IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

UNITED STATES OF AMERICA and THE STATE OF CONNECTICUT *ex rel.* RUSSELL BUCHNER and CHARLES HATHEWAY **Plaintiffs-Relators,** **vs.** **THE HARTFORD DISPENSARY, INC. and THE HARTFORD DISPENSARY ENDOWMENT CORPORATION** **Defendants.**	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730 AND C.G.S.A. § 17b-301b** **No. 3:14-cv-00493 (JAM)** **SECOND AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

On behalf of the United States of America pursuant to the United States False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and on behalf of the State of Connecticut pursuant to the Connecticut False Claims Act, Conn. Gen. Stat. Ann. § 17b-301b *et seq.*, Plaintiffs-Relators, Russell Buchner and Charles Hatheway (collectively, "Plaintiffs" or "Relators"), file this Second Amended *qui tam* Complaint for treble damages and civil money penalties against Defendants, The Hartford Dispensary, Inc. ("HD") and The Hartford Dispensary Endowment Corporation ("HDE") (collectively "Defendants"). These claims arise out of Defendants' knowing submission of false and fraudulent claims for payment to Medicaid for services that were performed in violation of numerous federal and state requirements, or not provided at all. In support of these claims, Relators allege as follows:

I. THE PARTIES

1. Relator, Russell Buchner ("Buchner"), is an individual citizen of the State of Connecticut. Since May 2012, Buchner has been employed by HD as the Director of

Performance Improvement. Buchner began working at HD in 1999 as a consultant to help the agency gain accreditation from the Commission on Accreditation of Rehabilitation Facilities ("CARF"), and to provide process and quality improvement and special project assistance. In these positions and from his prior education and experience, Buchner gained substantial expertise in Medicaid compliance requirements.

2. Relator, Charles Hatheway ("Hatheway"), is an individual citizen of the State of Connecticut. Since 1996, Hatheway has been employed as HD's Management Information Systems Director/Billing Manager with duties and responsibilities that include Medicaid billing.

3. Defendant, HD, is a Connecticut corporation with its principal place of business located at 335 Broad Street, Manchester, Connecticut 06040. HD is a private, non-profit behavioral healthcare organization whose services include mental health and substance abuse treatment with services primarily for medication assisted treatment (*e.g.*, methadone) to address opioid addiction. The organization provides an array of out-patient services to primarily low-income clients including psychiatric treatment, individual and group counseling, medical and dental services, laboratory services, prenatal care and counseling, and infectious disease screening and counseling. HD also participates in preventative and community health initiatives. HD has nine (9) licensed, CARF accredited, and SAMSHA certified clinics across central Connecticut and treats approximately 5,000 patients per day.

4. HD operates under a board of directors ("BOD"), a chief executive officer ("CEO") and president, an associate director, a medical director, a chief of medical staff and nine (9) clinic supervisors. Its longtime CEO and president (formerly executive director) is Paul McLaughlin, and its associate director is Phil Richmond. HD is a wholly-owned subsidiary of

the Hartford Dispensary Holding Corporation ("HDHC"). HDHC is an umbrella entity which also owns HDE and another related entity, Hartford Dispensary Real Estate, Inc. ("HDRE").

5. Defendant, HDE, is a Connecticut corporation with its principal place of business located at 335 Broad Street, Manchester, Connecticut 06040. HDE is a nonprofit charitable organization which holds funds ostensibly to use for charitable purposes. On an annual basis, HD transfers substantial excess funds from its operating budget to HDE. Since some 70% of HD's annual revenue is derived from Medicaid reimbursements, a large portion of HDE's assets consist of funds received from Medicaid for services either improperly documented and/or not provided.

6. Relators have direct and independent knowledge upon which the allegations contained in this Complaint are based, are each an original source of this information to the United States and the State of Connecticut, and have voluntarily provided the information to the United States and to the State of Connecticut before filing this action based on the information.

7. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relators, they are each an original source under 31 U.S.C. § 3730(e)(4) and Conn. Gen. Stat. Ann. § 17b-301e(f).

8. Relators have fulfilled all jurisdictional and other prerequisites to commence this action and have standing to assert the claims contained herein on behalf of the United States of America and the State of Connecticut.

II. JURSIDICTION AND VENUE

9. This Court has subject matter jurisdiction over this case pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over this

case for the claims brought on behalf of the State of Connecticut pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, as recovery is sought on behalf of the State of Connecticut arising from the same transactions and occurrences as the claims brought on behalf of the United States.

10. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) and (c) because Defendants transact business in this District and/or one or more of the acts committed by Defendants and proscribed by 31 U.S.C. § 3729 occurred in this District.

11. This Court has personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because they are located in Connecticut and submitted false and/or fraudulent claims directly or indirectly to the federal and state governments in Connecticut.

III. STATUTORY AND REGULATORY BACKGROUND

A. Medicaid

12. Medicaid reimbursements constitute the majority of HD's revenue. Medicaid is a federal health insurance system that is administered by the states and is available to low-income individuals and families who meet eligibility requirements determined by federal and state law. Medicaid pays for items and services pursuant to plans developed by the states and approved by the Department of Health and Human Services ("HHS") through the Center for Medicare and Medicaid Services ("CMS"). *See* 42 U.S.C. §§ 1396a(a)-(b). States pay health care providers, including addiction treatment facilities, according to established rates, and the federal government then pays a statutorily established share of "the total amount expended … as medical assistance under the State plan." *See* 42 U.S.C. §§ 1396b(a)(1).

13. At all times relevant hereto, the United States has provided funds to Connecticut for its Medicaid program, which Connecticut administers through the Connecticut State

Department of Social Services ("DSS"), and HHS, through CMS, has ensured that Connecticut has complied with minimum federal standards in its administration of the Medicaid program.

B. The United States False Claims Act

14. The United States False Claims Act ("USFCA") prohibits, *inter alia*, the following:

> knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval;
>
> knowingly making or using (or causing to be made or used) a false record or statement material to a false or fraudulent claim; and
>
> knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money to the Government.

31 U.S.C. §§ 3729(a)(1),(2) and (7) (2006), amended by U.S.C. §§ 3729(a)(1)(A), (13) and (g).

C. The Connecticut False Claims Act

15. The Connecticut False Claims Act ("CTFCA") prohibits a person or entity from, *inter alia*, the following:

> Knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;
>
> Knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim under a medical assistance program administered by the Department of Social Services; and
>
> 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 state under a medical assistance program administered by the Department of Social Services.

See Conn. Gen. Stat. Ann. § 17b-301b(a)(1), (2) and (7).

D. Regulatory Framework

16. Healthcare providers in Connecticut contract with the state in order to receive reimbursement for services provided to Medicaid-eligible patients. In order to receive these funds, providers must be compliant with state and federal regulations designed to ensure that the providers maintain high standards of patient care. The regulations require that almost all services be thoroughly documented to not only prove that the service was provided, but also to demonstrate that it was provided consistent with the particular standard of care which applies to that service. The regulations require documentation of items such as: treatment plans and treatment plan revisions for patients, progress notes of patient treatment, staffing and supervision levels, credentials of staff administering services, staff training, amounts of time spent delivering services, times and amounts of medications administered and clinical contacts with patients. The regulations establish the documentation standards; it is up to the providers themselves to develop the best internal systems and processes to meet those standards.

(i) Federal Regulations

17. Opioid Treatment Programs ("OTPs") are regulated under Title 42 of the Code of Federal Regulations, Part 8. *See* 42 C.F.R. § 8.1 *et seq*. Subpart A governs accreditations of OTPs and Subpart B establishes certifications and treatment standards. *Id.* The Substance Abuse and Mental Health Services Administration ("SAMHSA") administers the regulations through the Center for Substance Abuse Treatment ("CSAT"). CSAT publishes "Guidelines for the Accreditation of Opioid Treatment Programs," which provides specific procedures and standards designed to provide guidance to OTPs on how to comply with 42 C.F.R. § 8.12, entitled "Federal opioid treatment standards."

18. 42 C.F.R. § 8.12(g)(1) establishes documentation requirements as follows: "OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction." The Guidelines for the Accreditation of Opioid Treatment Programs interprets Section 8.12 in Chapter 2(t) and lists the various aspects of the treatment process which must be documented.

19. Under 42 C.F.R. § 8.1(a)(1) and (2), an OTP must not only meet the standards established in § 8.12 (via CSAT), but also maintain accreditation by a SAMHSA-approved independent accrediting body. HD maintains its accreditation through CARF. CARF publishes an annual Opioid Treatment Program Standards Manual ("CARF Manual"). Appendix "A" to the CARF Manual contains a comprehensive list of all documentation standards which apply to OTPs.

20. HHS has established a mechanism for providers who discover improper billing practices, documentation failures or fraud within their organizations. Through the HHS Office of the Inspector General's ("OIG") Provider Self-Disclosure Protocol, health care providers are encouraged to voluntarily disclose potential fraud involving federal health programs. In exchange for self-disclosing, providers are given consideration for exclusions from integrity agreement obligations and lower multipliers on damages.

(ii) Connecticut State Regulations

21. Several sections of the Regulations of Connecticut State Agencies govern HD's operations. These regulations establish licensure requirements, standards of care, documentation requirements, and payment procedures for HD's operation as a non-profit, out-patient OTP with multiple satellite facilities.

a. Department of Social Services

22. Title 17B of the Regulations of Connecticut State Agencies governs "Social Services." Title 17B provides a subset of regulations entitled, "Requirements for Provider Participation in the Connecticut Medical Assistance Program." *See* CT ADC § 17b-262-522 *et seq*. In order to receive payment through Medicaid, HD must meet the standards set forth in this subsection. Specifically, to receive payment, providers must:

> (1) Meet and maintain all applicable licensing, accreditation and certification requirements;
>
> (2) meet and maintain all departmental enrollment requirements…; and
>
> (3) have a valid provider agreement on file which is signed by the provider and the department…. **The provider agreement specifies the conditions and terms that govern the program and to which the provider is mandated to adhere in order to participate in the program**.

See "Provider Participation" CT ADC § 17b-262-524(a)(1)-(3) (emphasis added).

23. The Provider Enrollment Agreement ("Provider Agreement") is a contract drafted by DSS. The agreement sets forth the standards that a medical provider agrees to adhere to in order to receive reimbursement for medical services from DSS through Medicaid. The first two paragraphs of the Provider Agreement mandate that a provider "comply continually with all enrollment requirements established under rules adopted by DSS" and "comply with all federal and state statutes, regulations, and policies pertaining to Provider's participation…." *See* Provider Agreement at ¶¶ 1-2.

24. By signing the Provider Agreement, the provider agrees that it is submitting for payment only those claims "that are documented by the provider as being (a) for medically necessary goods and services … [and] (c) for compensation that Provider is legally entitled to receive." *Id.* at ¶ 15. A Provider must refund any erroneous payments within thirty (30) days

after receipt. *Id.* at ¶ 18. In addition, a provider is required to "maintain fiscal, medical, and programmatic records with fully disclosed services and goods rendered and/or delivered to eligible clients." *Id.* at ¶ 21. By signing the Provider Agreement, providers agree that "any payment, or part thereof, for Connecticut Medical Assistance Program goods or services, which represent excess over the appropriate payment, or any payment owed to DSS because of violation due to abuse or fraud, shall be immediately paid to DSS." *Id.* at ¶ 23.

25. The Provider Agreement also specifically cites the CTFCA, and prohibits providers from making "false statements, claims, [and] misrepresentation[s]" or engaging in concealment, failing to disclose or the conversion of benefits. *Id.* at ¶ 27(a). The same paragraph also prohibits "charging or receiving reimbursement in excess of that provided by the state." *Id.* at ¶ 27(c).

26. Pursuant to the Provider Agreement, HD is obligated to follow all state and federal regulations which pertain to an OTP. *Id.* at ¶¶ 1-2. Therefore, HD is both legally and contractually required to comply with documentation regulations. The Provider Agreement states that a provider is required to "maintain fiscal, medical, and programmatic records which fully disclose services and goods rendered and/or delivered to eligible clients." *Id.* at ¶ 21.

27. HD's operations are also controlled by Title 17 of the Regulations of Connecticut State Agencies, which governs "Public Assistance." Under the subheading "Department of Social Services (4)" is a subsection, entitled "Medical and remedial care and services." *See* CT ADC § 17-134d-2. This subsection states that "[m]edical assistance may be granted to eligible persons for the following items of medical and remedial care and services … (9) clinic services… (13) … rehabilitation services …." *Id.* The subsection entitled "Reimbursement of

clinic outpatient services and clinic off site medical services furnished by free standing clinics" addresses the requirements for clinics to be reimbursed. *See* CT ADC § 17-134d-56.

28. HD falls squarely within the definitions section of § 17-134d-56, which defines a "free-standing clinic" as "a facility providing medical or medically related outpatient services by or under the direction of a physician or dentist and the facility is not part of, or related to a hospital. Such facilities provide mental health, rehabilitation, dental and medical services…." *See* CT ADC § 17-134d-56(a)(1). Facilities falling within this categorization must adhere to the procedures outlined in the DSS Provider Manual. *Id.*; *see also* CT ADC § 17-134d-56(f)(2)(F) ("[a]ll such sites must otherwise comply with the provisions of Sections 171 through 171.4 of the Department's Manual covering clinic services"). The Provider Manual delineates the specific program and documentation requirements which HD is obligated to follow. *See e.g.*, Section 171.1G.III of the Provider Manual enumerating treatment documentation requirements. The Provider Manual is cited and incorporated by reference in multiple subsections of the regulation, giving the procedures in the Manual the force of law. *See* CT ADC § 17-134d-56(b), (c), (f)(2), (g)(1). While the Provider Agreement, Provider Manual and DSS regulations establish the standards HD must meet, DSS may also apply other related regulations when conducting an audit.

29. Similar to the HHS OIG's self-disclosure program, DSS has likewise established a mechanism for providers who discover improper billing practices or documentation failures within their organizations. Through DSS's "Self-Disclosure Program," an organization can return improper payments to DSS and, in exchange, be considered for forgiveness of fines or sanctions, reduced interest rates and extended repayment terms. The Program is subject to

various exclusions and enumerates a procedure for a provider to follow when it becomes aware of improper payments.

b. Department of Mental Health and Addiction Services

30. The Department of Mental Health and Addiction Services ("DMHAS") supplies HD with substantial state and federal grant monies pursuant to contracts. In order to remain eligible for these funds, HD must follow its contractual requirements. CT ADAC § 17-226d (1-4). These requirements mirror DSS and DPH regulations in the areas of treatment plans, treatment plan reviews, progress notes and required licensure and supervision. These monies supplement the cash payments made by the thirty percent (30%) of HD patients not covered by Medicaid.

c. Department of Public Health

31. HD's operations also come under the purview of the Connecticut Department of Public Health ("DPH"). Two subsections of the Connecticut regulations governing the DPH apply to HD: CT ADC § 19a-495-570 ("Licensure of private freestanding facilities for the care or treatment of substance abusive or dependant persons") and CT ADC § 19a-495-550 ("Licensure of private freestanding mental health day treatment facilities, intermediate treatment facilities and psychiatric outpatient clinics for adults"). Subsection (m)(3)(A)-(I) of both sections enumerates the documentation requirements that apply to substance abuse rehabilitation facilities covered by the regulations. The remainder of the regulation establishes standards for issues such as the storage and use of drugs on the premises, physical conditions of the buildings, individualized treatment plans, and personnel policies. The DSS regulations specifically reference the requirement of providers to comply with DPH regulations. *See* CT-DSS Medicaid Provider Manual, Chapter 7, October 9, 2013. Sec. 17b-262-818-828.

IV. FACTUAL BACKGROUND

32. Historically, low income adults who received treatment at HD were covered by the General Assistance Behavioral Health Program ("GABHP"),[1] which was administered by DMHAS. Effective April 1, 2010, coverage for these patients was transferred from DMHAS to DSS's new Low Income Adults ("LIA") program, which is funded by Medicaid. While HD always had some Medicaid patients, the switch from SAGA to Medicaid for low income adults dramatically increased the percentage of Medicaid recipients in HD's patient population. The Affordable Care Act has further increased the number of HD's Medicaid patients to its current level of approximately 70%.

33. As set forth in greater detail below, Medicaid and DSS regulations require that a variety of events throughout the course of a patient's treatment be thoroughly documented in order to ensure high standards of care. For example, initial physical examinations must be performed or reviewed by a licensed doctor; master treatment plans must be established; all treatment plan revisions must be documented; all medication dosages must be recorded; charts must include monthly progress notes signed by the properly credentialed staff members; and periodic counseling sessions must be the proper length of time and be documented.

34. In November 2011, SAGA auditors commenced a routine audit of claims paid to HD from July 1, 2008 through June 30, 2009. Using a sampling and extrapolation methodology, the auditors determined (based on a review of 96 randomly selected claims) that HD owed $500,142.72 to DMHAS in overpayments for services that HD had not sufficiently documented. HD supplied additional information seeking to substantiate some of the disputed claims and, in June 2012, HD staff, including Associate Director Phil Richmond, met with the auditors in the

[1]The predecessor to GABHP was the State Administered General Assistance ("SAGA") program, and HD's staff continue to refer to GABHP by the former acronym, SAGA. Accordingly, the term "SAGA" will be used herein to refer to GABHP.

hope of negotiating a lower payment. On June 20, 2012, DMHAS issued its final report reducing the overpayment amount to $160,557.18 due to a "combination of treatment plan reviews, updates, or progress notes [being] insufficiently documented."

35. At the June 2012 meeting, the DMHAS auditors warned HD that DSS auditors were much tougher than they were, and that because any future audits would be conducted by DSS, HD was at risk of greater liability in the future.

36. One issue confronting HD was that Medicaid was not supposed to be billed for off-site treatment services, but HD's billing records did not identify when medication delivered to patients off-site was, in fact, being billed to Medicaid. This issue took on increased importance with HD's higher percentage of Medicaid patients beginning after 2010. HD estimated that it improperly received approximately $130,000 in payments from Medicaid for off-site services from July 1, 2008 to December 31, 2011. HD finally stopped billing for off-site services in January 2012, but did not repay DSS at that time for past overpayments.

37. HD management decided in approximately July 2012 that HD should conduct an internal audit to determine its potential exposure in the event of a DSS audit. It was decided that an outside firm with expertise in this area should conduct the audit.

38. Throughout the spring of 2013, HD's Corporate Compliance and Ethics Committee members ("CC&E Committee") discovered violations similar to those identified in the SAGA audit, *e.g.*, overpayments made by DSS for services that either were not provided or not documented as required by the applicable regulations. In response, the CC&E Committee developed a Compliance Review Program to address HD's documentation problems. This process involved numerous meetings between and among the CC&E Committee members and

clinic supervisors. Regular discussions of the planned corrective actions also occurred at the monthly agency-wide Quality Improvement Committee meetings.

39. In April 2013, the CC&E Committee finalized multiple corrective actions to augment documentation compliance which would constitute the Compliance Review Program. In addition, CEO and President Paul McLaughlin also fired one clinic supervisor and several counselors based on documentation and service delivery issues.

40. During the summer of 2013, the CC&E Committee members devoted considerable time to implementing the corrective actions that it had developed to correct systemic compliance problems. Intensive training sessions were conducted with HD staff, counselors and supervisors at each of HD's facilities on the new procedures instituted to comply with Medicaid documentation and recordkeeping requirements. Rigorous quality assurance procedures were implemented, requiring the clinics going forward to identify and report any and all violations of Medicaid documentation requirements. Nevertheless, no steps were taken to correct or return past overpayments.

41. Since 2004, HD has conducted internal audits based on CARF OTP standards on a quarterly basis. The audits are conducted by the supervisors of each of HD's clinics auditing the records of another clinic for compliance with DSS documentation requirements. Supervisors visit a clinic, pull a certain number of random patient files and review them using a "Chart Audit" checklist to determine if all of the required documents are in the clinical record. Supervisors are instructed to note on the checklist when documentation is missing or inadequate. HD retains the Chart Audit checklists for six years.

42. HD's policy is to review at least 7% of the patient records on an annual basis. On average, this amounts to approximately 200 audits annually or 50 audits each quarter. Every

quarter, each clinic supervisor audits about 5-10 patient records of one of the other clinics. Audits can be conducted for other reasons as well. For instance, when a staff member leaves or is terminated, some of his or her records may be audited for compliance. Senior HD staff members may also conduct audits of particular clinics to monitor compliance. Likewise, supervisors conduct audits of counselors for supervisory and training purposes.

43. As part of the new Compliance Review Program developed in 2013, far more internal audits were conducted in 2013 than in previous years. These audits revealed consistent and rampant documentation errors, lapses and mistakes such as missing master treatment plans, missing treatment plan reviews and missing progress notes. The associate director, the clinic supervisors, and in the case of terminations, the CEO, have the authority to take corrective actions directed toward the clinic or counselor who is responsible for the mistake. However, only the CEO and the Board of Directors have the authority to actually return payments to DSS when documentation violations are discovered.

44. HD did not, however, repay any past overpayments or initiate any self-disclosure process. Despite the extensive violations which became known to HD's management staff, CEO Paul McLaughlin did not believe that self-disclosure and returning funds to DSS was required. To the contrary, McLaughlin believed that a DSS audit was unlikely and, if it were to occur, any overpayment determination could be negotiated down to an acceptable figure. Following a June 2013 HD BOD meeting, McLaughlin explicitly stated that HD would not return any money for past overpayments to DSS.

45. In late September 2013, HD conducted an internal follow-up audit of eight (8) patient charts from the Norwich Clinic after the clinic supervisor reported major compliance issues. Again, consistent with the results from previous supervisor Chart Audits, the audit

revealed a significant number of documentation violations such as missing master treatment plans, missing treatment plan reviews and missing progress notes.

46. After being made aware of the results from the Norwich Clinic audit, CEO McLaughlin still refused to return any payments received from DSS.

47. In 2014, HD completed an analysis of all audits conducted during 2013. Because of the improved compliance program that the CC&E Committee had developed and implemented, the number of audits in 2013 sharply increased from approximately 200 in prior years to 708 in 2013. The results of the analysis were jarring. Of the 708 chart audits completed, 284 or 40.1%, included errors which could potentially void a paid claim. The following chart shows the number of internal audits conducted at each facility, the number and percentage of errors found in the records, and the totals for 2013:

Clinic	Total 2013 Audits	Errors Potentially Needing Voiding of Paid Claims	Percentage (%) Error
1. Norwich	140	104	74.3 %
2. Manchester	63	20	31.7 %
3. New Britain	68	27	39.7 %
4. Henderson-Johnson	52	19	36.5 %
5. Doctors Clinic	58	26	44.8 %
6. Bristol	83	33	39.8 %
7. New London	179	34	19.0%
8. Willimantic	55	21	38.2 %
Totals:	**708**	**284**	**40.1 %**

48. In February of 2014, a randomized audit of paid claims was conducted using the audit method also utilized by DSS. A computer program was used to generate 100 random paid claims, distributed roughly evenly among all the clinics, from October, 2012 to October, 2013.

A paid claim consists of a one- to three-week period in which Medicaid paid a specified weekly amount for all services received by an individual Medicaid patient at HD. The charts of the patients selected by the computer were then audited using the chart audit forms. The analysis revealed that thirty-four percent (34%) of the paid claims contained errors which could void the claim.

49. HD's compliance program has been successful in uncovering serious deficiencies (especially since early 2013); however, HD has not taken any steps to repay the Medicaid funds it has accepted. HD maintains the quarterly Chart Audit forms going back six years. HD also retains forms from other audits. These forms evidence widespread documentation violations. Despite its knowledge of these deficiencies, HD has failed to take the required affirmative remedial action of repaying Medicaid, and has continued to submit bills to Medicaid, knowing (based on its audit results) that, for each service for which payment is claimed, there is a significant chance that Medicaid requirements for payment have not been satisfied. As a result, millions of dollars in claims which do not comply with state and federal documentation requirements have been submitted for payment, in direct violation of the FCA and the CT FCA.

V. ADDITIONAL FRAUDULENT CONDUCT

A. Legal Background

50. At all relevant times, HD has been enrolled as an outpatient medication assisted treatment provider with DSS. Between January 1, 2008, and December 31, 2014, HD filed executed DSS Provider Agreements with DSS in order to receive Medicaid reimbursements for its OTP services. HD filed the agreements biannually and they covered two year periods. The DSS Provider Agreement requires providers "to continually meet state and federal licensee,

accreditation, certification or other regulatory requirements." DSS Provider Enrollment Agreement, General Provision Requirement No. 3.

51. HHS has promulgated regulations applicable to behavioral health providers, which include OTP service providers like HD. As stated above, SAMHSA is the agency within HHS that administers these regulations. Since January 2001, the regulations have required such providers both to be accredited by a body approved by, and certified by, SAMHSA. *See* 42 C.F.R. § 8.2.

52. The accrediting body for HD is CARF. *See generally* www.carf.org.

53. To be accredited and certified by SAMHSA, an OTP provider must have a Medical Director. Specifically, 42 C.F.R. § 8.12 ("Federal opioid treatment standards") provides:

> ***b.*** ***Administrative and organizational structure***. An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. **At a minimum, each OTP shall formally designate a ... medical director. ... The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.**

42 C.F.R. § 8.12(b) (emphasis added).

54. SAMHSA requires providers, including HD, to file a Form SMA-162; the name of the Medical Director must be listed in Section 10 of the form. The regulations define the term "Medical Director" to mean:

> a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, **who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by**

> **delegating specific responsibility** to authorized program physicians and healthcare professionals functioning **under the medical director's direct supervision.**

42 C.F.R. § 8.2 (emphasis added).

55. In its DSS Provider Agreements filed separately every two years for each clinic, HD has certified its compliance with federal regulatory requirements, including having a Medical Director *as that term is defined by the applicable regulations.*

56. In addition, the Medicaid "Provider Enrollment/Re-enrollment Criteria" description for "Type/Specially 08/096 Methadone Clinic – Requirements" requires as attachments to each "Provider Agreement" a "Copy of the Medical Director's current physician license and a statement from Medical Director accepting full professional responsibility for services (standard form provided by [Hewlett-Packard] as part of the provider's follow on document)." At all times relevant hereto HD has fraudulently used Dr. O'Brien's license and a statement from Dr. O'Brien that he accepts "full professional responsibility for services" for HD, despite the fact that Dr. O'Brien has provided no services at any HD clinic nor has be directly supervised any medical staff.

57. In order to qualify for reimbursement by DSS for providing OTP services to Medicaid beneficiaries, both SAMSHA and Medicaid regulations require HD to have a Medical Director who either personally administers all of its medical services or who directly supervises the physicians and healthcare professionals performing those services.

B. Factual Allegations

58. The HD Board of Directors appointed James Edward O'Brien, M.D., Ph. D., as HD's Medical Director in 1986.

59. According to the Medical Director "Position Description," Dr. O'Brien assumed "the ultimate responsibility for the medical aspects of the program…and provides guidance and/or assistance to staff on an as need [*sic*] basis." The document specifies that the position is "NON-SALARIED."

60. Dr. O'Brien has been licensed to practice medicine in Connecticut since 1964, and he has been affiliated with HD for most of his career.

61. Dr. O'Brien is not Board certified in any medical specialty, but his practice has included a mix of clinical pharmacology, toxicology and internal medicine.

62. Now in his mid-80's, Dr. O'Brien is on information and belief no longer actively practicing medicine.

63. Dr. O'Brien continuously held the position of HD's Medical Director from the date of his appointment until his resignation effective November 20, 2015. Recent documents identifying Dr. O'Brien as HD's Medical Director during that time period include HD's official "Profile" and "Key Clinic Staff."

64. HD has identified Dr. O'Brien as its Medical Director in its Certification to Use Opioid Drugs in a Treatment Program Pursuant to 42 C.F.R. § 8.11 and repeated this certification in multiple Form SMA-162s filed over the years. HD has continued to file DSS Provider Agreements every two years relying on these certifications while also attaching to each Provider Agreement Dr. O'Brien's medical license and a statement from Dr. O'Brien that he accepts "full professional responsibility for services" at HD.

65. While Dr. O'Brien held the position of Medical Director, he performed *none of the duties* that the HHS regulations require of a Medical Director for many years.

a. On information and belief, Dr. O'Brien has not treated a single HD patient for ten years or more.

b. Dr. O'Brien routinely does not appear on the HD clinic physician schedules.

c. Dr. O'Brien is not covered under HD's insurance.

d. Dr. O'Brien has not performed any on-site management or oversight of HD's medical services.

e. Dr. O'Brien has not visited a single HD clinic in his role as Medical Director or provided any direct supervision to any other physician or health care provider of medical services at any HD clinic.

f. Dr. O'Brien has not reviewed staffing patterns, performed quality assurance of HD's programs, participated in hiring or training of any medical staff, participated in any training himself (as required by the Position Description), or been involved in the development or enforcement of any HD compliance programs.

66. Though Dr. O'Brien has been a Board member, the minutes do not reflect his attendance at a Board meeting since 2006.

67. On information and belief, the sole function that Dr. O'Brien performed in his role as HD Medical Director has been to sign SAMHSA certification forms and other regulatory documents in order to maintain the fiction that he serves as HD's Medical Director – or to permit others to do so on his behalf.

68. For example, when HD's Manchester clinic provider agreement expired in approximately May 2015, a courier took the re-enrollment forms to Dr. O'Brien's home to have him sign.

69. A recent example of this continuing fraud occurred in connection with the opening of HD's newest OTP clinic in Torrington, CT.

70. HD filed to apply for the initial, one-year, provisional SAMHSA certification using an on-line Form SMA-162. The form is dated July 9, 2014, identified Dr. O'Brien as the Medical Director, and provided supporting documentation including Dr. O'Brien's CV and an organizational chart.

71. On July 28, 2014, SAMHSA Public Health Advisor/Compliance Officer Mary Lou Ojeda, MS e-mailed HD Executive Secretary Darcie Boiano to advise her that "[t]here are a couple of items that are missing or need to be updated." Among those items was:

> 3) An organizational chart only reflecting the staff for Torrington, CT location with the titles and people's names. **Also make sure that the medical director Dr. O'Brien is directly linked overseeing the nursing staff."**

Id. (emphasis added).

72. On August 4, 2014, at approximately 10:30 a.m., Boiano revised the Torrington clinic staffing diagram to show the Medical Director directly supervising the clinic's nursing staff.

73. Accordingly, HD prepared and submitted to SAMHSA a revised organizational chart reflecting that Dr. O'Brien was responsible for direct supervision of the nursing staff at the Torrington clinic. Relying on this representation, SAMHSA granted provisional certification to the Torrington, CT clinic on September 8, 2014.

74. HD's certification that Dr. O'Brien was responsible for directly supervising nurses at Torrington, CT was blatantly false. To Relators' knowledge, Dr. O'Brien has not once visited the clinic since it opened 13 months ago.

75. Indeed, for at least the last ten years and continuing until November 20, 2015, all of HD's certifications to DSS and any other federal or state agency, or accrediting body authorized to act on behalf of any federal or state agency, that Dr. O'Brien was HD's Medical Director have been knowingly and materially false.

76. For at least the last ten years and continuing until November 20, 2015, HD and McLaughlin knew that Dr. O'Brien has performed none of the duties that the HHS regulations require of a Medical Director.

C. Relationship between additional fraudulent conduct alleged herein and allegations of original and First Amended Complaint

77. HD's repeated false certifications that Dr. O'Brien serves as the agency Medical Director in accordance with the applicable federal regulations are not mere technical violations. The significant and continuing consequences of HD's failure to have a real Medical Director are revealed in the results of both the internal and external audits of Medicaid patient records and DSS patient paid claims between January 2008 and December 2014. These audits demonstrate that DSS required Medicaid services were routinely not provided and/or do not have the documentation required to support Medicaid reimbursement.

78. If HD had a genuine Medical Director making a good faith attempt to perform the duties required of the position, that individual would long ago have identified and sought to correct the deficiencies in staffing, supervision, resources, and service delivery that resulted in these past and current audit findings. HD's knowing failure to have a *real* Medical Director as

required by federal regulations resulted in significant numbers of Medicaid claims that do not meet DSS regulatory requirements.

79. HD's certifications that Dr. O'Brien is a Medical Director in compliance with SAMHSA regulations are materially and knowingly false and fraudulent and should subject HD to FCA liability. McLaughlin and others at HD have known for many years that Dr. O'Brien was not performing any of the functions required of a Medical Director; indeed, Relators have complained about the issue previously.

80. At all relevant times, McLaughlin has known that HD needed a Medical Director to be certified by SAMHSA and to comply with the DSS provider agreement, so HD could be enrolled and re-enrolled with DSS as an OTP clinic provider.

81. At all relevant times, McLaughlin has known that a SAMHSA-certified Medical Director was necessary to continue billing and receiving reimbursement from DSS for OTP services rendered to the thousands of DSS recipients served by HD.

82. At all relevant times, McLaughlin and HD have pretended to meet the federal regulations that allow an OTP to be certified and the requirements of the DSS provider agreement that McLaughlin signs on a regular basis.

83. These false declarations were material because they directly influenced the SAMHSA accreditation process and, therefore, DSS's acceptance of HD's enrollment/re-enrollments as a DSS provider.

VI. FALSE CLAIMS AND DAMAGES

84. At all relevant times, Defendants have had numerous patients who are beneficiaries of the Medicaid program described above.

85. By continuing to submit claims for Medicaid reimbursement notwithstanding (1) external and internal audits demonstrating consistently high rates of noncompliance with applicable documentation requirements and (2) its failure to have a Medical Director performing the duties required by the applicable regulations, HD has knowingly expressly and/or impliedly falsely certified that its services satisfy the conditions for payment with respect to all claims that fail to satisfy these requirements.

86. HD's conduct is not merely negligent. Starting with the SAGA audit and continuing through and including the internal audits described above, HD has known that its deficient policies and procedures resulted in a very high rate of noncompliance with Medicaid/DSS regulations, and HD has known for years that keeping Dr. O'Brien in the position of Medical Director was perpetuating a fraud.

87. Based on these audit results, HD knows that every time it certifies compliance with the Medicaid/DSS regulations, there is a significant chance that the services for which reimbursement is sought are not, in fact, supported by the requisite documentation, and HD has known at all times relevant hereto that no Medical Director has performed the supervision and oversight of those services that HHS requires to qualify for Medicaid reimbursement.

88. HD has therefore acted with (at least) reckless disregard of the truth or falsity of its express and/or implied certifications of compliance, which satisfies the scienter requirement of the USFCA and CTFCA.

89. HD's express and/or implied false certifications give rise to liability under both the USFCA, 31 U.S.C. § 3729(a)(1)(A), (B) and CTFCA (Conn. Gen. Stat. Ann. § 17b-301b(a)(1), (2)).

90. By failing to timely reimburse Medicaid/DSS for payments received for services that HD knows are not supported by the requisite documentation, which were not provided at all, and/or which otherwise fail to satisfy Medicaid/DSS criteria for reimbursement, HD has also violated the "reverse false claims" provision of the USFCA (31 U.S.C. § 3729(a)(1)(G)) and CTFCA (Conn. Gen. Stat. Ann. § 17b-301b(a)(7)).

91. The United States, through its carriers and intermediaries, has made payments to the Defendants and has been damaged in an amount to be determined at trial. The United States is entitled to treble its actual damages and to civil penalties in the amount of $5,500 to $11,000 for each of the false claims submitted.

92. The State of Connecticut, through its carriers and intermediaries, has made payments to the Defendants and has been damaged in an amount to be determined at trial. The State of Connecticut is entitled to treble its actual damages and to civil penalties in the amount of $5,500 to $11,000 for each of the false claims submitted.

COUNT I

VIOLATION OF THE FALSE CLAIMS ACT – 31 U.S.C. § 3729(a)(1)(A)

93. Relators incorporate by reference and re-allege all paragraphs of this Complaint set forth above as if fully set forth herein.

94. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, false and/or fraudulent claims for payment or approval to the United States – *i.e.*, the foregoing false and fraudulent claims for payments from Medicaid -- in violation of 31 U.S.C. § 3729(a)(1)(A).

95. Said false and fraudulent claims were presented with Defendants' actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

96. The United States relied on these false and fraudulent claims, was ignorant of the truth regarding these claims, and would not have paid Defendants for these false and fraudulent claims had it known the falsity of said Medicaid claims made by Defendants.

97. As a direct and proximate result of the false and fraudulent claims made by Defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the False Claims Act in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such violation of the USFCA.

COUNT II

VIOLATION OF THE FALSE CLAIMS ACT – 31 U.S.C. § 3729(a)(1)(B)

98. Relators incorporate by reference and re-allege all paragraphs of this Complaint set forth above as if fully set forth herein.

99. Defendants knowingly made, used or caused to be made or used, and continue to make, use and cause to be made or used, false records or false statements material to the foregoing false or fraudulent claims to get these false or fraudulent claims paid and approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B).

100. Defendants' knowingly false records or false statements were material and, upon information and belief, continue to be material, to the false and fraudulent claims for payments they made and continue to make to the United States for Medicare and Medicaid reimbursements and benefits.

101. These said false records or false statements were made, used or caused to be made or used, and continue to be made, used and caused to be made and used, with Defendants' actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

102. As a direct and proximate result of these materially false records or false statements, and the related false or fraudulent claims made by Defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the USFCA in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such violation of the USFCA.

COUNT III

VIOLATION OF THE FALSE CLAIMS ACT – 31 U.S.C. § 3729(a)(1)(G)

103. Relators incorporate by reference and re-allege all paragraphs of this Complaint set forth above as if fully set forth herein.

104. Defendants knowingly made, used or caused to be made or used, and continue to knowingly make, use or cause to be made or used, false records or false statements, material to an obligation to pay or transmit money or property to the United States, or knowingly concealed and continue to conceal an obligation to pay or transmit money or property to the United States, or knowingly and improperly avoided or decreased, and continue to knowingly and improperly avoid and decrease, an obligation to pay or transmit money or property to the United States, in violation of 31 U.S.C. § 3729(a)(1)(G).

105. As a direct and proximate result of the above conduct by Defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the USFCA of

an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation of the USFCA.

COUNT IV

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT- Conn. Gen. Stat. Ann. § 17b-301b(a)(1)

106. Relators incorporate by reference and re-allege all paragraphs of this Complaint set forth above as if fully set forth herein.

107. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, false and fraudulent claims for payment or approval to the State of Connecticut – *i.e.*, the foregoing false and fraudulent claims for payments from Medicaid – in violation of Conn. Gen. Stat. Ann. § 17b-301b(a)(1).

108. Said false and fraudulent claims were presented with Defendants' actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

109. The State of Connecticut relied on these false and fraudulent claims, was ignorant of the truth regarding these claims, and would not have paid Defendants for these false and fraudulent claims had it known the falsity of the said Medicaid claims made by Defendants.

110. By virtue of the false or fraudulent claims, the State of Connecticut suffered damages and therefore is entitled to recover from Defendants treble damages under the CTFCA, in an amount to be proved at trial, plus a civil penalty of at least $5,500 to $11,000 for each violation.

COUNT V

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT- Conn. Gen. Stat. Ann. § 17b-301b(a)(2)

111. Relators incorporate by reference and re-allege all paragraphs of this Complaint set forth above as if fully set forth herein.

112. Defendants knowingly made, used or caused to be made or used, and continue to make, use and cause to be made or used, false records or false statements material to the foregoing false or fraudulent claims to get these false or fraudulent claims paid and approved by the State of Connecticut – in violation of Conn. Gen. Stat. Ann. § 17b-301b(a)(2).

113. Defendants' knowingly false records or false statements were material and, upon information and belief, continue to be material, to the false and fraudulent claims for payments they made and continue to make to the State of Connecticut for Medicaid reimbursements and benefits.

114. These said false records or false statements were made, used or caused to be made or used, and continue to be made, used and caused to be made and used, with Defendants' actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

115. As a direct and proximate result of these materially false records or false statements, and the related false or fraudulent claims made by Defendants, the State of Connecticut has suffered damages and therefore is entitled to recovery as provided by the CTFCA in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such violation of the CTFCA.

COUNT VI

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT- Conn. Gen. Stat. Ann. § 17b-301b(a)(7)

116. Relators incorporate by reference and re-allege all paragraphs of this Complaint set forth above as if fully set forth herein.

117. Defendants knowingly made, used or caused to be made or used, and continue to knowingly make, use or cause to be made or used, false records or false statements, material to an obligation to pay or transmit money or property to the State of Connecticut, or knowingly concealed and continue to conceal an obligation to pay or transmit money or property to the State of Connecticut, or knowingly and improperly avoided or decreased, and continue to knowingly and improperly avoid and decrease, an obligation to pay or transmit money or property to the State of Connecticut, in violation of Conn. Gen. Stat. Ann. § 17b-301b(a)(7).

118. As a direct and proximate result of the above conduct by Defendants, the State of Connecticut has suffered damages and therefore is entitled to recovery as provided by the CTFCA of an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation of the CTFCA.

VII. CLAIM FOR RELIEF

WHEREFORE, Relators request that judgment be entered against Defendants for treble the amount of the United States' and the State of Connecticut's respective damages to be determined at trial, and all allowable civil penalties, attorney's fees, interest and costs under the United States False Claims Act, the Connecticut False Claims Act, and for all other and further relief as the Court may deem just and equitable.

VIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury on all counts.

Dated: December 1, 2015

SHEPHERD FINKELMAN MILLER & SHAH, LLP

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