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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

X

UNITED STATES OF AMERICA and THE
STATE OF NEW YORK *ex rel.*
LUCILLE ABRAHAMSEN,

Plaintiff,

v.

COMPLAINT-IN-INTERVENTION

HUDSON VALLEY HEMATOLOGY-
ONCOLOGY ASSOCIATES, R.L.L.P.;
RAM R. KANCHERLA; PONCIANO L.
REYES; MICHAEL J. MARESCA; LEV
DAVIDSON; JULIA A. SCHAEFER-
CUTILLO; JEFFREY A. STEWARD;
GERALD A. COLVIN; TAUSEEF AHMED;
JOHN C. NELSON; CARMELLA A.
PUCCIO; KAREN P. SEITER; DELONG
LIU; ASIM AIJAZ; SHEETAL
SHRIMANKER,

14 Civ. 2653 (KMK)

Jury Trial Demanded

Defendants.

X

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

HUDSON VALLEY HEMATOLOGY-
ONCOLOGY ASSOCIATES, R.L.L.P.,

Defendant.

X

The United States of America (the “Government”), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, files this Complaint-In-Intervention against Hudson Valley Hematology Oncology Associates, R.L.L.P. (“Hudson Valley” or “Defendant”), alleging as follows:

PRELIMINARY STATEMENT

1. The Government brings this Complaint-In-Intervention seeking damages and civil penalties against Hudson Valley, a hematology and oncology medical practice, under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the “False Claims Act”), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the “Anti-Kickback Statute”), based on Hudson Valley’s schemes to defraud the United States in connection with federally-funded health care programs, namely the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* (“Medicare”), and the Medicaid Program, 42 U.S.C. §§ 1396 *et seq.* (“Medicaid”).

2. As set forth more fully below, the United States alleges in this action that Hudson Valley, a medical practice that provides services to individuals with cancer and blood disorders through its offices in the Hudson Valley region of New York, engaged in two separate fraudulent schemes, each resulting in the submission of false and fraudulent claims for reimbursements from Medicaid and/or Medicare.

3. In the first scheme, Hudson Valley provided kickbacks to Medicare beneficiaries by routinely waiving their copayments, which is the amount the beneficiaries were required to pay for services rendered, without an individualized determination of financial hardship or exhaustion of reasonable collection efforts. In addition, even though Hudson Valley waived the copayments, it included the copayment amounts in billings submitted to Medicare for reimbursement, thereby falsely inflating its bills to Medicare for those services.

4. In the second scheme, Hudson Valley submitted claims for Medicare and Medicaid reimbursements for Current Procedural Terminology (“CPT”) billing codes 99211 and 99212, although the services (i) were not medically necessary, (ii) were not actually performed, (iii) were not documented in the medical record, and/or (iv) failed to otherwise comply with Medicare and Medicaid rules and regulations. Hudson Valley submitted thousands of fraudulent claims to Medicare and Medicaid, and was paid based on those claims.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, as well as pursuant to the Court’s general equitable jurisdiction.

6. Venue is appropriate in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Hudson Valley is located in this District and a substantial part of the events or omissions giving rise to the claims occurred in this District.

PARTIES

7. Plaintiff is the United States of America.

8. Defendant Hudson Valley is a hematology and oncology practice, registered as a limited liability partnership, with three partners and owners: Ramamohana R. Kancharla, M.D., Michael J. Maresca, M.D., and Ponciano L. Reyes, M.D. Although it previously had as many as eleven offices, Hudson Valley currently has six offices located in Poughkeepsie, Carmel, Yorktown Heights, Middletown and Hawthorne, New York. Hudson Valley employs physicians, nurses, and other medical professionals who provide services to individuals with cancer and blood disorders, including chemotherapy and radiology.

9. Relator Lucille Abrahamsen (“Relator”) is a resident of New York. Relator is a former Accounts Receivable Representative at Hudson Valley, responsible for coding and charge entry for billing purposes.

FACTS

A. The Anti-Kickback Statute

10. The Anti-Kickback Statute makes it illegal for individuals or entities to knowingly and willfully offer or pay remuneration (including any kickback, bribe, or rebate) to any person to induce business that is reimbursed under a Federal health care program. 42 U.S.C. § 1320a-7b.

11. Congress enacted a prohibition against the payment of kickbacks in any form to protect the Medicare and Medicaid programs because remuneration can influence health care decisions that would result in services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. *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 Program Protection Act of 1987, Pub. L. No. 100-93.

12. As codified in the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), “a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act].”

B. Hudson Valley’s Copayment Waiver Scheme

13. Generally, Medicare covers 80% of the “reasonable charges” billed by the provider for the Medicare-approved health services provided to a patient. 42 U.S.C.

§ 1395(a)(1). Accordingly, the patient is normally required to contribute the remaining 20% as a copayment. 42 U.S.C. § 1395cc(a)(2)(A)(ii).

14. Waiver of copayments in consideration of a particular patient's financial hardship is permitted in exceptional circumstances. The hardship exception, however, must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient, supported by documentation of financial hardship. Except in such special cases, a good faith effort to collect deductibles and copayments must be made.

15. Hudson Valley routinely waived copayments, without making an individualized determination of financial hardship or exhausting reasonable collection efforts.

16. Hudson Valley waived copayments for various reasons, including for individuals who sought frequent medical services from Hudson Valley, had a high balance, whose insurance did not pay certain amounts, or who expressed an inability to pay. None of these reasons was an allowable exception. Additionally, Hudson Valley consistently waived the copayments without receiving any supporting documentation or additional information from the patients.

17. Hudson Valley noted the waiver of these copayments in its billing system using terms such as "write-off," "down coding for Medicare," and "professional courtesy."

18. As one example, between August 2012 and September 2014, Patient A was treated 34 times at Hudson Valley. Hudson Valley did not collect the copayment for any of these treatments and its records do not contain any documentation explaining the reasons for the waivers.

19. Further, specifically as to Current Procedural Terminology ("CPT") code 99212, Hudson Valley often waived the copayment associated with it even if the patient did not request

a waiver. Hudson Valley would note the automatic waiver in its billing systems by indicating “99212 courtesy write off.”

20. For example, Hudson Valley used CPT code 99212 to bill Medicare for services rendered to Patient B on eleven separate occasions. On each of those dates, Hudson Valley waived the copayment. Patient B’s medical charts contain no documentation of the basis on which Hudson Valley waived the copayments.

21. In addition to waiving copayments, Hudson Valley overbilled Medicare by including the value of the waived copayment in the amount that it billed Medicare for the service, instead of subtracting that copayment because Hudson Valley hadn’t actually received it, as dictated by Medicare guidance.

22. For example, in the case of Patient B, Hudson Valley submitted a claim for \$125.00 for each 99212 code and received reimbursement from Medicare for a percentage of that amount. However, Hudson Valley waived the \$9.21 copayment amount, and therefore, the actual amount of that claim should have been \$115.79, for which Medicare would have reimbursed a lower amount based on the same percentage.

C. Billing Codes

23. The CPT codes are a set of standardized medical codes developed and maintained by the American Medical Association. CPT codes are used to describe and report medical, surgical and diagnostic procedures and services to public and private health insurance programs for medical billing purposes.

24. The United States uses CPT codes to determine both coverage, *i.e.*, if it will pay for the billed medical procedures and services, and reimbursement, *i.e.*, how much it will pay for the billed medical procedures and services.

25. There are thousands of CPT codes; each procedure or service or item furnished to a patient has a specific CPT code. Each CPT code receives a certain level of reimbursement, which can vary depending on what other codes are billed. The amount of money a physician or medical provider is paid for his or her services by Medicare or Medicaid depends on which CPT codes are used.

26. As directed by the American Medical Association, in addition to CPT codes used to bill for a procedure, service or item, certain CPT codes, specifically 99211, 99212, 99213, 99214, and 99215, are used to indicate various degrees of evaluation and management (“E/M”) of established patients when they make an in-office visit for treatment. These codes are, accordingly, referred to as “E/M codes.” These codes differ depending on whether the patient is seen by a doctor, the amount of time spent with the patient, and what services are performed. As the patient’s examination becomes increasingly in-depth or greater time is spent with the patient, the code number increases, with 99211 as the lowest level and 99215 as the highest level.

27. Code 99211 is used when the patient’s problems are “minimal,” meaning they require little to no independent medical evaluation; typically only 5 minutes are spent “performing or supervising” routine patient services. Code 99211 is the only E/M code that explicitly states that it “may not require the presence of a physician or other qualified healthcare professional.” Code 99211 is typically used to bill for services provided exclusively by nurses.

28. Code 99212 is used for office or outpatient E/M visits with established patients that require two of three key components: (1) a problem-focused history; (2) a problem-focused examination; and (3) a straightforward medical decision. This code is typically appropriate where approximately 10 minutes are spent face-to-face with the patient and/or family.

29. Codes 99213-99215 are used when the patient's examination becomes increasingly in-depth, the medical decisions become more complex, and/or greater time is spent with the patient.

30. Some CPT codes used to bill for a procedure, service or item automatically include a designated E/M code (99211-99215). This is referred to as "bundling." For these codes, a separate E/M code should not be billed.

31. As relevant to Hudson Valley, for the administration of infusions, injections and chemotherapy, the relevant CPT codes for those treatments have been "bundled" with, *i.e.*, valued to automatically include, CPT code 99211. *See* <https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html> (CMS-published National Correct Coding Initiative Policy Manual for Medicare Services – 2015). Therefore, when nurses, under the guidance of a physician, administer an infusion, injection, or chemotherapy, claims for such services must be billed for only the specific procedure codes; E/M code 99211 cannot also be billed.

32. In order to use an E/M code that meets a higher complexity level than a code 99211 on the same day as another bundled procedure such as an infusion, injection, or chemotherapy, there must be "a significant, separately identifiable E/M service that is above and beyond the usual pre- and post-operative work of the procedure." *See* CMS Manual System, Transmittal 954, Pub. 100-04 (May 19, 2006).

33. Venipuncture, which is the puncturing of a vein as part of a medical procedure, typically to withdraw a blood sample or for an intravenous injection, also utilizes a bundled code. Unlike the services described above, it is permissible to code an E/M 99211 together with

the procedure code for venipuncture, but only so long as there is a separately identifiable E/M service that is above and beyond the usual pre- and post-operative work of the procedure.

34. For all codes, the medically necessary E/M service and the procedure must be appropriately and sufficiently documented by the physician or qualified non-physician practitioner in the patient's medical record to support the claim for these services. Medicare Claims Processing Manual, Chap. 12 at § 30.6.6(B).

35. Medicare reimburses only for "medically necessary," or "reasonable and necessary" services and procedures, including levels of E/M. 42 U.S.C. § 1395y(a)(1)(A).

D. Hudson Valley's Overcoding Scheme for CPT 99211 and 99212 Codes

36. On a daily basis, Hudson Valley created two schedules: an "M.D. schedule" and a "Chem/Inj/RN schedule" (the "R.N. schedule"). The patients on the R.N. schedule were scheduled to receive minor or routine services administered by a nurse, such as B12 injections, blood withdrawals or chemotherapy. The patients on the R.N. schedule typically were not seen by a doctor during the appointment.

37. In fact, given the large number of patients listed on both the R.N. and the M.D. schedules for any particular date, it typically would have been impossible for a physician to examine and/or manage all of the patients scheduled on both the R.N. and M.D. schedules.

38. Despite the fact that the physicians at Hudson Valley typically did not see any of the patients on the R.N. schedule, at the end of each day, the nonphysician practitioners who treated patients on the R.N. schedule left all of those patients' medical charts on the desk of one of the Hudson Valley physicians to sign the progress notes. For those charts, the doctor would falsely certify that he or she had participated in the evaluation and management of the patients on the R.N. schedule.

39. Specifically, the doctor would fill in a time period in the form portion of the progress note which stated “I spent ___ minutes in evaluation and management of the patient,” and would sign the note.

40. Thus, despite the fact that patients on the R.N. schedule typically were not treated by a physician and did not receive a “significant, separately identifiable service” while undergoing chemotherapy, a B12 injection, venipuncture, or other similar service, Hudson Valley billed Medicare or Medicaid an additional amount for those patients using a separate E/M code, based upon the false certifications by the Hudson Valley doctors.

41. For example, Patient C was treated on the R.N. schedule on three occasions in September 2012. The progress note for each of those dates states that Patient C received an infusion due to her anemia. The notes do not indicate any treatment above and beyond the usual infusion procedure, which was performed by a nurse. The patient’s chart, however, falsely certifies for each of those dates that a physician spent at least ten minutes “in evaluation and management of the patient,” and contains the physician’s signature. For these procedures Hudson Valley submitted claims to Medicare for CPT code 99212, in addition to the CPT codes relating to venipuncture and infusion, although no separate evaluation and management service was necessary, nor is there evidence that any such service was actually provided to the patient, apart from the doctor’s false certification.

42. Similarly, Patient D was treated on the R.N. schedule on three occasions in June and July of 2015. The progress notes for those dates indicate that the patient received venipuncture services, but no additional services were necessary or were provided to her. However, for those procedures, Hudson Valley submitted claims to Medicare for both the CPT code 36415 and the E/M code 99212.

43. Likewise, for Patient E, on May 19, 2014 and June 16, 2014, the progress notes indicate that he had his blood drawn and do not reflect that any other “significant, separately identifiable service” was necessary or was provided. Again, however, Hudson Valley submitted billings to Medicare for both the venipuncture and, unjustifiably, the E/M 99212 code.

CLAIM FOR RELIEF

FIRST CLAIM

Violation of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

44. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

45. The Government seeks relief against Hudson Valley under Section 3729(a)(1)(A) of the False Claims Act.

46. As a result of offering kickbacks in the form of waived copayments, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A), Hudson Valley knowingly caused false claims to be presented for reimbursement by Medicare, in violation of 31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

47. Specifically, Hudson Valley knowingly certified and/or represented that the reimbursements it sought were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

48. By reason of these false or fraudulent claims that Hudson Valley caused to be presented to Medicare, the United States has paid millions of dollars in Medicare reimbursements to Hudson Valley, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM

Violation of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))

49. The Government incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

50. The Government seeks relief against Hudson Valley under Section 3729(a)(1)(B) of the False Claims Act.

51. As a result of providing kickbacks in the form of waived copayments, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A), Hudson Valley knowingly caused false records or statements to be made that were material to getting false or fraudulent claims paid by Medicare, in violation of 31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

52. By reason of these false or fraudulent records or statements that Hudson Valley caused to be made, the United States has paid millions of dollars in Medicare reimbursements to Hudson Valley, and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

THIRD CLAIM

Violation of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

53. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

54. The Government seeks relief against Hudson Valley under Section 3729(a)(1)(A) of the False Claims Act.

55. By inflating the amount of the value of services rendered to Medicare beneficiaries by including the waived copayment amount when submitting its claims for reimbursement, Hudson Valley knowingly caused false claims to be presented for reimbursement by Medicare.

56. Accordingly, Hudson Valley knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

57. By reason of these false or fraudulent claims that Hudson Valley caused to be presented to Medicare, the United States has paid millions of dollars in Medicare and Medicaid reimbursements to Hudson Valley, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

FOURTH CLAIM

Violation of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))

58. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

59. The Government seeks relief against Hudson Valley under Section 3729(a)(1)(B) of the False Claims Act.

60. By inflating the amount of the value of services rendered to Medicare beneficiaries by including the waived copayment amount when submitting its claims for reimbursement, Hudson Valley knowingly caused false records or statements to be made that were material to getting false or fraudulent claims paid by Medicare.

61. By reason of these false or fraudulent records or statements that Hudson Valley caused to be made, the United States has paid millions of dollars in Medicare reimbursements to

Hudson Valley, and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

FIFTH CLAIM

Violation of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

62. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

63. The Government seeks relief against Hudson Valley under Section 3729(a)(1)(A) of the False Claims Act.

64. Hudson Valley falsified progress notes to state that routine procedures included separate and additional evaluation and management services, and then sought reimbursement from Medicare and Medicaid for these services.

65. Accordingly, Hudson Valley knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

66. By reason of these false or fraudulent claims that Hudson Valley caused to be presented to Medicare and Medicaid, the United States has paid millions of dollars in Medicare and Medicaid reimbursements to Hudson Valley, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SIXTH CLAIM

Violation of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))

67. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

68. The Government seeks relief against Hudson Valley under Section 3729(a)(1)(B) of the False Claims Act.

69. By falsifying progress notes to state that routine procedures included separate and additional evaluation and management services, Hudson Valley knowingly caused false records or statements to be made that were material to getting false or fraudulent claims paid for reimbursement by Medicare and Medicaid, in violation of 31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

70. By reason of these false or fraudulent records or statements that Hudson Valley caused to be made, the United States has paid millions of dollars in Medicare and Medicaid reimbursements to Hudson Valley, and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

PRAYER FOR RELIEF

WHEREFORE, the United States demands judgment against the defendant as follows:

- A. Treble the United States' damages, in an amount to be established at trial, plus an \$11,000 penalty for each false claim submitted or false record or statement made in violation of the False Claims Act;
- B. Award of costs pursuant to 31 U.S.C. § 3792(a)(3); and
- C. Such further relief as is proper.

Dated: New York, New York
October 18, 2016

Respectfully submitted,

PREET BHARARA
United States Attorney for the
Southern District of New York
Attorney for the United States

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