *indirect* subsidies and *prospective and retroactive* payments. CMS makes *prospective* payments to PPSs intended to cover a portion of the subsidies, then, after the end of the Plan year, there is a final reconciliation of the direct subsidy and the "risk sharing" based in part on actual costs reported. After final reconciliation, *retroactive* payments are made to the PPS as warranted.

52. Pharmacy Benefit Managers, ("PBM"), acting on behalf of the Part D PPS, contract with dispensing pharmacies. These pharmacies submit claims for payment for prescriptions to the PBMs. Those contracts require the PBMs and pharmacies "to comply with

the Part D sponsor's contractual obligations" and to "comply with all applicable Federal laws, regulations and CMS instructions." 42 C.F.R. § 423.505(i)(3)(iii), (4)(iv). The applicable federal laws include "Federal criminal law, the False Claims Act (31 U.S.C. 3729 et seq.) and the anti-kickback statute." *Id.* § 423.505(h)(1). Contractors that submit claims (including pharmacies) must certify the accuracy, completeness, and truthfulness of the claims data and acknowledge that it will be used for the purposes of obtaining Federal reimbursement. *Id.* § 423.505(k)(3).

53. Government Health Care Programs require compliance with these certifications as a material condition of payment, and claims that violate these certifications are false or fraudulent claims under the False Claims Act. CMS, its fiscal agents, and relevant State health agencies will not pay claims for claims for services that violate these certifications.

F. Claims for Payment Must Conform to Law and Regulation

54. Government Health Care Programs require compliance with all applicable CMS regulations as a material condition of payment, and claims that violate these requirements are false or fraudulent claims under the FCA. Relevantly, these regulations and requirements provide that:

1. Medicare Part B Requires Detailed Written Orders Prior to Billing and Refill Requests Prior to Dispensing Refills

55. To bill Medicare Part B for permitted prescription drugs, a pharmacy must obtain a Detailed Written Order (DWO) containing "the name of the drug, concentration (if applicable), dosage, [and] frequency of administration." *See* Medicare Program Integrity Manual § 5.2.3.

56. While a physician need not personally complete the DWO, "the treating physician/practitioner must review the detailed description and personally sign and date the order to indicate agreement." *Id.*; *see also id.* at § 3.3.2.4 ("For medical review purposes, Medicare requires that services provided/ordered be authenticated by the author. The method used shall be

a handwritten or electronic signature. Stamped signatures are not acceptable."). A signature helps to certify that the signer has reviewed the document, helps establish the identity and credentials of the signer, and establishes the signer's intent that the service be ordered. *See id.* (discussing the reasons for certain narrow exceptions to the signature requirements). Without the DWO, a pharmacy may dispense drugs, but shall not bill Medicare.

57. Medical reviews are carried out by CMS contractors including Medicare Administrative Contractors (MACs), for the purpose of "identifying inappropriate billing and avoiding improper payments." *Id.* at § 3.3.1.A. "The priority for MACs is to minimize potential future losses to the Medicare Trust Funds through targeted claims review." *Id.* at § 3.1.A. In cases of improper billing, MACs can recoup overpayments, return underpayments or take other administrative actions. *Id.*

58. If a pharmacy does submit improperly supported charges to the government, it must use modifier code (EY) indicating the lack of required documentation. *See, e.g.,* CGS Administrators, LLC, Local Coverage Determination (LCD): Immunosuppressive Drugs (L33824). Claims with modifier code EY are not reimbursable under Medicare rules and will be denied. To obtain reimbursement under Medicare Part B, a provider must use modifier code KX denoting "Requirements specified in the medical policy have been met." *See id.*

59. Medicare reimburses only medically necessary items and supplies. To ensure that items and supplies provided on a recurring basis remain reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order, Medicare requires that a supplier contact the beneficiary or designee no sooner than 14 calendar days prior to the delivery/shipping date. *See* Medicare Program Integrity Manual § 5.2.8.

60. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered to the beneficiary, require either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill record must include, *inter alia*, the beneficiary's name, a description of each item that is being requested, the date of refill request. This information must be kept on file and be available upon request. *See, e.g.,* CGS Administrators, *Items Provided on a Recurring Basis and Request for Refill Requirements – Annual Reminder* (Feb. 12, 2014).

2. All Claims Must Reflect Accurate Costs and Not Exceed "Usual and Customary Price"

61. Pharmacy prescriptions reimbursed under Medicare Part B, Medicare Part D, or Medicaid must "be expended in the most economical manner feasible." 42 C.F.R. § 50.503.

62. As part of this imperative, Medicare regulations mandate that payments for drugs under the program not exceed providers' "usual and customary charges to the general public." *Id.* § 447.512(b). These regulations "should be read to ensure that where the pharmacy regularly offers a price to its cash purchasers of a particular drug, Medicare Part D receives the benefit of that deal." *United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 644 (7th Cir. 2016), *cert. denied sub nom. Kmart Corp. v. U.S. ex rel. Garbe*, 137 S. Ct. 627 (2017). Thus, "[t]he [usual and customary price] term is included in state regulations, plans, and contracts related to Medicare Part D because the Medicare and Medicaid regulations demand that be." *Id.*

63. The CMS Medicare Prescription Drug Benefit Manual has long noted that "where a pharmacy offers a lower price to its customers throughout a benefit year," the lower price is considered the "usual and customary" price and the Plan reimburses the pharmacy on the basis of that lower price, even if the Plan's contract with the pharmacy would allow for a higher price.

Centers For Medicare & Medicaid Servs., Chapter 14—Coordination of Benefits, *in* Medicare Prescription Drug Benefit Manual 19 n.1 (2006), https://perma.cc/MW6A-H4P6.

64. Pharmacy prescription drug claims are submitted on forms and/or computer programs that require disclosure of the "usual and customary" price of the medication. 42 C.F.R. § 162.1102 (requiring use of NCPDP forms and programs); *see* Universal Claim Form D0 Version 1.2, Field 79, https://www.asbaces.com/NEWACES/Images/00362/PUCF-D02PT%20(VER%201.2).pdf. As with Medicare, Medicaid regulations in Kentucky (and many other states) set the maximum reimbursement rate at no more than the "usual and customary" charge. Kentucky Medicaid Pharmacy Provider Point-of-Sale (POS) Billing Manual (Oct. 1, 2015) §§ 6.1, 6.1.1, https://kyportal.magellanmedicaid.com/public/client/static/kentucky/documents/KY_Provider_Manual.pdf.

65. HHS's 340B Program requires manufacturers participating in Medicaid, to provide outpatient drugs to covered entities at significantly reduced prices. Covered entities are defined in the statute and include hospitals serving large numbers of low-income individuals (known as "Disproportionate Share Hospitals") such as Jewish Hospital. Because of its enrollment in the program, Jewish Hospital has access to outpatient drugs at substantially reduced prices that drive its actual acquisition costs far below that available to retail pharmacies.

66. In order to prevent covered entities from receiving both low 340B prices and Medicaid fee-for-service rebates, they must to elect whether to use 340B drugs for their Medicaid fee-for-service patients (carve-in) or whether they will purchase drugs for their Medicaid patients through other mechanisms (carve-out). Covered entities that will carve-in are required to inform HRSA (by providing their Medicaid provider number/NPI) at the time they

enroll in the 340B Program that they will purchase and dispense 340B drugs for their Medicaid patients. Jewish Hospital is a "carve-out" entity; it receives Medicaid rebates and therefore must not dispense 340B drugs to patients reimbursed by Medicaid.

3. Routine Waiver of Co-Pays and Deductibles Results in False Claims and Violates the Anti-Kickback Statute

67. Patient cost-sharing via copayments and deductibles is an integral part of the legislative scheme for Medicaid and Medicare. 42 U.S.C. § 1396o-1 (permitting states to impose cost-sharing for Medicaid); 42 U.S.C. § 1395w-102 (providing for deductibles and co-payments under Medicare Part D).

68. The Health and Human Services Office of the Inspector General ("HHS-OIG") notes that "[r]outine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare." *See* HHS-OIG, *Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B*, 59 Fed. Reg. 65372, 65374 (Dec. 19, 1994).

69. False claims result because "[a] provider, practitioner or supplier who routinely waives Medicare copayments or deductibles is misstating its actual charge," by, for example, representing a prescription cost at $100 (supporting a government payment of $80) when failure to collect the $20 co-pay renders the actual charge $80 (supporting only a government payment of $64). *Id.* at 65375. Where, as here, a supplier forgives financial obligations to induce patients to purchase its services and doctors to refer services to it, the provider is "liable under the Medicare and Medicaid anti-kickback statute," which "makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid." *Id.; see also* 42 U.S.C. § 1320a-7b(b).

70. The AKS also explicitly enumerates the waiver of copayments and deductibles as a form of remuneration. 42 U.S.C. § 1320a-7a(i)(6).

71. Finally, while "it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. . . . In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services." *See* HHS-OIG, *Special Fraud Alert*, 59 Fed. Reg. at 65375. Thus, routine waiver of co-pays and deductibles can give rise to false claims for the payment of medically unnecessary items.

72. While suppliers may waive copayments and deductibles in cases of financial hardship, this exception "must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good faith effort to collect deductibles and copayments must be made." *Id.*

73. The HHS-OIG notes that "routine use of 'Financial hardship' forms which state that the beneficiary is unable to pay the coinsurance/deductible (*i.e.*, there is no good faith attempt to determine the beneficiary's actual financial condition)," and refusal "to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (*e.g.*, a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals)" are indications of such improper waiver.

4. In-Kind Services Are Illegal Remuneration under the AKS

74. The OIG has long described as "suspect" certain "Hospital Incentive Arrangements" that implicate the AKS. These include: "Provision of free or significantly

discounted billing, nursing or other staff services." *Id.* at 65376. *See also* HHS-OIG, *OIG Compliance Program for Individual and Small Group Physician Practices*, 65 Fed. Reg. 59434, 59447 (Oct. 5, 2000).

75. The provision of staff services serves as an inducement prohibited under the AKS when the staff member "performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs *or other nursing functions*, testing for the physician's office laboratory, or *performing clerical services*." *See* HHS-OIG, *Special Fraud Alert*, 59 Fed. Reg. at 65377 (Dec. 19, 1994) (emphasis added) (discussing the illegal provision of phlebotomy services to physicians).

76. For example, the United States has charged hospital executives and physicians with felony violations of the AKS when the hospital paid physicians' assistants as a form of remuneration to the physicians. *See* Complaint at 11, *United States v. Novak et al.*, No. 1:13-cr-312 (N. D. Ill., Apr. 15, 2013). In *Novak*, a hospital paid 75% of the salary of a physician assistant and the salary of a registered nurse for one physician, and provided a group of physician assistants and nurse practitioners to support other physicians, to induce referrals to the hospital. *See id.* at 36-37, 40-42. One physician who was so remunerated was subsequently convicted of health care fraud. *See* Judgment as to Venkateswara R. Kuchipudi, *United States v. Novak et al.*, No. 1:13-cr-312 (N. D. Ill., Aug. 19, 2016) (finding defendant guilty of 6 counts of "Soliciting and receipt of concealed kickbacks and bribes").

V. FACTS AND ALLEGATIONS

A. Summary of Defendants' Unlawful Conduct

77. Jewish Hospital initially established its in-house pharmacy, Pharmacy Plus, for the benefit of hospital employees who were covered under its employer-sponsored health plan and patients being discharged from the hospital. The transplant population was a population that

was not initially viewed as a potential market because their prescriptions were being serviced by a mail-order pharmacy located in a different state. Jewish Hospital management soon realized, however, that the hospital was missing out on a substantial revenue stream from dispensing immunosuppressant drugs to hospital transplant patients. Transplant patients require expensive immunosuppressive drugs, often for life, which are among the few reimbursed by Medicare Part B.

78. The out-of-state specialty pharmacy had impressed the medical and nursing staff at Jewish Hospital by providing small gifts and favors to the staff, who were initially resistant to referring patients to Pharmacy Plus for these services. Inducing UL Physicians practicing at Jewish Hospital to refer their patients to Pharmacy Plus became an explicit goal that was ultimately established through several fraudulent schemes designed to reduce the costs and aggravation of the transplant physicians (and their patients) and other high value physician groups at the expense of Government Health Care Programs such as Medicare. These schemes were continued and their scope expanded, upon the opening of Pharmacy Plus Specialty in 2014.

79. These schemes result in false and fraudulent claims to Government Health Care Programs from Pharmacy Plus and Pharmacy Plus Specialty Departments that:

a. violate Medicare Part B Detailed Written Order and refill request rules;

b. overcharge the government for prescription medications;

c. illegally waive copayments and deductibles;

d. violate the anti-kickback statute because the prescriptions were procured in exchange for remuneration including the provision of care coordination staff, paid to Defendant University of Louisville-employed physicians; and

e. violate the Stark self-referral law.

The resulting referrals have turned Pharmacy Plus and Pharmacy Plus Specialty into a revenue center for Defendants, earning tens of millions of dollars annually. *See, e.g.*, Jewish Hospital IRS Form 990 (2014) (identifying $32 million in "Pharmacy Services" revenue).

80. University of Louisville Hospital has partnered with KentuckyOne since 2012, but will be leaving the partnership in July 2017. While the revised operating agreement maintains the transplant physicians' affiliation with Jewish Hospital, there continues to be significant pressure on Pharmacy Plus to engage in schemes to induce the transplant doctors' continued affiliation with and referrals to KentuckyOne Health services and Pharmacy Plus.

81. Jewish Hospital and its Pharmacy Plus and Pharmacy Plus Specialty know that their claims are false and fraudulent, and their schemes violate the False Claims Act, because of, *inter alia*, the statutory and regulatory scheme requiring accurate claims data and certifications and prohibiting kickbacks, the rejection of claims under third-party MAC reviews, and because of internal efforts to raise concern about compliance with law and regulation.

82. Both the statutory and regulatory schemes requiring accurate claims data and certifications, and the rejection of claims through Medicare audits, show that Defendants' false and/or fraudulent claims are "capable of influencing" the Government's payment decisions and hence are material under the FCA.

83. Defendant UL Physicians likewise have submitted or caused to be submitted claims that violate the False Claims Act.

B. Violation of Detailed Written Order and Refill Request Requirements

84. Jewish Hospital physicians frequently communicate requests for medication orally to nurses who record and transmit dispensing orders (these orders are designated by a "TO" or "VO" for "telephone order" or "verbal order" – "RV" is often included to indicate "repeated and verified"). Physicians view personally signing each prescription to accommodate

billing requirements as an unwelcome administrative burden. As part of its scheme to indulge the transplant doctors and other high value physician groups, Pharmacy Plus almost never obtains DWOs (despite the fact that Medicare Part B requires pharmacies to procure DWOs signed by physicians to support claims for reimbursement) yet nevertheless regularly bills Medicare for these drugs with a KX rather than EY modifier code.

85. An estimated 90% of Pharmacy Plus's Medicare Part B prescriptions are billed without obtaining valid DWOs or using the required modifier. [1]

86. CGS Industries, LLC ("CGS"), the CMS Medicare Administrative Contractor ("MAC") for Kentucky, reviews 15-30 of Pharmacy Plus's claims for immunosuppressive drug prescriptions each month due to "data demonstrating a high claims payment error rate." *See, e.g.*, CGS Administrators, LLC, Notice of Service-Specific Prepayment Review: Immunosuppressive Drugs - HCPCS Code J7507 (October 13, 2016), https://www.cgsmedicare.com/jb/pubs/news/2016/10/cope790.html.

87. Jewish Hospital responses to claim reviews likewise regularly lack DWOs and instead contain dispensing orders bearing the signatures of nurses who signed for ordering physicians using the acronym "T.O." or "per" to signify that they are signing on behalf of the physician.

88. Because Pharmacy Plus does not obtain DWOs as required by law, and is therefore unable to submit any to claim reviews, approximately 80% of the reviews result in a rejection of Pharmacy Plus's claim for payment. These rejections are communicated to Jewish Hospital via Remittance Notices. Where the claim is denied for lack of required documentation, the allowed amount shows as 0.00 and the "Group/Reason Code" shows CO-151 indicating

[1] A more detailed recitation of Relator's evidence is being provided to the Government as part of Relator's mandatory disclosures.

"Contractual Obligation - Payment adjusted because the payer deems the information submitted does not support this many services."

89. In December 2016, for example, Pharmacy Plus received fifteen requests for further documentation and responded with adequate documentation in only two of them – the others were rejected for payment. Yet Pharmacy Plus continued its deficient signature practices when billing Medicare Part B.

90. As a business matter, Pharmacy Plus viewed and continues to view these denials of payment as a relatively small cost of keeping the transplant doctors (and their patients) satisfied and thereby securing their stream of referrals and their lucrative drug prescriptions.

91. Medicare regulations mandate that suppliers document a patient's request prior to dispensing a refill to ensure that Medicare reimburses only items and supplies actually necessary for a patient's use. Some Jewish Hospital Pharmacy Coordinators ignore this requirement and send medication each month without contacting the patients or their caregivers. These employees create false records reflecting adequate patient contact to ensure that Pharmacy Plus will be reimbursed should the MAC demand the records.

92. As a result of Pharmacy Plus's failure to verify that refills are only dispensed pursuant to actual need, Pharmacy Plus dispenses medication in situations in which the patient has moved or passed away.

93. When the MAC learns of these situations, it demands that Jewish Hospital return the improper payment. The MAC (and by extension the Government) remain unaware that these are not isolated incidents, but are caused by Jewish Hospital's violation of Medicare dispensing requirements.

C. Overcharging the Government

94. Pharmacy Plus bases claims for payment, including those to Medicare Part D plans, on the Average Wholesale Price ("AWP"). "Statutes and regulations do not define AWP, and AWPs do not represent actual transactional prices. Rather, AWPs are the list prices established by drug manufacturers and reported by publishers such as Red Book." HHS-OIG, *Part B Payments for Drugs Infused Through Durable Medical Equipment*, Report OEI-12-12-00310, 3 (Feb. 2013), *available at* https://oig.hhs.gov/oei/reports/oei-12-12-00310.pdf.

95. Because Jewish Hospital is a 340B qualified medical center, it obtains some branded prescription drugs at vastly reduced prices from what non-qualified entities pay nationwide.

96. To induce referrals from doctors and purchases by patients, Pharmacy Plus has established a "cash" price that it offers to individuals, including employees, walk-ins, and patients, when doing so is cheaper than that person's out-of-pocket insurance costs. The cash price is based on Jewish Hospital's actual cost of acquiring the drug.

97. In many cases, the cash price for prescription drugs is far less than the rate charged to the government, in violation of federal law and regulation.

98. Pharmacy Plus patients with third party insurance – frequently including Medicare Part D payers– often paid many multiples of the price paid by "cash" payers for the same medication.

99. In some cases, Jewish Hospital staff exploited this pricing issue to offer discounts from out-of-pocket costs to transplant doctors' Medicare patients and to the patients of other high value physician groups. This would be done when the cash price was less than a reimbursed drug's co-pay or the patient was subject to "deductible" or "coverage gap" payments (meaning

that the patient was covering the cost of the prescription under the Medicare cost-sharing scheme).

D. Illegal Copayment and Deductible Waivers and Write-Offs

100. To cater to the transplant doctors and other high value physician groups and induce patients to utilize its services, Pharmacy Plus regularly writes off patient copayments and/or deductibles. Jewish Hospital employees have informed patients and doctors in advance that they would not seek to collect on copayments and deductibles. Pharmacy Plus has explicitly made these promises to cardiologists and their patients and at least one transplant surgeon who also performs gastroenterology procedures at Jewish Hospital.

101. When Pharmacy Plus-Jewish Hospital was seeking to win the transplant physicians' business from the mail order pharmacy, it agreed to dispense brand name drugs (which the doctors preferred), but charge co-pays as if the drugs were generic. One such drug was the branded drug Prograf – a widely prescribed oral immunosuppressant – which the doctors preferred over the generic formulation. This pricing structure pleased patients and helped Pharmacy Plus obtain referrals at the expense of the mail-order pharmacy, which could not offer the same price structure because it was not a 340B/non-profit entity.

102. Later, when Jewish Hospital's 340B price for Prograf increased due to the existence of generic competition, Pharmacy Plus renegotiated with the transplant doctors who agreed to try and move patients onto generics while Pharmacy Plus agreed to apply a zero-dollar co-pay while the patients transitioned from the brand formulation.

103. Jewish Hospital has written off over $1 million of co-pays and deductibles since the summer of 2016.

104. Jewish Hospital has a charity program under which patients may obtain relief from their charges if they demonstrate financial hardship. However, less than $200,000 per year

is approved under this program. In most cases, the copayments and deductibles are simply waived without any formal program or procedure. Moreover, patients' approval for the charity program turns not on demonstrated hardship, but on whether Kathy Anderson, the Pharmacy Services manager, had a good relationship with the Care Coordinator making the request and the patient in question.

E. Illegal Kickbacks and Violations of the Stark Law

105. Jewish Hospital's Pharmacy Plus provides and pays for "Care Coordinators" to assist UL Physicians by assisting their patients in obtaining insurance reimbursement and in filling prescriptions. The "Care Coordinators" who work in the transplant and oncology centers, as well as potentially in other high value physician centers, make sure that the patients have prescriptions and payments set up (these are also the individuals who attempt various mechanisms to help patients avoid copayments). Some of this work would otherwise be done by physician assistants or other physician staff. In this way, Jewish Hospital provides valuable remuneration to UL Physicians in exchange for UL Physicians referrals to its Pharmacy.

106. The Care Coordinators act as a direct resource for the patients to request refills or if they have issues in obtaining their medications. Among other things, the Care Coordinators notify the nurses to obtain new orders from the physician (which are usually verbal) when prescriptions are expired or out of refills. The Care Coordinators forward such orders to the pharmacy. This process saves physicians several minutes per patient during the working day and constitutes a form of remuneration in exchange for referrals.

107. Some of the patient assistance provided by Care Coordinators was previously performed by Jewish Hospital nurses who now have more time to directly support the physicians, thereby, demonstrating the value of the Care Coordinators as remuneration to the physicians.

108. Jewish Hospital's tolerance of deficient DWOs save UL Physicians time and effort hence constitute a further form of remuneration. Pharmacy Plus and Pharmacy Plus Specialty's failure to follow-up with physicians in response to claim reviews and denials caused by the deficient DWOs also constitute a form of remuneration in exchange for referrals.

109. Pharmacy Plus and Pharmacy Plus Specialty's promises to physicians to waive their patient co-pays and deductibles, decline to follow up on outstanding charges, charge patients generic co-pays consistent with brand drugs, and charge patients a cash price reflecting Jewish Hospital's very low purchase price constitute illegal remuneration under the AKS.

110. This remuneration is offered in exchange to physicians for referrals of prescriptions to Pharmacy Plus and Pharmacy Plus Specialty and also to induce transplant, heart failure, oncology, and other high value physician groups to perform lucrative procedures at Jewish Hospital.

111. Pharmacy Plus and Pharmacy Plus Specialty's promise to patients to waive patient co-pays and deductibles, decline to collect on outstanding charges, charge patients generic co-pays consistent for brand drugs, and charge patients a cash price reflecting Jewish Hospital's very low purchase price constitutes illegal remuneration under the AKS offered to patients in exchange for their business.

112. These kickbacks taint Pharmacy Plus and Pharmacy Plus Specialty's claims for prescription reimbursement and also Jewish Hospital's and UL Physicians' claims for transplant, oncology and other high value services.

113. Similarly, violation of the Stark self-referral laws by Defendant UL Physicians taint Pharmacy Plus and Pharmacy Plus Specialty's claims for prescription reimbursement and

also Jewish Hospital's and UL Physicians' claims for transplant, oncology and other high value services.

F. Damages

1. Damages from Violation of Medicare Part B Requirements

114. Since 2010, Medicare Part B has reimbursed Jewish Hospital pharmacies millions of dollars. The issues identified above affect the vast majority of prescriptions.

2. Damages from Overcharging Usual and Customary Price

115. Jewish Hospital has charged the government millions of dollars above its "usual and customary costs" since 2010.

3. Damages from Copayment and Deductible Waiver False Claims

116. Jewish Hospital has written off over $10 million dollars in co-pays and deductibles since 2010, however the damage to the government is much greater.

117. The failure to charge co-pays and deductibles results in government over-reimbursement due to misrepresented drugs costs (75% of the value of waived co-pays and greater); reimbursement of subsequent claims due to misrepresenting that patients have exceeded their deductible (100% of value of waived deductible); and the reimbursement of claims for medically unnecessary medications (three to four times the value of the waived deductible).

4. Damages from Illegal Kickbacks and Self-Referrals

118. Jewish Hospital has induced the referral of prescriptions to its pharmacies and transplant and oncology procedures to its hospital through the kickbacks detailed above, and Defendant UL Physicians has made such referrals, including in violation of the Stark law.

119. The government's damages are equivalent to the claims procured by these kickbacks and self-referral violations: likely the majority of Jewish Hospital's pharmacy revenue

($32 million in 2014). It also includes tens of millions of dollars in transplant and oncology procedures procured by and tainted by these kickbacks and self-referral violations.

VI. CLAIMS FOR RELIEF

Count I

Federal False Claims Act – False Claims
31 U.S.C. § 3729(a)(1)(A)

120. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

121. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

122. By and through the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval.

123. The Government, unaware of the falsity of all such claims made or caused to be made by Defendants, has paid and continues to pay such false or fraudulent claims that would not be paid but for Defendants' illegal conduct.

124. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

125. Additionally, the United States is entitled to the maximum statutory penalty for each and every violation alleged herein.

Count II

Federal False Claims Act – False Records or Statements
31 U.S.C. § 3729(a)(1)(B)

126. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

127. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

128. By and through the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

129. The Government, unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

130. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

131. Additionally, the United States is entitled to the maximum statutory penalty for each and every violation alleged herein.

Count III

Federal False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(1)(C)

132. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs above as though fully set forth herein.

133. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

134. By and through the acts described above, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), (B), and (G). Further to Defendants' conspiracy and fraudulent scheme, despite knowing that tens of millions of dollars in payments from the federal government have been received in violation of the False Claims Act and in violation of the Anti-Kickback Statute's prohibitions on receipt of remuneration for services billed to a Government

Health Care Program, Defendants have refused and failed to refund these payments and have continued to submit false or fraudulent claims, statements, and records to the United States.

135. The Government, unaware of the Defendants' conspiracy and fraudulent schemes, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

136. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

137. Additionally, the United States is entitled to the maximum penalty of up to the statutory maximum provided for by law for each and every violation alleged herein.

Count IV

Federal False Claims Act – Reverse False Claims
31 U.S.C. § 3729(a)(1)(G)

138. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

139. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

140. By and through the acts described above, Defendants have knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay money to the Government and they have concealed and improperly avoided an obligation to pay money to the Government, including specifically Defendants' obligation to report and repay past overpayments of Medicare and other Government Health Care Program claims for which Defendant knew it was not entitled to be paid and therefore refunds were properly due and owing to the United States.

141. The Government, unaware of the concealment by the Defendants, has not made demand for or collected the years of overpayments due from the Defendants.

142. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

143. Additionally, the United States is entitled to the maximum statutory penalty for each and every violation alleged herein.

VII. PRAYERS FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants are enjoined from violating the federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*;

B. That judgment be entered against Defendants and in favor of the United States and the Relator in an amount equal to three times the amount of damages caused by Defendants' misconduct, as well as a civil penalty for each FCA violation in the maximum statutory amount;

C. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

D. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, litigation costs, expert fees, and all attorneys' fees permitted under 31 U.S.C. § 3730(d);

E. That Relator be awarded the maximum amount permitted under 31 U.S.C. § 3730(d); and

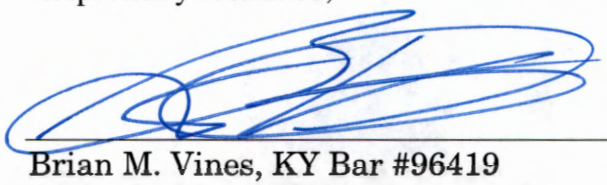
G. That the Court award such other relief as the Court deems proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff-Relator requests a jury trial.

Dated: September 4, 2019

Respectfully submitted,



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