

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS

SUPERIOR COURT

THE COMMONWEALTH OF MASSACHUSETTS,

Plaintiff,

v.

BOSTON CLINICAL LABORATORIES, INC. AND
ZAHRA SHEIKHINEJAD

Defendants.

07-4556 B-L S.

CIVIL ACTION NO.

2017 OCT 17 11:28 AM
MICHAEL J. ...
CLERK/REGISTRAR

COMPLAINT

I. PRELIMINARY STATEMENT

1. Attorney General Martha Coakley, on behalf of the Commonwealth of Massachusetts, brings this action against an independent clinical laboratory and its sole officer, director and owner. This action alleges that over many years the defendant laboratory knowingly and intentionally filed thousands of false claims with MassHealth by filing claims and receiving reimbursement for urine drug screens which were improperly ordered, improperly documented, and not medically necessary, resulting in significant overpayments by the Commonwealth and its taxpayers. Through these acts, the laboratory, and its sole owner and director, have violated the Massachusetts Medicaid False Claims Act and the Massachusetts False Claims Act, breached

their MassHealth Provider Agreement and MassHealth Trading Partner Agreement, and have been unjustly enriched. The Attorney General seeks restitution, triple damages, civil penalties, attorneys' fees, and investigative and litigation costs.

II. JURISDICTION AND VENUE

2. The Attorney General of the Commonwealth of Massachusetts is authorized to bring this action pursuant to M.G.L. c. 118E, §§ 44 and 45 and M.G.L. c. 12, § 5B.

3. The relief requested is authorized pursuant to M.G.L. c. 118E, § 44, M.G.L. c. 12, § 5B, and the common law.

4. Venue is proper pursuant to M.G.L. c. 118E, § 45 and M.G.L. c. 223, §5.

III. PARTIES

Plaintiff

5. The Plaintiff Commonwealth of Massachusetts is a sovereign state and body politic duly organized by law, and is represented by the Attorney General of the Commonwealth, who brings this action in the public interest and on behalf of the Commonwealth and its citizens and taxpayers.

Defendants

6. Defendant Boston Clinical Laboratories, Inc. ("Boston Clinical") is a Massachusetts corporation with its principal place of business at 1231 Washington Street, Unit 1, West Newton, Massachusetts.

7. Defendant Dr. Zahra Sheikhejad ("ZS") is the sole owner, officer and director of Boston Clinical. ZS is an individual who resides at 159 Whitewood Road in Westwood, Massachusetts.

IV. FACTS COMMON TO ALL CLAIMS

8. The Massachusetts Medicaid Program, known as MassHealth, is a health care program administered by the Executive Office of Health and Human Services. The Massachusetts Medicaid Program is established pursuant to 42 U.S.C. 1396 *et seq.*, 42 U.S.C. 1397 *et seq.*, M.G.L. c. 118E and other applicable laws, to provide and pay for medical services to eligible low-income individuals, including people with disabilities, children and elder citizens. (Hereinafter referred to as “MassHealth” or “Medicaid.”)

9. In May of 1999, Boston Clinical, by and through its director, ZS, completed an application to become a MassHealth Provider.

10. In 1999, it was MassHealth’s usual and customary practice to, upon receipt of a request for a provider application, send the provider applicant a copy of the current MassHealth All Provider Manual (130 CMR 450 *et seq.*) and a copy of the relevant specific provider manual (i.e., the Independent Clinical Laboratory Services Manual 130 CMR 401 *et seq.*) with the provider application itself.

11. On May 4, 1999, Boston Clinical Laboratories, by and through its director, ZS, entered into a MassHealth Provider Agreement, whereby Boston Clinical agreed to: (1) comply with all applicable state and federal statutes, rules, and regulations; (2) provide services to all eligible MassHealth members without regard to religion, race, color or national origin; (3) keep such records as are necessary to disclose fully the extent of the services to members; and (4) upon request, provide MassHealth, and any other state and federal agencies, with information, including medical records, regarding any services for which payment was claimed from MassHealth.

12. In the Provider Agreement, MassHealth agreed to reimburse Boston Clinical, the Provider, at the applicable Division of Health Care Finance And Policy (“DHCFP”) rates or applicable MassHealth fee schedules for all reimbursable services actually and properly delivered to eligible members and properly billed to MassHealth both in accordance with the terms of the Provider Agreement and in accordance with all applicable federal and state laws, regulations, rules and fee schedules.

13. By its own terms, the MassHealth Provider Agreement continues in effect until terminated by either party upon written notice to the other party.

14. Boston Clinical’s MassHealth Provider Agreement is still in effect and has not been terminated by either party.

15. On August 22, 2002, Boston Clinical, by and through ZS, entered into a MassHealth Trading Partner Agreement whereby it agreed that Boston Clinical could submit claims to MassHealth in electronic form, as long as Boston Clinical complied with the terms of the contract and “all laws, rules, and regulations governing its relationship with MassHealth.”

16. During all times relevant to this complaint, the MassHealth regulations governing independent clinical laboratory services have been contained at 130 CMR 401 *et seq.* and have required that: (1) all laboratory services be ordered in writing by an authorized prescriber; and (2) that all laboratory services be medically necessary. See 130 CMR 401.410; 130 CMR 401.411; 130 CMR 401.416; and 130 CMR 450.204.

17. From December 15, 1999 through September 2007, the MassHealth regulations governing independent clinical laboratory services specifically required that “the independent clinical laboratory may not bill for a service until it has received a written request to perform that

specific service from the authorized prescriber. Each request to perform a specific service must be signed in ink by the authorized prescriber. Stamped or preprinted signatures are not acceptable. Any independent clinical laboratory billing for a service must maintain such request in its records to be made available to the Division upon the Division's request. If the laboratory that billed for the service cannot produce the original request, the Division may deny or recover payment for all services that laboratory provided based on that request." 130 CMR 401.416.

18. From December 15, 1999 through September 2007, the MassHealth regulations defined "Authorized Prescriber" as "any individual who is authorized under state law to prescribe drugs." 130 CMR 401.402.

19. On October 25, 2001, ZS, as Director of Boston Clinical, drafted a form letter on Boston Clinical letterhead in which she informed her clients that: "In order for Boston Clinical Laboratories to bill Massachusetts Medicaid for laboratory testing for your patients, it is necessary for us to obtain written signature from the authorized ordering provider on each requisition that is submitted to us. The Massachusetts Medicaid Regulation 401.406 [sic], effective 12/1/99, further specifies that stamped or preprinted signatures are not acceptable. **Please have all requisitions signed by your authorized ordering provider before sending them to us.** Thank you for your cooperation in this matter. Sincerely, Zahra Sheikhejad, Ph.D., Director" (Emphasis in original).

20. On April 28, 2003, MassHealth transmitted a Remittance Message Text to all of its laboratory services providers, including Boston Clinical. The Remittance Message Text reminded its laboratory services providers that 130 CMR 401.416 requires that they must "have and maintain written requests from authorized prescribers" and MassHealth "will only pay for

medically necessary testing, and does not pay for tests performed for forensic purposes, such as court ordered drug testing (i.e. monitoring for drugs of abuse), social service monitoring purposes, or any other purpose that is not determined by a prescriber to be medically necessary. 130 CMR 401.411.”

21. On July 12, 2004, MassHealth transmitted another Remittance Message Text to all of its laboratory services providers, including Boston Clinical. This Remittance Message Text stated: “Providers are reminded that MassHealth may sanction a provider for prescribing laboratory or other services that are not medically necessary. For additional information see regulation 130 CMR 450.204. Requests for laboratory services must be in writing and signed in ink by an authorized prescriber (an individual who is authorized under state law to prescribe drugs). Additionally, Masshealth will only pay for medically necessary laboratory testing, and does not pay for tests performed for forensic purposes, such as court ordered drug testing, (i.e. monitoring for drugs of abuse), social service monitoring purposes, or any other purpose that is not determined to be medically necessary.”

22. In September 2007, the MassHealth regulations governing independent clinical laboratory services were revised. See MassHealth Transmittal Letter LAB-30, September 2007. Among other changes, the September 2007 revisions: (1) eliminated the requirement that each lab requisition form had to be “signed in ink” by an authorized prescriber (i.e., have an original authorized prescriber signature on it) (130 CMR 401.416); (2) clarified that laboratory tests performed only for purposes of civil, criminal, administrative or social service agency investigations, proceedings or monitoring activities and laboratory tests performed for residential monitoring purposes are non-covered services (130 CMR 401.411(B)(4) and (5)); and (3) further

defined “authorized prescriber” as “any individual who is authorized under state law to prescribe drugs pursuant to M.G.L. c. 94C and also authorized to order the test under M.G.L. c. 111D” (130 CMR 401.402). The 2007 revisions, however, did not change or eliminate the requirements that, in order to be reimbursable by Medicaid, all laboratory tests must be ordered in writing by an authorized prescriber for a medically necessary purpose. The September 2007 revisions are retroactive to February 2, 2007.

23. From January 2000 to the present, Boston Clinical, by and through its director, ZS, has submitted in excess of sixty-six thousand (66,000) paper and electronic claims to MassHealth seeking reimbursement for urine drug screens, and has received in excess of \$3.8 million in reimbursement on such claims.

24. The paper claims were submitted to MassHealth on “Form 9’s”, claim forms on which ZS certified, under the pains and penalties of perjury, that each claim complied with all laws, rules and regulations governing MassHealth.

25. The electronic claims were submitted pursuant to the MassHealth Trading Partner Agreement in which ZS agreed that all of Boston Clinical’s electronic claims would comply with all laws, rules and regulations governing its relationship with MassHealth.

26. However, many, if not all, of the urine drug screen claims Boston Clinical submitted to MassHealth during this time period did not comply with 130 CMR 401 *et seq.*, in that they were not properly ordered by an authorized prescriber and/or were not ordered for a medically necessary purpose, and thus should not have been paid for by MassHealth. The defendants’ repetitive submission of claims for improperly ordered urine drug screens constitutes a continuing wrong which, upon information and belief, is ongoing.

COUNT I

Violations of the Massachusetts Medicaid False Claims Act
(M.G.L. c. 118E, §§ 40 and 44)

27. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through twenty-six (1-26) above, as if they were fully set forth here.

28. Boston Clinical, acting by and through its director, ZS, is an independent clinical laboratory which provides laboratory services for which MassHealth makes payment.

29. The defendants knowingly and willfully made or caused to be made false statements and/or representations of material facts, directly and indirectly to MassHealth, to obtain reimbursement for improperly ordered urine drugs screens, in violation of M.G.L. c. 118E, §§ 40 and 44.

30. The defendants knowingly and willfully submitted claims to MassHealth for urine drug screens which did not comply with 130 CMR 401 *et seq.*, in that they were not properly ordered by an authorized prescriber and/or were not ordered for a medically necessary purpose.

31. As a result of these false statements and/or representations of material facts by the defendants, MassHealth has paid, and continues to pay, a significant amount of money in excess of the amount that should have been paid to the defendants.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against the defendants as prayed for below.

COUNT II

Violations of the Massachusetts False Claims Act
(M.G.L. c. 12, § 5 *et seq.*)

32. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts contained in paragraphs one through twenty-six (1-26) above, as if they were fully set forth here.

33. Boston Clinical, by and through its director, ZS, is an independent clinical laboratory which provides laboratory services for which MassHealth makes payment.

34. The defendants knowingly and willfully made or caused to be made false statements and/or representations of material facts, directly and indirectly to MassHealth, to obtain reimbursement for improperly ordered urine drugs screens, in violation of M.G.L. c. 12, § 5 *et seq.*

35. The defendants knowingly and willfully submitted claims to MassHealth for urine drug screens which did not comply with 130 CMR 401 *et seq.*, in that they were not properly ordered by an authorized prescriber and/or were not ordered for a medically necessary purpose.

36. As a result of these false statements and/or representations of material facts by the defendants, MassHealth has paid, and continues to pay, a significant amount of money in excess of the amount that should have been paid to the defendants.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against the defendants as prayed for below.

COUNT III

Breach of Contract

37. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through twenty-six (1-26) above, as if they were fully set forth here.

38. Boston Clinical, acting by and through its director, ZS, entered into a MassHealth Provider Agreement on May 4, 1999, in which the defendants agreed to comply with all applicable state and federal statutes, rules and regulations when providing services for, submitting claims to, and receiving reimbursement from MassHealth.

39. On August 22, 2002, Boston Clinical, acting by and through its director, ZS, entered into a MassHealth Trading Partner Agreement, in which the defendants agreed to comply with all laws, rules and regulations governing their relationship with MassHealth in connection with all electronic claims submitted to MassHealth.

40. By submitting thousands of claims to MassHealth for urine drug screens which did not comply with the governing MassHealth laboratory services regulations at 130 CMR 401 *et seq.*, the defendants breached both their MassHealth Provider Agreement and their MassHealth Trading Partner Agreement.

41. As a result of the defendants' breach of their MassHealth Provider Agreement and

their MassHealth Trading Partner Agreement, MassHealth has been damaged in that it has paid a significant amount of money to the defendants for urine drug screens which were not properly ordered, did not comply with the governing MassHealth regulations, and thus should not have been reimbursed by MassHealth.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against the defendants as prayed for below.

COUNT IV

Unjust Enrichment

42. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through twenty-six (1-26) above, as if they were fully set forth here.

43. As a result of the defendants submitting thousands of claims to MassHealth for urine drug screens which were not properly ordered by an authorized prescriber and/or not ordered for a medically necessary purpose and thus did not comply with the governing MassHealth regulations, the Commonwealth of Massachusetts paid the defendants significantly more money than they were entitled to.

44. The defendants knew that many of the urine drug screen claims they were submitting to MassHealth did not comply with 130 CMR 401 *et seq.*, and thus were not properly eligible for MassHealth reimbursement.

45. As a result of these improperly ordered urine drug screen claims, the defendants received millions of dollars in MassHealth reimbursement and were unjustly enriched at the expense of the Commonwealth of Massachusetts and its taxpayers.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against the defendants as prayed for below.

PRAYER FOR RELIEF

Based on the foregoing, the Commonwealth of Massachusetts respectfully demands judgment as follows:

- A. An order of this Honorable Court enjoining the defendants from engaging in practices that violate M.G.L. c. 118E, §§ 40 and 44, M.G.L. c. 12, § 5 *et seq.*, 130 CMR 401 *et seq.* and 130 CMR 450 *et seq.*;
- B. Damages in such amount as is proved at trial;
- C. Damages trebled pursuant to M.G.L. c. 118E, § 44 and M.G.L. c. 12, § 5B;
- D. Civil penalties pursuant to M.G.L. c. 12, § 5B;
- E. Reimbursement for all investigative and litigation costs, including experts' fees, pursuant to M.G.L. c. 118E, § 44 and M.G.L. c. 12, § 5B;
- F. An award of attorneys' fees pursuant to M.G.L. c. 12, § 5B; and
- G. Such other and further relief as this Honorable Court deems proper and just.

JURY DEMAND

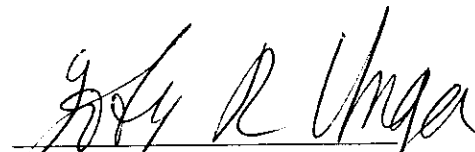
The Commonwealth of Massachusetts demands trial by jury on all claims so triable.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS
By its attorney,

MARTHA COAKLEY
Attorney General

By:



~~Christopher Walsh (BBO # 565145)~~

~~Steven Hoffman (BBO# 237280)~~

Toby K. Unger (BBO #633805)

Assistant Attorneys General

One Ashburton Place, Room 1813

Boston, MA 02108

(617) 727-2200, ext. 2388

October 17, 2007