IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION

UNITED STATES OF AMERICA *ex rel.*, KATHERINE KEATON;	)	
	)	**Case No.** 22-cv-55-LTS-MAR
Plaintiff,	)	
	)	
v.	)	**FILED IN CAMERA AND UNDER SEAL**
	)	
CEREBRAL, INC.,	)	
	)	
And	)	
	)	**Jury Trial Demanded**
CEREBRAL MEDICAL GROUP, P.A.	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff, the Relator, Katherine Keaton, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA"), files this Complaint against Defendants Cerebral, Inc. and Cerebral Medical Group, P.A. In support, Keaton alleges as follows:

INTRODUCTION

1. Katherine Keaton (hereinafter "the Relator" or "Keaton") brings this action on behalf of the United States of America against Defendant for treble damages and civil penalties arising from the Defendants' false statements and false claims in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* The violations involve false statements and false claims regarding mental health telemedicine services provided by Defendant Cerebral, Inc. and Cerebral Medical Group, P.A. (hereinafter "Defendants" or "Cerebral") due to their unlawful kickback scheme described herein.

2. The federal Anti-Kickback Statute (the "AKS") bars Defendants from soliciting or receiving "any remuneration (including any kickback, bribe, or rebate) directly or indirectly,

overtly or covertly, in cash or in kind," to purchase, lease, order, or arrange for the purchase, or order of any good or item "for which payment may be made in whole or in part under a Federal healthcare program." 42 U.S.C. § 1320a-7b(b)(2)(A).

3. Defendants Cerebral induced their providers to prescribe a specified and excessive amount of controlled substances to ADHD patients in exchange for reimbursement of their federal Drug Enforcement Administration (DEA) certification costs.

4. As a result of Defendants' improper inducement, federal health insurance programs, including but not limited to, Medicare, Medicaid, and TRICARE, have been caused to pay false and fraudulent claims for reimbursement of Cerebral's telemedicine mental health care services and medications.

5. The FCA provides for the award of treble damages and civil penalties for a variety of false and fraudulent practices.

6. Specifically, the FCA proscribes any person from "knowingly" presenting, or causing to be presented any "false or fraudulent claim" or any "false record or statement material to a false or fraudulent claim" for payment from the United States. 31 U.S.C. § 3729(a)(1)(A) and (B). In turn, the FCA defines "knowingly" as to the relevant false or fraudulent information as: having "actual knowledge of the information;" acting with "deliberate ignorance of the truth or falsity of the information;" or acting "in reckless disregard of the truth or falsity of the information." Moreover, "no proof of specific intent to defraud [the United States] is required." 31 U.S.C. § 3729(b)(1).

7. As required by the False Claims Act, 31 U.S.C. § 3730(b)(2), Keaton has provided the Attorney General of the United States and the United States Attorney for the District of Kansas with a disclosure statement of all material evidence and information related to this Complaint. That

disclosure statement is supported by material evidence establishing the existence of Defendants' false claims, which is known to Keaton at the time of the filing of this Complaint. The disclosure statement includes attorney-client communications and work product of Keaton's attorneys, and is submitted to the Attorney General and to the United States Attorney in their capacity as potential co-counsel in the litigation. Therefore, Keaton understands the disclosure to be confidential.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331.

9. In accordance with 31 U.S.C. § 3730(e)(4)(A), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. None of the allegations set forth in this Complaint are based on a public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional, administrative or General Accounting Office report, hearing, audit or investigation, or from the news media. Relator Keaton has direct and independent knowledge of the information on which the allegations set forth in this Complaint are based. In accordance with 31 U.S.C. § 3730(e)(4)(B), Relator is an original source with direct and independent knowledge of the allegations contained herein.

10. This Court has personal jurisdiction over the Defendants pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because each of the two Defendants transact business in the Northern District of Iowa.

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because the Defendants transact business in the Northern District of Iowa.

FEDERALLY FUNDED HEALTH INSURANCE PROGRAMS

A. Medicare Program

12. In 1965, Congress enacted Title XVIII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled. Medicare is a health insurance program for: people age 65 or older; people under age 65 with certain disabilities; and people of all ages with end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).

13. Medicare now has four parts: Part A, Part B, Part C, and Part D.

14. Medicare Part A (Hospital Insurance) helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). Medicare Part A also helps cover hospice care and some home health care.

15. Medicare Part B (Medical Insurance) helps cover doctors' services and outpatient care, as well as other medical services not covered by Part A such as "durable medical equipment" including HME equipment and supplies. Part B also helps pay for covered health services and supplies when they are medically necessary.

16. Medicare Part C, also known as "Medicare Advantage," is a managed care program that can be utilized by Medicare beneficiaries as a replacement for benefits otherwise generally available under Medicare Parts A and B, as described above. Medicare Part C is federally funded through contracts with private commercial insurance carriers who pay claims on behalf of Medicare beneficiaries.

17. Medicare Part D (Prescription Drug Plan) provides beneficiaries with assistance in paying for out-patient prescription drugs.

18. Payments from the Medicare Program come from a trust fund, known as the Medicare Trust Fund, which is funded through payroll deductions taken from the work force, in

addition to government contributions. Over the last forty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

19. The Medicare Program is administered through the United States Department of Health and Human Services ("HHS") and, specifically, the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS.

20. Much of the daily administration and operation of the Medicare Program is managed through private insurers under contract with the federal government.

21. Under Medicare Part A, contractors serve as "fiscal intermediaries," administering Medicare in accordance with applicable rules and regulations.

22. Under Medicare Part B, the federal government contracts with insurance companies and other organizations known as "carriers" to handle payment for physicians' services in specific geographic areas. These private insurance companies, or "Medicare Carriers", are charged with and responsible for accepting Medicare claims, determining coverage, and making payments from the Medicare Trust Fund.

23. Under Medicare Part C (Medicare Advantage), the federal government provides funding and contracts with private insurers who provide CMS-approved managed care insurance plans to provide health care services and supplies to Medicare beneficiaries. A Medicare beneficiary must affirmatively enroll in one of the many Medicare Advantage plans offered by private insurers to receive benefits as provided in the relevant plan in lieu of receiving benefits under Medicare Parts A and B.

24. Under Medicare Part D, Medicare beneficiaries must affirmatively enroll in one of many hundreds of Part D plans ("Part D Sponsors") offered by private companies that contract with the

federal government. Part D Sponsors are charged with and responsible for accepting Medicare Part D claims, determining coverage, and making payments from the Medicare Trust Fund.

25. The principal function of both intermediaries and carriers is to make payments for Medicare services, and to audit claims for those services, to assure that federal funds are spent properly.

26. To participate in Medicare, providers must assure that their services are provided economically and only when, and to the extent they are medically necessary. Medicare will only reimburse costs for medical services that are needed for that prevention, diagnosis, or treatment of a specific illness or injury.

B. Medicaid Program

27. Medicaid was created in 1965, at the same time as Medicare, when Title XIX was added to the Social Security Act. The Medicaid program aids the states in furnishing medical assistance to eligible needy persons, including indigent and disabled people. Medicaid is the largest source of funding for medical and health-related services for America's poorest people.

28. Medicaid is a cooperative federal-state public assistance program which is administered by the states.

29. Funding for Medicaid is shared between the federal government and the respective states.

30. Title XIX of the Social Security Act allows considerable flexibility within the states' Medicaid plans and therefore, specific Medicaid coverage and eligibility guidelines vary from state to state.

31. However, in order to receive federal matching funds, a state Medicaid program must meet certain minimum coverage and eligibility standards. A state must provide Medicaid coverage to needy individuals and families in five broad groups: pregnant women; children and teenagers;

seniors; people with disabilities; and people who are blind. In addition, the state Medicaid program must provide medical assistance for certain basic services, including inpatient and outpatient hospital services.

C. Other Federal Health Care Programs

32. In addition to Medicare and Medicaid, the federal government reimburses a portion of the cost of prescription medication, equipment, and supplies under several other federal health care programs, including but not limited to, TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

33. TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veteran Affairs, is a health care program for the families of veterans with a 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for hundreds of thousands of federal employees, retirees, and survivors.

THE ANTI-KICKBACK STATUTE

34. Enacted in 1972, the main purpose of the federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b, is to protect patients and federal health care programs from fraud and abuse by curtailing the corrupting influence of money and financial incentives on health care decisions.

35. When a company pays kickbacks to a medical equipment provider, such as an HME company, in order to induce the provider to use the company's products, it fundamentally compromises the integrity of the provider/patient relationship. Government-funded healthcare programs, such as Medicare and Medicaid, rely upon health care providers to decide what treatment and/or medical

equipment is appropriate and medically necessary for patients, and, therefore, payable by that healthcare program. As a condition of its reimbursement, government healthcare programs require that individuals and companies must render their services without the conflict of receipt of a kickback.

36. The federal Anti-Kickback Statute makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person:

(1) to refer an individual to a person for the furnishing of any item or service covered under a federal health care program; or

(2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a Federal health care program.

42 U.S.C. §1320a-7b(b)(l) and (2).

37. As to the Anti-Kickback Statute, "[t]he scope of prohibited conduct includes not only that which is intended to induce referrals, but also that which in intended to induce the purchasing, leasing, ordering or arranging for any good, facility, service or item paid for by Medicare or Medicaid. 61 Fed. Reg. 2122, 2124 (Final Rule, Jan. 25, 1996).

38. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1).

39. In fact, one form or "remuneration" expressly identified as a type of kickback which prompted Congress to strengthen the Anti-Kickback Statute by, among other things, broadening the definition of covered kickbacks to encompass "any remuneration" was unduly favorable "credit arrangements[.]" H. Rep. No. 393, Part II, 95 Cong., 1st Session 53, *reprinted in* 1997 U.S. Code Cong. & Admin. News 3039, 3048-49.

40. The federal Anti-Kickback Statute has been interpreted by the United States Court of Appeals for the Third Circuit, as well as other federal courts, to cover any arrangement where

one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *See United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).

41. Proof of an explicit quid pro quo is not required to show a violation of the Anti-Kickback Statute. Neither actual knowledge of the prohibitions of the Anti-Kickback Statute nor specific intent to commit a violation of the Anti-Kickback Statute is required. 42 U.S.C. § 1320a-7(b)(h).

42. A violation of the federal Anti-Kickback Statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. A party convicted under the federal Anti-Kickback Statute may be excluded (i.e., not allowed to bill for any services rendered) from Federal health care programs. 42 U.S.C. § 1320a-7(a).

43. In addition to criminal penalties, a violation of the Anti-Kickback Statute can also subject the perpetrator to exclusion from participation in federal health care programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose. 42 U.S.C. § 1320a-7a(a).

44. HHS has published safe harbor regulations that define practices that are not subject to prosecution or sanctions under the federal Anti-Kickback Statute because such practices would unlikely result in fraud or abuse. *See* 42 C.F.R. § 1001.952. However, only those arrangements that precisely meet all of the conditions set forth in the safe harbor are afforded safe harbor protection. None of the practices at issue here meet these safe harbor regulations.

45. Compliance with the Anti-Kickback Statute is a condition of payment under the Medicare and Medicaid programs, and that condition applies regardless of which entity is

submitting the claim to the government.

46. Claims that result from a kickback scheme are per se false because the Anti-Kickback Statute prohibits the government from paying for services or items tainted by kickbacks. No further express or implied false statement is required to render such infected claims false, and none can render the claim legitimate.

47. The FCA imposes liability where a defendant knowingly causes such tainted claims to be presented to the Medicare, Medicaid, or other government funded healthcare programs.

48. Consequently, if a party pays a kickback to induce the provision of prescribing controlled substances to patients, it renders false the submitter's implied or express certification of compliance that the resulting claim complies with the requirements of the Anti-kickback Statute.

49. Moreover, on March 23, 2010, as part of the Affordable Healthcare for America Act, the Anti-Kickback Statute was amended to clarify that all claims tainted from a violation of the Anti-Kickback Statute are a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). That amendment to the Anti-Kickback Statute codified the long-standing case law that a claim tainted by a violation of the Anti-Kickback Statute renders a claim false under the FCA. See e.g., *United States ex rel. Schmidt v. Zimmer, Inc*., 386 F.3d 235 (3d Cir. 2004); *United States v. Rogan,* 517 F.3d 449 (7th Cir. 2008).

DEFENDANTS' FRAUD

A. Background

50. Relator Keaton was employed by Defendant Cerebral Medical Group, P.A. as a "prescriber" for its mental health telehealth patients from approximately May 4, 2021 until her resignation on January 27, 2022. Keaton is a nurse practitioner who provided telemedicine care and prescribed medication for patients with a variety of mental health disorders including anxiety,

depression, and attention deficit/hyperactivity disorder (ADHD).

51. Defendant Cerebral, Inc. is a mental health telehealth start-up based in San Francisco, California that provides patients with access to care and medication management on a monthly, subscription basis throughout the United States.

52. Providers who provide services to Cerebral, Inc.'s mental health patients are employed by Defendant Cerebral Medical Group, P.A.

53. After launching in January of 2020, Defendants have been valued at $4.8 billion.

54. Cerebral offers a variety of mental health, nutrition and weight loss, and opioid use treatment subscription plans including medication and care counseling plans, medication and therapy plans, therapy plans, and medication and coaching plans.

55. Cerebral refers to its patients as "subscribers."

56. Cerebral accepts payment for its subscriptions through private insurance and self-pay and federal health insurance programs, including but not limited to, Medicare, Medicaid, and TRICARE. Cerebral bills between $85 to $325 each month for its subscriptions for mental health services.

57. Cerebral's monthly-subscription cost does not include the cost of medication which is billed separately.

58. When Relator Keaton began her employment with Cerebral she provided services to patients with a variety of mental health disorders. Relator estimates that she visited with patients for approximately 10 hours each week. As a nurse practitioner, Keaton prescribed various medications to Cerebral's subscribers to treat such disorders.

B. Cerebral Focuses on Prescribing Controlled Substances to ADHD Subscribers

59. However, shortly after her employment began, Keaton recognized that Defendant Cerebral prioritized prescribing stimulant drugs used to treat ADHD, such as Adderall, to as many subscribers as possible.

60. In approximately, October 2021, Relator's supervisor, Ernst Emery, encouraged Relator Keaton to apply for her federal Drug Enforcement Administration (DEA) certification so that she could prescribe stimulants used to treat ADHD. Generally, providers must have a certification from the DEA in each state in which they prescribe controlled substances.[1]

61. The United States Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five categories or schedules dependent on the drug's acceptable medical use and the drug's abuse or dependency potential. Schedule I drugs have the highest potential for abuse and potential to create severe psychological and/or physical dependence. Whereas, Schedule V drugs have the least potential for abuse. Adderall is a Schedule II drug, along with Vicodin, cocaine, methamphetamine, methadone, Dilaudid, Demerol, OxyContin, Fentanyl, Dexedrine, and Ritalin.

62. In approximately mid-October 2021, Relator Keaton received her DEA certification to prescribe Schedule II controlled substances.

63. Immediately, Cerebral increased the volume of Relator Keaton's scheduled ADHD subscribers. Rather than Cerebral scheduling 10 hours of subscriber visits each week, Cerebral scheduled Relator Keaton for 25 to 28 hours of subscriber visits each week.

64. Cerebral scheduled new subscribers for 30 minutes in order to diagnose and prescribe stimulants. Relator Keaton expressed concern that 30 minutes was not an adequate amount of

[1] Due to the covid-19 Public Health Emergency, the DEA relaxed its rules to allow reciprocity of state DEA licenses.

time to accurately diagnose and prescribe stimulants to treat ADHD.

65. Cerebral scheduled existing subscribers for monthly, 15-minute medication management visits. Cerebral prescribers are required to visit with patients who have been prescribed stimulants before receiving a monthly refill of the stimulant.

66. Cerebral recognized and took advantage of the large economic potential for treating patients with ADHD using stimulants. In addition to stimulants like Adderall being known as having a high potential for abuse, continuation of Adderall prescriptions requires frequent telehealth visits.

67. Relator Keaton noticed Cerebral's large marketing presence on social media which specifically targeted patients seeking treatment for ADHD and specifically stimulant medications to treat ADHD.

68. Keaton further noticed that Cerebral removed hurdles of subscribers seeking ADHD diagnoses and prescriptions. When Keaton's employment began, prescribers used an ADHD diagnostic quiz during video telehealth appointment in order to diagnose subscribers with ADHD. Later, Cerebral allowed patients to complete the diagnostic quiz on their own prior to visiting with a provider. This change in policy both simplified drug seeking subscribers' ability to answer questions to intentionally indicate they suffer from ADHD and pressured prescribers to rely on the quiz results to diagnosis subscribers with ADHD.

69. Overall, Cerebral signaled to potential subscribers and, likely, drug seekers that it would provide easy access to ADHD treating stimulants.

C. Cerebral's Kickback

70. In approximately November 2021, Relator Keaton inquired about employment benefits such as health insurance to her pod-supervisor, Earnest Emery, via email.

71. Relator's pod-supervisor replied that Cerebral has an "opportunity" that Relator Keaton will like and that someone from Cerebral's Human Resources will provide her with detailed information.

72. Shortly thereafter, in approximately November 2021, Relator Keaton received an email from a Cerebral human resources email account. The email explained that Cerebral had a "great offer" or "great opportunity" for Keaton.

73. Cerebral offered Keaton reimbursement for her $800 DEA certification in exchange for Keaton prescribing at least 400 prescriptions of stimulant drugs to treat ADHD.

74. Cerebral's effort to induce prescribers to write prescriptions for controlled substances to ADHD patients in exchange for reimbursement of prescribers' DEA certification costs violates the AKS.

75. Defendant knowingly and willfully offered valuable remuneration in the form of reimbursement of DEA certification costs to prescribers to induce them to write prescriptions for controlled substances to ADHD patients.

76. When Defendant intentionally decided to employ this illegal kickback scheme, it filed kickback-tainted, and therefore false, claims for reimbursements from health insurance programs funded by the federal government when seeking federal reimbursement for such kickback-tainted prescriptions, subscription services, mental health appointments for ADHD patients, and medicine management appointments.

77. By offering, paying, receiving, and/or soliciting the bribes in violation of the AKS,

Defendant knowingly presented false or fraudulent claims for payment or approval to the Medicare, Medicaid, and TRICARE programs in violation of the Federal and State False Claims Acts. *E.g.* 31 U.S.C. § 3729(a)(1)(A) (2009) and 31 U.S.C. § 3729(a)(1) (1986).

Count I

Federal False Claims Act
31 U.S. C. §§ 3729(a)(l) and (a)(2)

78. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs of this Complaint.

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

80. By virtue of the acts described above, Defendants knowingly caused false or fraudulent claims to be made to federally-funded health care programs.

81. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements, and omitted material facts, to induce the Government, or third-party intermediaries, to approve or pay such false and fraudulent claims.

82. Defendants provided offered to provide illegal remuneration to providers in the form reimbursement of DEA certification costs to induce prescribing stimulant-controlled substances to treat ADHD to beneficiaries of federally-funded health care programs in violation of the federal Anti-Kickback Statute.

83. Claims that arise from Defendants' respective kickback schemes are false, and violate the FCA, because they are the tainted by kickbacks—no further express or implied false statements are required to render such kickback-tainted claims false, and none can render the claims legitimate.

84. Defendants' violations of the federal Anti-kickback Statute give rise to liability under the FCA for causing false claims for reimbursements for the kickback-tainted items.

85. Defendants violated the FCA by submitting and/or causing to be submitted claims for reimbursement from federal health care programs, including Medicare and Medicaid, knowing that those claims would be ineligible for the payments demanded due to federal Anti-Kickback Statute violations associated with illegal remuneration.

86. Each claim for reimbursement for monthly subscription payments of ADHD patients who were prescribed ADHD treated stimulants such as Adderall and/or reimbursement for appointments related to diagnosing or treating ADHD where stimulant medications were prescribed that were submitted to a federal health insurance program resulting from illegal inducements represents a false or fraudulent claim for payment under the FCA.

87. Each claim for reimbursement for prescription stimulant-controlled substances to treat ADHD such as Adderall submitted to a federal health insurance program resulting from illegal inducements represents a false or fraudulent claim for payment under the FCA.

88. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by respective Defendants, paid the claims that were non-payable as a result of Defendants' illegal kickbacks, and that were therefore false under the FCA.

89. By reason of the Defendants' acts, the United States has been damaged in a substantial amount to be determined at trial. Federal health insurance programs have paid many tens of thousands of claims, amounting to millions of dollars, for the provision of ADHD treatment that was illegally induced by Defendants.

DEMAND FOR JURY TRIAL

Relator, on behalf of herself and the United States, demand a jury trial on all claims alleged herein.

DESIGNATED PLACE OF TRIAL

Plaintiff hereby designates Cedar Rapids, Iowa as the place of trial.

PRAYER FOR RELIEF

WHEREFORE, the Relator Keaton respectfully prays this Court:

a) Award the United States damages in the amount of three times the actual damages it sustained because of the false claims and fraud alleged within this Complaint, as provided by the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*;

b) Impose civil penalties of $22,363 for each and every false claim that Defendants presented to the United States and/or its agencies;

c) Award the Relator Keaton pre- and post-judgment interest, reasonable attorneys' fees, costs, and expenses for these costs necessarily incurred in bringing and pressing this case;

d) Grant permanent injunctive relief to prevent any recurrence of the False Claims Act for which redress is sought in this Complaint;

e) Award the Relator Keaton the maximum amount allowable under the False Claims Act;

f) Such other relief the Court deems proper.

Respectfully submitted,

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