

false claims for outpatient psychotropic medications prescribed to children and youth for which claims were made to the federal Medicaid Program.

2. The False Claims Act was enacted during the Civil War. Congress amended the False Claims Act in 1986 to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the False Claims Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments 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.

3. The False Claims Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government.

4. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (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.

5. Under Medicaid,

- (a) psychiatrists and other prescribers,
- (b) mental health agencies, and
- (c) pharmacies,

all have specific responsibilities to prevent false claims from being presented and are liable under the False Claims Act for their role in the submission of false claims.

6. This is an action for treble damages and penalties for each false claim and each false statement under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

II. PARTIES

7. Relator, _____, was prescribed and given psychiatric medications when a minor which constitute false claims under the False Claims Act.

8. Defendant _____ (Psychiatrist), resides in the District of _____, and prescribed psychiatric medications to Relator and other children and youth when minors, knowing that claims for such medication would be submitted to Medicaid for reimbursement, and which constitute false claims under the False Claims Act.

9. Defendant _____ (Provider), transacts business in the District of _____, and

- (a) submitted or caused to be submitted claims to Medicaid for psychiatric medications prescribed and given to Relator and other minors, and
- (b) continues to submit or cause to be submitted claims to Medicaid for psychiatric medications prescribed and given to minors,

which constitute false claims under the False Claims Act.

10. Defendant, _____, transacts business in the District of _____, and

(a) submitted claims to Medicaid for psychiatric medications prescribed and given to Relator and other minors, and

(b) continues to submit claims to Medicaid for psychiatric medications prescribed and given to minors,

which constitute false claims under the False Claims Act.

III. JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

12. There have been no public disclosures of the allegations or transactions contained herein that bar jurisdiction under 31 U.S.C. §3730(e).

13. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because all the defendants have at least minimum contacts with the United States, and can be found in, reside, or transact or have transacted, business in the District of _____.

14. Venue exists in the United States District Court for the District of _____ pursuant to 31 U.S.C. § 3730(b)(1) because all of the defendants have at least minimum contacts with the United States, and all the defendants can be

found in, reside, or transact or have transacted business in the District of

_____.

IV. APPLICABLE LAW

A. Medicaid

15. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments.

16. Federal reimbursement for prescription drugs under the Medicaid program is, as relevant, limited to “covered outpatient drugs.” 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3).

17. Outpatient drug prescriptions, as relevant, are covered under Medicaid, *i.e.*, reimbursable only if the drug is prescribed for a medically accepted indication, defined as indications approved by the Food and Drug Administration (FDA), or supported by one or more of the following Compendia:

- (i) American Hospital Formulary Service Drug Information,
- (ii) United States Pharmacopeia-Drug Information (or its successor publications), or
- (iii) DRUGDEX Information System,

(Covered Outpatient Drugs).

18. Every Medicaid provider must agree to comply with all Medicaid requirements.

B. False Claims Act

19. False Claims Act liability attaches to any person who knowingly presents or causes a false or fraudulent claim to be presented for payment, or to a false record or statement made to get a false or fraudulent claim paid by the government. 31 U.S.C. §3729(a)(1)&(2).

20. Under the False Claims Act, "knowing" and "knowingly" mean that a person, with respect to information:

- (1) has actual knowledge of the information;
- (2) acts in deliberate ignorance of the truth or falsity of the information; or
- (3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required. 31 U.S.C. §3729(b).

21. The False Claims Act is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a course of conduct that causes the government to pay a false or fraudulent claim for money.

V. ALLEGATIONS

22. Psychiatrist prescribed the psychotropic drugs on Attachment A to Relator while a minor that were not for an indication approved by the FDA or supported by one or more of the Compendia.

23. Pharmacy submitted claims to Medicaid for reimbursement for the psychotropic drugs prescribed to Relator set forth in Attachment A that were not for an indication approved by the FDA or supported by one or more of the Compendia:

VI. CAUSES OF ACTION

Count 1: Psychiatrist Liability For Uncovered Drugs

24. Psychiatrist prescribed the psychotropic drugs to Relator set forth in Attachment A, and to other minors, that are not for an indication approved by the FDA or supported by one or more of the Compendia, thereby causing claims for such prescriptions to be made to Medicaid for reimbursement

- (1) with actual knowledge;
- (2) in deliberate ignorance; or
- (3) in reckless disregard

that such claims are false, and is liable under the False Claims Act therefor.

25. Upon information and belief, Psychiatrist continues to prescribe psychotropic drugs to minors that are not for an indication approved by the FDA or supported by one or more of the Compendia, thereby causing claims for such prescriptions to be made to Medicaid for reimbursement

- (1) with actual knowledge;
- (2) in deliberate ignorance; or
- (3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 2: Provider Liability for Uncovered Drugs

26. Provider has submitted and/or caused the submission to Medicaid and continues to submit or cause to be for reimbursement of the psychotropic drugs

prescribed to Relator set forth in Attachment A, and to other minors, that are not for an indication that is approved by the FDA or supported by one or more of the Compendia

- (1) with actual knowledge;
- (2) in deliberate ignorance; or
- (3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 3: Pharmacy Liability For Uncovered Drugs

27. Pharmacy submitted claims to Medicaid for reimbursement of outpatient pediatric prescriptions for psychotropic drugs to Relator and other minors that are not for an indication that is approved by the FDA or supported by one or more of the Compendia

- (1) with actual knowledge;
- (2) in deliberate ignorance; or
- (3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

VII. DEFENDANTS' LIABILITY

28. By virtue of the acts described above, defendants knowingly (a) submitted, and continue to submit, and/or (b) caused and/or continue cause to be submitted, false or fraudulent claims to the United States Government for payment of psychiatric drugs prescribed to Relator and other minors that are not for an indication that is approved by the FDA or supported by one or more of the Compendia.

29. The Government paid and continues to pay such false claims.

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

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, United States of America, through Relator, requests the Court enter the following relief:

A. That defendants be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq.*

B. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. §3729;

C. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act.

D. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

E. That Relator recover such other relief as the Court deems just and proper.

DATED: _____.

By: _____

Certificate of Service

The undersigned hereby certifies that a copy of this Complaint and written disclosure of substantially all material evidence and information Relator possesses has been served on the Government as provided in FRCP 4.

Dated: _____

ATTACHMENT A.