UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 16-CV-1718

ACACIA MENTAL HEALTH CLINIC, LLC, and ABE FREUND,

Defendants.

ANSWER

Defendants, Acacia Mental Health Clinic, LLC ("Acacia") and Abe Freund ("Freund") (collectively, "defendants"), hereby respond to the Complaint herein (the "Complaint") as follows:

1. The plaintiff, United States of America ("United States"), brings this action against Acacia Mental Health Clinic, LLC ("Acacia"), and its owner, Abe Freund, under the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA") to recover losses and penalties resulting from the submission of false claims for payment to the Wisconsin Medicaid program and under the common law theory of unjust enrichment.

RESPONSE: In response to paragraph 1 of the Complaint, defendants deny the allegations set forth therein, except they admit that the United States purports to so proceed.

2. Since at least 2011, Acacia and Freund pursued a scheme to defraud the Wisconsin Medicaid program. Acacia provides services to Wisconsin Medicaid members who suffer from mental health and substance abuse problems. However, at Freund's direction, Acacia used these vulnerable individuals as tools to bilk Medicaid for Freund's personal gain.

RESPONSE: In response to paragraph 2 of the Complaint, defendants deny the allegations set forth therein, except they admit that Acacia provides services to Wisconsin Medicaid members, individuals who are underserved and in need of subsidized health care services, who suffer from mental health and severe substance abuse problems.

3. Freund, who has no background providing health care, purchased Acacia in 2009 and promptly worked to inflate Acacia's Medicaid billings. Medicaid pays for urine drug screens to test members for drug use, but only as a treating physician deems it necessary in individual cases. Without regard to necessity, Freund ordered that Acacia bill Medicaid for urine drug screens for a wide array of tests on every patient. From January 2011 until October 2012, Acacia routinely submitted false claims that resulted in a $230 reimbursement for each drug screen when the proper reimbursement was only approximately $20 – and Acacia's cost for the test was just $5. From there, Acacia's scheme grew aggressively so that, by 2013, Acacia was obtaining an average of $474.66 per testing event. Based in large part on these false billings, Acacia's overall Wisconsin Medicaid reimbursement grew from about $332,000 in 2011 to about $3.3 million in 2014, for a total of over $7.3 million from 2011 to 2014.

RESPONSE: In response to paragraph 3 of the Complaint, defendants admit that Freund purchased Acacia in 2009 and that Medicaid pays for urine drug screens in some circumstances; defendants assert that the allegations concerning the circumstances under which Medicaid pays for drug urine screens constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny said allegations; defendants deny all other allegations set forth in paragraph 3 of the Complaint.

4. Freund and Acacia's misconduct extended beyond subjecting patients to needless urine drug screens for personal gain. Despite knowing that Medicaid prohibited payments to

providers who were located outside the United States, they also billed Wisconsin Medicaid for telemedicine services provided by psychiatrists located in Israel.

RESPONSE: In response to paragraph 4 of the Complaint, defendants deny the allegations set forth therein.

5. The United States alleges that Freund and Acacia violated the FCA by knowingly submitting false or fraudulent claims for payment to Wisconsin Medicaid for services that were misrepresented on the applicable claim forms, duplicative, not medically necessary, and/or otherwise performed in violation of the Medicaid rules.

RESPONSE: In response to paragraph 5 of the Complaint, defendants deny the allegations set forth therein.

I. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1345 because the action is brought by the United States as plaintiff pursuant to the FCA. The Court has supplemental jurisdiction to entertain the common law cause of action for unjust enrichment under 28 U.S.C. § 1367(a).

RESPONSE: In response to paragraph 6 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein, except they admit that this Court has jurisdiction over this action.

7. The Court has personal jurisdiction over Acacia and Freund, and venue is appropriate in this Court pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because Acacia and Freund transacted business in the Eastern District of Wisconsin and caused false claims to be submitted in this District.

RESPONSE: In response to paragraph 7 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein, except they admit that this Court has personal jurisdiction over defendants and that venue is proper in this Court.

II. PARTIES

8. The plaintiff in this action is the United States, suing on its own behalf and on behalf of its operating division, the Department of Health and Human Services ("HHS") and HHS's component agency, the Centers for Medicare & Medicaid Services ("CMS").

RESPONSE: In response to paragraph 8 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, except they admit that the United States purports to so proceed.

9. Acacia is a Wisconsin limited liability corporation with a principal place of business at 5228 West Fond du Lac Ave, Milwaukee, Wisconsin. Acacia is a mental health and substance abuse clinic that provides services to Medicaid members including, but not limited to, counseling and medication management services by licensed healthcare providers such as psychiatrists and advance practice nurses and counseling services provided by professional counselors.

RESPONSE: In response to paragraph 9 of the Complaint, defendants admit the allegations set forth therein; further answering, defendants assert that Acacia serves an underserved population with severe problems in need of treatment.

10. Defendant Freund is a citizen of the United States who resides in Monroe, New York and, at all times relevant to the complaint, was owner and chief executive officer of Acacia. Freund was involved in the day-to-day operations of Acacia, including establishing and

overseeing policies and procedures for the clinic, its urine drug testing services, and the billing of services to third party payers, including the Wisconsin Medicaid Program.

RESPONSE: In response to paragraph 10 of the Complaint, defendants deny the allegations set forth therein, except they admit that Freund is a citizen of the United States who resides in Monroe, New York, and is the principal owner of Acacia.

III. THE FALSE CLAIMS ACT

11. The FCA provides, in part, that any entity that (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States for damages and penalties. 31 U.S.C. §§ 3729(a)(1)(A)-(B).

RESPONSE: In response to paragraph 11 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the statutes cited therein for the full text and import thereof.

12. The term "knowingly" under the FCA means 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. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required to show that person acted knowingly under the FCA. *Id.*

RESPONSE: In response to paragraph 12 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the statute cited therein for the full text and import thereof.

13. Violations of the FCA subject the defendant to civil penalties of not less than $5,500 and not more than $11,000 per false claim plus three times the amount of damages that the Government sustains as a result of the defendants' actions. 31 U.S.C. § 3729(a).

RESPONSE: In response to paragraph 13 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the statute cited therein for the full text and import thereof.

IV. THE MEDICAID PROGRAM

14. Medicaid is a program jointly funded by the federal government and participating states to provide health insurance to indigent families with dependent children and to aged, blind, and disabled individuals whose income and resources are insufficient to meet the cost of medical services. 42 U.S.C. §§ 1396, et seq. (the "Medicaid Act"). The Medicaid Act sets forth minimum requirements for state Medicaid programs to meet in order to qualify for federal funding and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program.

RESPONSE: In response to paragraph 14 of the Complaint, defendants admit that Medicaid is an insurance program jointly funded by the federal government and participating states; with respect to the remaining allegations of this paragraph, defendants assert that all other allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny said allegations and they refer this Court to the statutes cited therein for the full text and import thereof.

15. Wisconsin participates in the Medicaid program ("Wisconsin Medicaid"). In Wisconsin, the Medicaid program was established pursuant to Wisconsin Statutes Chapter 49

and its administrative regulations. The United States pays for approximately 63% of the program.

RESPONSE: In response to paragraph 15 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the statutes cited therein for the full text and import thereof, except they admit that Wisconsin participates in the Medicaid program ("Wisconsin Medicaid") and deny knowledge or sufficient information to form a belief as to the truth of the allegation regarding the portion of Wisconsin Medicaid paid for by the United States.

16. Wisconsin Medicaid provides reimbursement for health care services provided to eligible individuals who are enrolled in the program. To assist with the administration of the Medicaid Program, Wisconsin contracts with a company, HPE, which is responsible for processing and paying claims submitted on behalf of the Medicaid members.

RESPONSE: In response to paragraph 16 of the Complaint, defendants admit the allegations set forth therein.

17. In order to submit claims to Wisconsin Medicaid for health care services provided to its members, a provider must enter into a written Medicaid Provider Agreement with the Wisconsin Department of Health Services. Providers that are accepted into the Medicaid Program, and who have signed a Medicaid Provider Agreement, are referred to as "certified" providers.

RESPONSE: In response to paragraph 17 of the Complaint, defendants admit the allegations set forth therein.

18. Freund, on behalf of Acacia, signed a Medicaid provider agreement in 2009. Among other things, Freund, and thereby Acacia, agreed to the following:

> Provider acknowledges that the restrictions and conditions listed in this section govern its participation as a provider in Wisconsin Medicaid:
>
> a. Provider is subject to certain requirements and restrictions under state and federal laws in addition to those referred to in Section 1. above, as well as applicable Wisconsin Medicaid provider publications.
>
> The Provider further acknowledges that by submitting claims as a Wisconsin Medicaid provider, the Provider becomes subject to the foregoing and all other applicable Wisconsin Medicaid restrictions and conditions.

RESPONSE: In response to paragraph 18 of the Complaint, defendants admit all allegations of material fact set forth therein, except that they deny that the allegation accurately quotes the provider agreement and respectfully refer this Court to the agreement for the full text and import thereof.

19. One of the conditions of the Wisconsin Medicaid Program is that it only covers, and reimburses for, services that are "medically necessary" and "appropriate." Wis. Admin. Code DHS §§ 106.02(5) and 107.01. The term "medically necessary" is defined by Wisconsin Medicaid to include only services that are "not duplicative with respect to other services being provided to the recipient. . . ." DHS § 101.03(96m)(b)(6).

RESPONSE: In response to paragraph 19 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the regulations cited therein for the full text and import thereof.

20. Further, the Wisconsin Medicaid Program will not pay for services that "fail to comply with program policies or state and federal statutes, rules and regulations. . . ." Wis. Admin Code DHS § 107.02(2)(a).

RESPONSE: In response to paragraph 20 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is

required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the regulation cited therein for the full text and import thereof.

V. PAYMENT OF CLAIMS BY WISCONSIN MEDICAID

21. Medicaid providers may submit claims for reimbursement to Wisconsin Medicaid either on paper or electronically.

RESPONSE: In response to paragraph 21 of the Complaint, defendants admit the allegations set forth therein.

22. Medicaid providers are responsible for the truthfulness, accuracy, timeliness and completeness of all claims submitted to Medicaid. Wis. Admin. Code DHS § 106.02(9)(e). To certify to the accuracy and completeness of a claim, claims must be signed by the provider. Wis. Admin. Code DHS § 106.03(2)(d).

RESPONSE: In response to paragraph 22 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the regulations cited therein for the full text and import thereof.

23. Claims are submitted to Wisconsin Medicaid using a standardized claim form known as the 1500 Health Insurance Claim Form. When submitting a claim to Wisconsin Medicaid with that form, the provider must sign and date the form. By doing so, the provider certifies that "the services listed above were medically indicated and necessary to the health of this patient. . . ." Further, by submitting a claim to Wisconsin Medicaid, the provider further certifies:

> [T]he foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal and State laws.

RESPONSE: In response to paragraph 23 of the Complaint, defendants admit that a Form 1500 is a Health Insurance Claim Form and that the quoted text is contained on the form; with respect to all other allegations set forth therein, defendants assert that said allegations constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny said allegations and they refer this Court to the document cited therein for the full text and import thereof.

24. In order to be permitted to submit claims electronically to Wisconsin Medicaid, providers must enter into an agreement with Wisconsin Medicaid called a Trading Partner Agreement. The provider's signature on the Trading Partner Agreement substitutes for the required signature and certification of the accuracy and completeness of each electronic claim. Wis. Admin. Code DHS §106.03(2)(d).

RESPONSE: In response to paragraph 24 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and they refer this Court to the regulation cited therein for the full text and import thereof.

25. Acacia entered into a Trading Partner Agreement with Wisconsin Medicaid and, as a result, submitted claims electronically to Medicaid and thereby certified to the accuracy and completeness of the claims.

RESPONSE: In response to paragraph 25 of the Complaint, defendants admit the allegations set forth therein.

26. When submitting a claim for services to Wisconsin Medicaid, the provider designates a numeric code assigned to that service or procedures by the American Medical Association. These codes are known as Current Procedural Terminology, or CPT codes, and are

used by health care providers to represent what services have been provided and for which they are seeking reimbursement.

RESPONSE: In response to paragraph 26 of the Complaint, defendants admit the allegations set forth therein.

27. In addition, CMS has assigned and published numeric codes for supplies and services that supplement the CPT codes. This coding system is known as the Healthcare Common Procedure Coding System, or HCPCS. HCPCS codes are similarly used by health care providers to represent what services have been provided and for which they are seeking reimbursement.

RESPONSE: In response to paragraph 27 of the Complaint, defendants admit the allegations set forth therein.

28. To submit claims to Wisconsin Medicaid, providers must include a CPT or HCPCS code on the claim that accurately represents the service provided or the procedure performed.

RESPONSE: In response to paragraph 28 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

29. In addition, providers must include a numeric code on the claim that represents the diagnosis for which the member is being treated. That diagnosis is documented on the claim by a code selected from the International Classification of Diseases, or ICD-9 code, which is overseen by the National Center for Health Statistics and CMS. To submit claims to Wisconsin Medicaid, providers must include an ICD-9 code that accurately represents the patient's diagnosis.

RESPONSE: In response to paragraph 29 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

VI. ACACIA AND FREUND'S ALLEGED FALSE CLAIMS FOR URINE DRUG SCREENS

30. Since at least 2011, Acacia has routinely submitted false claims to Wisconsin Medicaid for urine drug testing known as urine drug screens ("UDS"). Acacia administered these tests purportedly to determine whether patients were taking any illegal substances and to verify they were taking their prescribed medications. Many of the claims submitted by Acacia to Wisconsin Medicaid for UDSs were false because Acacia (1) misrepresented the nature of the test being performed; (2) failed to record or maintain any results from the test; (3) misrepresented the number of tests being performed; and/or (4) performed a test for which there was no medical need.

RESPONSE: In response to paragraph 30 of the Complaint, defendants deny the allegations set forth therein.

31. In order to perform laboratory tests such as UDSs in a clinic, a healthcare provider must first be certified pursuant to the Clinical Laboratory Improvements Act (CLIA). For purposes of CLIA certification, a provider may either obtain a certificate of waiver, which permits the provider to perform very simple tests in the clinic, or it may obtain a certificate of accreditation, which allows the provider to perform more complex testing in the clinic.

RESPONSE: In response to paragraph 31 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

32. Urine drug screens include two different types of tests. The first type of test produces "qualitative" or "presumptive" results; that is, the results indicate that the sample is positive or negative for specified classes of drugs. These tests can be performed under a certificate of waiver or a certificate of accreditation, depending on the equipment and the methodology used.

RESPONSE: In response to paragraph 32 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

33. The second type of test produces "quantitative" or "definitive" results; that is, the results indicate the specific substance or drug and the quantity of the substance or drug in the sample. The quantitative test is a more sophisticated test that requires the laboratory to use costly, high-complexity equipment. In order to perform these types of tests in a medical clinic, the clinic must possess a CLIA certificate of accreditation.

RESPONSE: In response to paragraph 33 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

34. While UDSs can play an important role in mental health and substance abuse treatment, a physician must make an individualized, patient-specific determination about the frequency of testing and the types of drugs to be tested in order for the testing to be considered medically necessary. See e.g., *Drug Testing: A White Paper of the American Society of Addiction Medicine (2013); Public Policy Statement on Drug Testing as a Component of Addiction Treatment and Monitoring Programs and in Other Clinical Settings*, American Society of Addiction Medicine (2010). Because the drug testing must be tailored to each patient's particular

medical needs, standard panels of tests and testing at set intervals (such as at every designated office visit) are not medically necessary.

RESPONSE: In response to paragraph 34 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and respectfully refer this Court to the authorities cited therein for the full text and import thereof.

35. Starting in at least 2010, Freund mandated that (1) every Acacia patient was required to "drop" a urine drug sample every time the patient had an appointment with a prescriber (typically either a physician or advance practice nurse) at the clinic or had a group therapy session and (2) each patient be tested for the same panel of drugs. Freund's policy did not take into account the treating physician's clinical judgment or the diagnosis or history of the patient. Among other things, Freund's drug testing policy did not distinguish between patients with substance abuse disorders and those with mental health diagnoses.

RESPONSE: In response to paragraph 35 of the Complaint, defendants deny the allegations set forth therein.

36. Because Acacia physicians did not make individualized determinations about the need for UDS testing or the frequency based on the patient's diagnosis and history, many of the UDSs billed by Acacia to the Medicaid program were not medically necessary.

RESPONSE: In response to paragraph 36 of the Complaint, defendants deny the allegations set forth therein.

A. January 2011 – October 2012

37. From January 2011 until October 2012, Acacia had a CLIA certificate of waiver to enable it to perform certain types of UDS.

RESPONSE: In response to paragraph 37 of the Complaint, defendants deny the allegations set forth therein.

38. From January 2011 to October 2012, Acacia administered a qualitative or presumptive test that utilized specimen cups, referred to as "Point of Care" or "POC" cups. These cups identify only the presence or absence of several drug classes but do not identify specific drugs or the quantities of those drugs in the urine. Because each cup is able to identify whether multiple drug classes are present in the sample simultaneously and in one procedure, they are referred to as "multiplexed" screening tests or kits. Determining the results of the test simply involves a staff person of the clinic, who needs little special training, to read the results on the side of the cup with no additional equipment needed. These tests may be performed by providers who have a CLIA certificate of waiver.

RESPONSE: In response to paragraph 38 of the Complaint, defendants admit the allegations set forth therein; except, with respect to the allegation as to who may perform such tests set forth in the last sentence of said paragraph, defendants assert that the allegation states a conclusion of law to which no response is required; to the extent a response is deemed necessary, required, defendants deny said allegation.

39. The cost of each POC cup to Acacia was approximately $5.00.

RESPONSE: In response to paragraph 39 of the Complaint, defendants deny the allegations set forth therein.

40. During the time period at issue, UDSs performed with POC cups were properly billed to Wisconsin Medicaid by describing the test using either CPT code 80104 or HCPCs code G0434. The description of CPT code 80104 was a qualitative drug screening test for "multiple drug classes. . ., each procedure." The description of HCPCs code G0434 was "Drug screen, other than chromatographic; any number of drug classes, by CLA waived test or moderate

complexity test, per patient encounter." The Wisconsin Medicaid reimbursement associated with the tests using either of these codes was approximately $20 per test.

RESPONSE: In response to paragraph 40 of the Complaint, defendants admit only that the descriptions of CPT code 80104 and HCPCs code G0434 contain the quoted text; defendants assert that all other the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny said allegations.

41. During this time, it was not proper to bill for UDSs done by POC cups using CPT code 80101. The description of code 80101 was a qualitative drug screen test using a "single drug class method. . . each drug class." Because CPT code 80101 reflects tests of individual drugs classes, providers were permitted to bill one unit for each drug class tested. However, the AMA issued a specific directive that code 80101 excluded testing "multiple drug classes or drug class by multiplexed screening kits" and stated that those tests were covered by CPT code 80104.

RESPONSE: In response to paragraph 41 of the Complaint, defendants assert that the allegations set forth in the first and third sentences thereof constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny said allegations; with respect to the allegations set forth in the second sentence of this paragraph, defendants admit that the description of CPT code 80101 contains the quoted text; with respect to the allegations set forth in the fourth sentence of this paragraph, defendants state that the document speaks for itself and therefore no response is required, and as a result deny any factual allegations stated in said sentence; and defendants deny any remaining allegations set forth in this paragraph.

42. Acacia submitted thousands of false claims to Wisconsin Medicaid for these POC tests performed with POC cups. Rather than accurately describing these POC cup tests using

either CPT code 80104 or HCPCS code G0434, Acacia improperly used CPT code 80101 to describe the tests and billed multiple units for each drug class included on the cup. By using CPT code 80101, Acacia misrepresented that it performed more complex tests than what it actually performed. Each time Acacia billed Medicaid for a test performed in a POC cup during this time period, it improperly billed the test using CPT code 80101 and falsely represented that it had performed between 12 and 14 units of that code (representing that it had performed separate tests for 12 to 14 drug classes).

RESPONSE: In response to paragraph 42 of the Complaint, defendants deny the allegations set forth therein.

43. Between January 2011 and October 2011, Acacia received approximately $230 in reimbursement from the Medicaid program each time it submitted a false claim for these tests under CPT code 80101. Between November 2011 and October 2012, Acacia increased the number of units billed from 12 to 13, and then to 14, units under CPT code 80101 and, thereby, increased its average reimbursement for each test from about $230 to about $253.

RESPONSE: In response to paragraph 43 of the Complaint, defendants deny the allegations set forth therein.

B. November 2012 – August 2013

44. In January 2012, Acacia received a certificate of accreditation pursuant to CLIA, allowing it to conduct presumptive or qualitative testing using more complex drug analyzing equipment.

RESPONSE: In response to paragraph 44 of the Complaint, defendants admit the allegations set forth therein.

45. In November 2012, in addition to using the POC cups, Freund purchased a desk-top analyzer (the Siemen's "VivaE analyzer") for Acacia to perform qualitative drug tests in the

clinic. In order for a clinic to perform tests using this type of analyzer, it must possess a CLIA certificate of accreditation.

RESPONSE: In response to paragraph 45 of the Complaint, defendants deny the allegation set forth in the first sentence therein, except they admit that in 2012 Acacia obtained the described equipment; with respect to the second sentence therein, defendants assert that the allegation states a conclusion of law to which no response is required; to the extent that a response is deemed necessary, defendants deny said allegation.

46. The cost to Acacia for the VivaE analyzer was approximately $40,000.

RESPONSE: In response to paragraph 46 of the Complaint, defendants admit the allegation set forth therein.

47. While the VivaE analyzer was able to detect lower levels for the drug classes being tested than the POC cups, the analyzer used the same technology as the POC cups and similarly identified multiple drug classes in a single test procedure. The VivaE analyzer also produced results similar to the POC cups – that is, the results indicated whether a sample was positive or negative for a class of drugs and did not identify a specific drug detected in the sample or the quantity of the drug in the sample.

RESPONSE: In response to paragraph 47 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, except, with respect to the allegations set forth in the second sentence, defendants admit said allegations.

48. After purchasing the VivaE analyzer, Acacia began to perform and bill Medicaid for two sets of tests using the same technology during the same patient encounter: one using the POC cups, and the other using the VivaE analyzer. Because the tests were performed for the same purpose and generated similar results, they were duplicative and not medically necessary.

RESPONSE: In response to paragraph 48 of the Complaint, defendants deny the allegations set forth therein; except, with respect to the allegation that the tests used the same technology, defendants deny knowledge or information sufficient to form a belief as to the truth of said allegations.

49. Performing and billing tests with the VivaE analyzer was not medically necessary unless a physician identified a need to test for drugs with lower identification limits and/or to test for a drug or drug class that was not able to be tested with a POC cup.

RESPONSE: In response to paragraph 49 of the Complaint, defendants deny the allegations set forth therein.

50. The electronic claims software used by Wisconsin Medicaid rejected claims that had certain pairs of codes billed together by the same provider on the same day. For example, the claims system would reject a claim that included both 80101 and 80104 or both G0431 and G0434 on the same date of service for the same member because each code pair represented qualitative or presumptive testing using the same technology.

RESPONSE: In response to paragraph 50 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

51. In order to avoid having the claims for these duplicative services denied by the Medicaid billing system, Acacia and Freund opted to use HCPCS code G0434 for the tests performed with the POC cups and CPT code 80101 for the tests run on the VivaE analyzer. Acacia chose this particular pair of codes because the misuse of code 80101 allowed Acacia to bill for up to sixteen individual drug classes, or units, for every test, thereby significantly increasing the reimbursement for the tests.

RESPONSE: In response to paragraph 51 of the Complaint, defendants deny the allegations set forth therein.

52. By billing both tests, Acacia was again able to increase its average reimbursement for each testing event, which included one POC cup and one test on the VivaE analyzer, to approximately $310.

RESPONSE: In response to paragraph 52 of the Complaint, defendants deny the allegations set forth therein.

53. Despite the fact that Freund and Acacia chose to bill Wisconsin Medicaid for duplicative tests, when submitting claims to Wisconsin Medicaid Acacia and Freund expressly certified that these services were medically indicated and necessary.

RESPONSE: In response to paragraph 53 of the Complaint, defendants deny the allegations set forth therein.

54. Between November 2012 and August 2013, Acacia submitted thousands of false claims to Wisconsin Medicaid for duplicative urine drug tests performed with both the VivaE analyzer and the POC cups. Additionally, many of these tests were not medically necessary because a physician did not order the UDSs, and because no physician made an individualized determination as to the appropriate frequency of the testing or as to the drugs to be tested based on the patient's diagnosis and history.

RESPONSE: In response to paragraph 54 of the Complaint, defendants deny the allegations set forth therein.

C. September 2013 – December 2014

55. In addition to continuing the false billings described above, in about August 2013, Freund obtained an additional analyzer (the AbSciex Triple Quad 4500-AMCR, or Triple Quad)

for Acacia to process quantitative tests in-house. In order for a clinic to perform tests with this analyzer, it must possess a CLIA certificate of accreditation.

RESPONSE: In response to paragraph 55 of the Complaint, defendants deny the allegation set forth in the first sentence that false billings occurred, but admit the remaining allegations set forth therein; in response to the allegation set forth in the second sentence of this paragraph, defendants assert that this allegation states a conclusion of law for which no response is required; to the extent a response is deemed necessary, they deny said allegation.

56. Acacia's cost for the Triple Quad analyzer was approximately $200,000.

RESPONSE: In response to paragraph 56 of the Complaint, defendants deny the allegations set forth therein.

57. In about December 2013, Freund obtained a second quantitative analyzer (the AbSciex Q Trap 4500-AMCR, or QTrap) for Acacia to process quantitative tests.

RESPONSE: In response to paragraph 57 of the Complaint, defendants deny the allegations set forth therein.

58. Acacia's cost of the QTrap analyzer was approximately $220,000.

RESPONSE: In response to paragraph 58 of the Complaint, defendants deny the allegations set forth therein.

59. Freund purchased both the Triple Quad and the QTrap analyzers so that Acacia could perform quantitative tests in-house and bill Wisconsin Medicaid for those tests, rather than send samples to a third-party lab that billed Wisconsin Medicaid directly for those tests.

RESPONSE: In response to paragraph 59 of the Complaint, defendants deny the allegations set forth therein.

60. Confirmatory or quantitative testing is medically necessary only when a physician identifies a specific need for additional testing and the specific substances for which there is a

clinical benefit to confirm or quantify. Confirmatory or quantitative tests are, therefore, not medically necessary following all qualitative urine drug screens.

RESPONSE: In response to paragraph 60 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

61. Since at least August 2013 when Acacia acquired the first quantitative analyzer, Freund required that Acacia employees perform quantitative or confirmatory testing on all urine samples, regardless of whether the result of the original test was positive or negative. Although Acacia employed several physicians, there was no physician involvement in ordering these tests for Acacia patients or in determining which substances were tested. Moreover, Acacia utilized a standard panel of tests for all samples; that is, Acacia performed the same quantitative or confirmatory test on each sample without regard to patient history or the results of the qualitative or presumptive test.

RESPONSE: In response to paragraph 61 of the complaint, defendants deny the allegations set forth therein.

62. Despite the fact that Freund and Acacia required all patient samples be quantitatively tested for a set panel of drugs without a physician's determination that the testing was indicated and necessary, Acacia and Freund expressly certified by submitting claims to Wisconsin Medicaid that the services billed for on the claims were medically indicated and necessary.

RESPONSE: In response to paragraph 62 of the Complaint, defendants deny the allegations set forth therein.

63. Acacia also billed Wisconsin Medicaid for quantitative tests for which there is no evidence in the clinical record that the test was performed.

RESPONSE: In response to paragraph 63 of the Complaint, defendants deny the allegations set forth therein.

64. Acacia submitted thousands of false claims to Wisconsin Medicaid for quantitative or confirmatory testing because (1) Acacia and Freund's policy failed to take into account a physician's independent judgment about the need for quantitative testing or the particular substances to be tested, or (2) the clinical record contained no evidence that such a test had been performed.

RESPONSE: In response to paragraph 64 of the Complaint, defendants deny the allegations set forth therein.

D. Acacia and Freund's Knowledge of the Billing Requirements and the Alleged False Claims

65. Acacia and Freund knew that the claims submitted to the Wisconsin Medicaid Program for urine drug screens were false or they acted in deliberate ignorance or reckless disregard of the truth or falsity of such claims.

RESPONSE: In response to paragraph 65 of the Complaint, defendants deny the allegations set forth therein.

66. Between 2011 and 2014, Acacia received the following reimbursement from Wisconsin Medicaid for urine drug testing:

Year	UDS – Number of Claims	UDS – Medicaid Reimbursement
2011	1,558	$179,191.08
2012	3,521	$757,854.26
2013	7,611	$1,992,813.15
2014	8,997	$2,959,545.84
Total	**21,687**	**$5,889,404.33**

RESPONSE: In response to paragraph 66 of the Complaint, defendants deny the allegations set forth therein.

67. As a certified Medicaid provider, Freund and Acacia had a duty to understand Medicaid's billing rules and requirements and to submit claims to Wisconsin Medicaid that were accurate and truthful.

RESPONSE: In response to paragraph 67 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

68. Between 2011 and 2014, Acacia billed Wisconsin Medicaid for vastly more urine drug screens than any other mental health provider in the State of Wisconsin. In fact, Acacia's reimbursement from Wisconsin Medicaid accounted for 99% of all Medicaid reimbursement provided to mental health and substance abuse providers in the State of Wisconsin during those years.

RESPONSE: In response to paragraph 68 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein; further answering, defendants assert that Acacia is the largest provider in Wisconsin, serving underserved groups, of services for mental health and substance abuse treatment.

69. Since 2009, Acacia has employed an individual, Malkah Wajchman, to perform billing for Acacia, including billing to Wisconsin Medicaid. Ms. Wajchman is trained in medical billing and coding and received a certificate as a "billing and coding specialist" from the American Healthcareer Association. Under Freund's supervision, Ms. Wajchman coded Acacia's claims to insurance carriers and Medicaid and submitted the resulting bills.

RESPONSE: In response to paragraph 69 of the Complaint, defendants admit the allegations set forth therein, except they deny that Freund supervised Ms. Wajchman in the coding and submission of claims.

70. In 2010, the AMA and CMS published guidance about the changes to both the CPT codes and the HCPCS codes for urine drug testing, which became effective January 1, 2011. Among other things, the AMA's publication "CPT Assistant" published in December 2010 (Volume 20, Issue 12, p. 7) discussed the introduction of CPT code 80104. The article discussed that, under older drug testing technology, urine drug screen tests could test for just one class of drugs in each test and each test was appropriately billed using CPT code 80101. Because a provider may have had to conduct multiple tests, each test was billed as a unit. When the technology advanced to allow for the testing of multiple classes of drugs with one test (multiplexed POC tests), it was no longer appropriate to bill multiple units under CPT code 80101. As a result, CPT code 80104 was created "to describe a non- chromatographic method wherein multiple drugs classes were screened in a single procedure. . . ."

RESPONSE: In response to paragraph 70 of the Complaint, defendants state that the referenced document speaks for itself and therefore no response is required, and as a result deny any factual allegations set forth in said paragraph.

71. In 2010, CMS also stopped paying claims submitted to Medicare with CPT code 80101 and, effective January 1, 2011, instituted two new HCPCS codes to replace CPT code 80101. HCPCS code G0434 was introduced to report very simple tests, such as POC cups, and other types of drug tests that were designated as moderate complexity by CLIA. HCPCS code G0431 was introduced to report more complex testing methods, such as tests that were designated as high complexity under CLIA. Providers were instructed that the new codes should

only be reported once per patient encounter. MLN Matters SE1105 "Medicare Drug Screen Testing."

RESPONSE: In response to paragraph 71 of the Complaint, defendants state that the referenced document speaks for itself and therefore no response is required, and as a result deny any factual allegations set forth in said paragraph.

72. Although CMS's coding changes were implemented for Medicare billings, state Medicaid programs were not mandated to adopt the changes. As a result, Wisconsin Medicaid incorporated the new HCPCS codes G0434 and G0431, while also continuing to reimburse for drug tests billed with CPT code 80101 and the new CPT code 80104 consistent with the code descriptions provided by CMS and the AMA, respectively.

RESPONSE: In response to paragraph 72 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

73. Despite the implementation of CPT code 80104, between January 2011 and November 2012, Acacia and Freund knowingly submitted false claims to Wisconsin Medicaid for each drug class tested with POC cups with CPT code 80101 and recorded a separate unit for each drug class included in the POC cup. Acacia and Freund thereby misrepresented on the nature of the test performed by using CPT code 80101.

RESPONSE: In response to paragraph 73 of the Complaint, defendants deny the allegations set forth therein.

74. In September 2011, Wisconsin Medicaid published a notice that it would begin checking claims for laboratory tests against the submitting provider's CLIA certification and would reject claims that were submitted by a provider without the appropriate corresponding CLIA certification. Each CPT and HCPCS code used to bill for a laboratory test is associated

with a specific level of CLIA certification. CPT code 80101, which was used by Acacia to bill for tests performed with multiplexed cups, was not identified as a code that could be used to bill for CLIA waived tests, such as the POC cups.

RESPONSE: In response to paragraph 74 of the Complaint, defendants admit that Wisconsin Medicaid published a notice concerning the stated subject matter; further answering, defendants state that the referenced document speaks for itself and therefore no response is required, and as a result deny any factual allegations set forth in said paragraph.

75. In October 2011, after Wisconsin Medicaid issued the above notice, it began denying Acacia's claims submitted with CPT code 80101 because Acacia had only a certificate of waiver and CPT code 80101 was not associated with CLIA waived tests.

RESPONSE: In response to paragraph 75 of the Complaint, defendants deny the allegations set forth therein.

76. In response to those denials, Acacia resubmitted claims for the claims that had been denied using HCPCS code G0434, which was a code associated with CLIA waived tests and for which Acacia could only bill one unit. As a result, Acacia's reimbursement for the tests performed with the multiplexed cups dropped from $230 to approximately $20 per test.

RESPONSE: In response to paragraph 76 of the Complaint, defendants deny the allegations set forth therein.

77. In November 2011, Freund applied for a CLIA certificate of accreditation on behalf of Acacia. The CLIA certificate of accreditation allows providers to perform complex clinical laboratory testing. In order to obtain that certificate, Freund falsely represented on Acacia's application for accreditation that Acacia owned a particular high complexity laboratory analyzer. However, Acacia never owned that particular high complexity analyzer and did not purchase a similar analyzer until August 2013. In fact, Freund did not intend to perform high

complexity at that time. Rather, Freund applied for the CLIA certificate of accreditation so that the Wisconsin Medicaid claims system would pay Acacia's claims for the POC cups using CPT code 80101.

RESPONSE: In response to paragraph 77 of the Complaint, defendants admit the allegations set forth in the first sentence therein; in response to the allegations set forth in the remaining sentences of paragraph 77, defendants deny said allegations.

78. After Acacia received its CLIA certificate of accreditation in January 2012, it resumed billing for qualitative tests performed with the POC cups using CPT code 80101 and increased the number of units billed to Medicaid to 13 and 14 units. As a result, Acacia increased its average reimbursement per claim from $20 per claim back up to $253 per claim (above the average reimbursement per claim prior to September 2011).

RESPONSE: In response to paragraph 78 of the Complaint, defendants deny the allegations set forth therein.

79. In November 2012, Acacia purchased the VivaE analyzer. After purchasing the analyzer, Acacia and Freund chose to use HCPCS code G0434 for the tests performed with the POC cups and CPT code 80101 for the tests run on the VivaE analyzer in order to avoid having the claims for these duplicative services denied by the Medicaid billing system. Other than to maximize reimbursement by billing duplicate tests, Freund and Acacia had no reason to change the coding for the tests performed with the POC cups from CPT code 80101 to HCPCS G0434.

RESPONSE: In response to paragraph 79 of the Complaint, defendants deny the allegations set forth therein.

80. Finally, Freund and Acacia knew, or recklessly disregarded, the fact that Acacia's confirmatory or quantitative testing of samples between August 2013 and December 2014 was not medically necessary.

RESPONSE: In response to paragraph 80 of the Complaint, defendants deny the allegations set forth therein.

81. From at least January 2011 until November 2012 and prior to purchasing the Triple Quad analyzer, Acacia utilized an outside laboratory, Ameritox Labs, to perform quantitative or confirmatory tests on urine samples. Ameritox billed Wisconsin Medicaid directly for any testing it performed on Acacia's patients. While using Ameritox, Acacia sought quantitative testing only with respect to samples that tested positive for one or more substances with POC cups and/or the VivaE analyzer, demonstrating that Freund and Acacia knew that performing additional testing on negative samples was not necessary. Indeed, since Acacia only provided to Ameritox the positive samples, Ameritox performed quantitative or confirmatory testing on approximately 50% of the tests performed by Acacia.

RESPONSE: In response to paragraph 81 of the Complaint, defendants admit the allegations set forth in the first sentence therein; with respect to the remaining allegations of paragraph 81, defendants deny said allegations.

82. From December 2012 until September 2013, Acacia used another outside laboratory, Quest Diagnostics, to perform quantitative or confirmatory tests on the samples that tested positive for one or more substances with POC cups and/or the VivaE analyzer. Freund instructed the Acacia lab staff to only send to Quest samples that had tested positive on a qualitative test, again demonstrating that Freund knew that performing additional testing on negative samples was not medically necessary. In addition, Quest typically only tested for the individual substances that tested positive on a qualitative test, rather than testing a panel of substances.

RESPONSE: In response to paragraph 82 of the Complaint, defendants admit the allegations set forth in the first sentence therein; with respect to the remaining allegations of paragraph 82, defendants deny said allegations.

83. After Acacia and Freund spent $200,000 for the Triple Quad analyzer in August 2013, Acacia began performing a panel of quantitative testing on every sample, regardless of whether the sample had tested positive or negative on the qualitative test. Based on the testing policies of the outside laboratories previously utilized by Acacia for quantitative testing, Acacia and Freund knew that testing every sample – including negative samples – for a board panel of substances was not medically necessary.

RESPONSE: In response to paragraph 83 of the Complaint, defendants deny the allegations set forth therein.

E. Patient A

84. Patient A received health care and mental health services through Acacia from January 2011 until December 2014. Patient A received benefits from Wisconsin Medicaid during part of this time period.

RESPONSE: In response to paragraph 84 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

85. Between January 12, 2011 and October 17, 2011, Acacia performed 7 qualitative urine drug screen tests on Patient A using a POC cup and billed those tests to Wisconsin Medicaid.

RESPONSE: In response to paragraph 85 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

86. Acacia submitted a claim to Wisconsin Medicaid for each of these tests using CPT code 80101 and recording 12 units of service, falsely representing to Wisconsin Medicaid that 12 separately billable drug classes were tested. Those tests were performed with POC cups and should have been billed using either CPT code 80104 or HCPCS code G0434.

RESPONSE: In response to paragraph 86 of the Complaint, defendants deny the allegations set forth therein.

87. In October 2011, Acacia submitted claims to Wisconsin Medicaid for UDSs on two dates of service for Patient A using CPT code 80101, which were denied because Acacia's CLIA certificate of waiver did not permit billing for services using CPT code 80101. After receiving the denials, Acacia resubmitted these claims to Wisconsin Medicaid using HCPCS code G0434. For each date of service, Acacia submitted 2 claims to Wisconsin Medicaid using HCPCS code G0434, although Patient A's medical records do not contain evidence that two tests were performed on those dates.

RESPONSE: In response to paragraph 88 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

88. Acacia received an average of $224 in reimbursement from Wisconsin Medicaid for each test that was allowed using CPT code 80101 between January and October 2011. Acacia received $19.22 in reimbursement from Wisconsin Medicaid for each test that was allowed during this time period using HCPCS code G0434. Acacia was reimbursed $1,200.08 for the claims submitted to Wisconsin Medicaid for Patient A's UDSs during this time period.

RESPONSE: In response to paragraph 88 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

89. Each claim submitted between January 12, 2011 and October 17, 2011 using CPT code 80101 and reflecting 12 units were performed was false because (1) it misrepresented the type of test performed as the underlying test was performed with a POC cup and not by a single drug class method; and (2) it misrepresented that 12 separate tests had been performed, when in fact one test had been performed.

RESPONSE: In response to paragraph 89 of the Complaint, defendants deny the allegations set forth therein.

90. Between September 1, 2013 through December 11, 2014, Acacia submitted 26 claims to Wisconsin Medicaid for qualitative tests on urine samples given by Patient A on 15 dates.

RESPONSE: In response to paragraph 90 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

91. Between September 1, 2013 and December 11, 2014, Acacia submitted 15 claims to Wisconsin Medicaid for quantitative tests on urine samples given by Patient A.

RESPONSE: In response to paragraph 91 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

92. Acacia was reimbursed $12,017.97 by Wisconsin Medicaid for urine drug tests on Patient A between September 1, 2013 and December 11, 2014.

RESPONSE: In response to paragraph 91 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

93. As to the qualitative tests during this time period, Acacia submitted claims to Wisconsin Medicaid for (1) 10 dates of service using both CPT code 80101 (recording 16 units or separately billable drug classes) and HCPCS code G0434 and (2) 5 dates of service using only CPT code 80101 (recording 16 units or separately billable drug classes).

RESPONSE: In response to paragraph 93 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

94. For each date of service between September 1, 2013 and December 11, 2014, qualitative tests were performed by Acacia on samples given by Patient A with both a POC cup and the VivaE analyzer. The tests performed with the VivaE analyzer were not medically necessary unless a physician determined that there is a need for a lower detection limit or because the analyzer can test for a particular drug or drug class not available on a POC cup. Because both methods employ the same technology and generate a similar result, the tests are duplicative. Additionally, many of the qualitative tests were not medically necessary because (1) there was no evidence that treatment staff from the clinic reviewed the results and/or addressed positive results with the patient, and (2) the qualitative tests were known to result in false positives for certain drugs being tested. The claims for these medically unnecessary tests were false.

RESPONSE: In response to paragraph 94 of the Complaint, defendants deny the allegations set forth therein.

95. As to the quantitative tests during this time period, these tests were not medically necessary because (1) all the urine samples - both those that had tested positive and those that had tested negative on qualitative tests – were tested quantitatively and without a physician determination as to the need for quantitative tests; (2) samples were tested quantitatively for a

panel of drugs and there was no individualized determination of what substances should be quantified; and (3) there was no clinical evidence that treatment staff from the clinic reviewed the results of the tests and/or addressed unexpected positive results with the patient.

RESPONSE: In response to paragraph 95 of the Complaint, defendants deny the allegations set forth therein.

F. Patient B

96. Patient B was a Wisconsin Medicaid member and received health care and mental health services through Acacia from June 2011 to April 2014.

RESPONSE: In response to paragraph 96 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

97. Between June 2011 and November 2012, Acacia performed 25 qualitative urine drug screen tests on Patient B using a POC cup.

RESPONSE: In response to paragraph 97 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

98. Acacia submitted claims to Wisconsin Medicaid for each of these tests using CPT code 80101 and recording between 12 and 14 units of service, falsely representing to Wisconsin Medicaid that 12 to 14 separately billable drug classes were tested. Those tests were performed with POC cups and should have been billed using either CPT code 80104 or HCPCS code G0434.

RESPONSE: In response to paragraph 98 of the Complaint, defendants deny the allegations set forth therein.

99. Between October 2011 and December 2011, Acacia submitted claims to Wisconsin Medicaid on 4 dates of service for Patient B using CPT code 80101 which were denied because Acacia's CLIA certificate of waiver did not permit billing for services using CPT code 80101. After receiving the denials, Acacia resubmitted these claims to Wisconsin Medicaid using HCPCS code G0434. For each date of service, Acacia submitted two claims to Wisconsin Medicaid using HCPCS code G0434, although Patient B's medical records do not contain evidence that two tests were performed on those dates.

RESPONSE: In response to paragraph 99 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

100. After Acacia received its CLIA certification of accreditation in January 2012, it resumed submitting claims to Wisconsin Medicaid for urine drug screens performed with a POC cup using CPT code 80101 and increased the number of units or separately billable drug classes to 16.

RESPONSE: In response to paragraph 100 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

101. Acacia received an average of approximately $250 in reimbursement from Wisconsin Medicaid for each test that was allowed using CPT code 80101 between June 2011 and November 2012. Acacia received $19.22 in reimbursement from Wisconsin Medicaid for each test that was allowed during this time period using HCPCS code G0434. Acacia was reimbursed $5,420.70 for the claims submitted to Wisconsin Medicaid for Patient' B's UDSs during this time period.

RESPONSE: In response to paragraph 101 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

102. Each claim submitted between June 2011 and November 2012 using CPT code 80101 and reflecting 12 to 16 units were performed was false because (1) it misrepresented the type of test being performed as the underlying test was performed with a POC cup and not by a single drug class method; and (2) it represented that 12 to 16 separate tests had been performed, when in fact one test had been performed.

RESPONSE: In response to paragraph 102 of the Complaint, defendants deny the allegations set forth therein.

103. Between December 2012 and August 5, 2013, Acacia performed qualitative tests on samples given by Patient B on 11 dates. On each date, a urine sample from Patient B was tested with both a POC cup and the VivaE analyzer. Both tests are not medically necessary because they are duplicative tests in that they both employ the same technology and generate a similar result. Additionally, many of the qualitative tests were not medically necessary because (1) there was no clinical evidence that treatment staff from the clinic reviewed the results of the tests and/or there was no clinical evidence that treatment staff from the clinic addressed unexpected positive results with the patient, and (2) because the qualitative tests were known to result in false positives and were, therefore, not medically indicated. As a result, the claims submitted by Acacia for these services were false.

RESPONSE: In response to paragraph 103 of the Complaint, defendants deny the allegations set forth therein.

104. Between August 13, 2013 and April 2014, Acacia submitted claims to Wisconsin Medicaid for qualitative tests on 11 dates and for quantitative tests on 14 dates on urine samples given by Patient B. Acacia was reimbursed $10,277.96 for these services.

RESPONSE: In response to paragraph 104 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

105. For each date of service between August 13, 2013 and April 2014, qualitative tests were performed by Acacia on samples given by Patient B with both a POC cup and the VivaE analyzer. Both tests are not medically necessary because they are duplicative tests in that they both employ the same technology and generate a similar result. Additionally, many of the qualitative tests were not medically necessary because (1) there is no evidence that treatment staff from the clinic reviewed the results and/or there was no clinical evidence that treatment staff from the clinic addressed unexpected positive results with the patient, and (2) because the qualitative tests were known to result in false positives. The claims for these medically unnecessary tests were false.

RESPONSE: In response to paragraph 105 of the Complaint, defendants deny the allegations set forth therein.

106. As to the quantitative tests during this same time period, many of the tests were not medically necessary because (1) samples – both those that had tested positive and those that had tested negative on a qualitative tests – were tested quantitatively and without a physician determination as to the need for a quantitative tests; (2) samples were tested quantitatively for a panel of drugs and there was no individualized determination of what substances should be quantified; (3) there was no clinic evidence that treatment staff from the clinic reviewed the results of the test and/or addressed unexpected positive results with the patient.

RESPONSE: In response to paragraph 106 of the Complaint, defendants deny the allegations set forth therein.

VII. ACACIA AND FREUND'S ALLEGED FALSE CLAIMS FOR TELEMEDICINE PSYCHIATRY SERVICES

107. Acacia contracts with physicians to provide psychiatry services to its patients and those physicians primarily provided services to Acacia's clients by telemedicine technology. Telemedicine is the provision of healthcare services by a Medicaid-enrolled provider at a remote location to a patient at an originating site via interactive video and audio.

RESPONSE: In response to paragraph 107 of the Complaint, defendants admit the allegations set forth therein.

108. When a claim is submitted to Wisconsin Medicaid for a service that is provided by telemedicine, the provider must include a "GT" modifier with the appropriate CPT code to signify that the service was provided via telemedicine. *Wisconsin Medicaid Mental Health and Substance Abuse Services Handbook* (April 2006); *Forward Health Outpatient Mental Health and Substance Abuse Online Handbook*, Topic 510. For example, if a physician provided 45 minutes of psychotherapy by telehealth, the appropriate code to be included on a claim to Wisconsin Medicaid would be 90806 GT.

RESPONSE: In response to paragraph 108 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

109. In December 2010, CMS issued a notice to all states participating in the Medicaid program that the Affordable Care Act of 2010 prohibited payment by any state Medicaid program to telemedicine providers located outside the United States or its territory. Therefore, Congress designated the requirement that a telemedicine provider be located inside the United States as a condition of payment. CMS began enforcing this requirement on June 1, 2011.

RESPONSE: In response to paragraph 109 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

110. In accordance with the requirement that telemedicine providers be located inside the United States, HPE (the contractor that processes and pays claims submitted to Wisconsin Medicaid) implemented a policy effective June 1, 2011, to deny claims submitted to Wisconsin Medicaid by providers known to be outside the United States.

RESPONSE: In response to paragraph 110 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

111. Wisconsin Medicaid further notified providers via its provider portal that "Wisconsin Medicaid is prohibited from paying providers located outside of the United States and its territories. . . ."

RESPONSE: In response to paragraph 111 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

112. The State of Wisconsin further designated this requirement as a condition of payment when it amended the statutory provisions that designate covered mental health services by including a provision that mental health services provided through telehealth may only be reimbursed if the provider is located inside the United States. 2013 Assembly Bill 458, creating Wis. Stat. § 49.45(29w).

RESPONSE: In response to paragraph 112 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is

required; to the extent a response is deemed necessary, they deny the allegations set forth therein and respectfully refer this Court to the statute cited therein for the full text and import thereof.

113. Because the restriction on providers located outside the United States was directly linked to payment of a claim by such a provider, the location of the provider when providing services was material to Wisconsin Medicaid's payment determination.

RESPONSE: In response to paragraph 113 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein.

114. While Wisconsin Medicaid permits mental health clinics to provide service by telemedicine, it does not permit mental health clinics or providers to facilitate group therapy by telehealth. *Wisconsin Medicaid Mental Health and Substance Abuse Services Handbook* (April 2006); *Forward Health Outpatient Mental Health and Substance Abuse Online Handbook*, Topic 510.

RESPONSE: In response to paragraph 114 of the Complaint, defendants assert that the allegations set forth therein constitute conclusions of law to which no response is required; to the extent a response is deemed necessary, they deny the allegations set forth therein and respectfully refer this Court to the authorities cited therein for the full text and import thereof.

115. Since at least 2010, Acacia and Freund provided psychiatry services to Acacia's patients using, among others, two Medicaid-enrolled physicians, Dr. Isaac Nagel and Dr. Matthew Medwick, who resided primarily in Israel and provided telemedicine services from Israel.

RESPONSE: In response to paragraph 115 of the complaint, defendants admit that Dr. Isaac Nagel and Dr. Matthew Medwick provided psychiatry services to Acacia's patients

and that they were Medicaid-enrolled physicians; defendants deny all other allegations set forth therein.

116. Dr. Nagel enrolled as a Wisconsin Medicaid provider in 2010. His application to become a Medicaid provider lists his office address as 6040 W. Lisbon Ave, Milwaukee, Wisconsin, which was Acacia's office location in 2010. Neither Dr. Nagel nor Acacia disclosed to Wisconsin Medicaid that Dr. Nagel was outside the United States when providing services to Acacia's patients by telemedicine.

RESPONSE: In response to paragraph 116 of the Complaint, defendants admit the allegations set forth in the first and second sentences therein; defendants deny all other allegations set forth therein.

117. Dr. Medwick enrolled as a Wisconsin Medicaid provider in 2010. His application to become a Medicaid provider lists his office address as 6040 W. Lisbon Ave, Milwaukee, Wisconsin, which was Acacia's office location in 2010. Neither Dr. Medwick nor Acacia disclosed to Wisconsin Medicaid that Dr. Medwick was outside the United States when providing services to Acacia's patients by telemedicine.

RESPONSE: In response to paragraph 117 of the Complaint, defendants admit the allegations set forth in the first and second sentences therein; defendants deny all other allegations set forth therein.

118. Acacia knew that Wisconsin Medicaid would not reimburse for services by a provider located outside the United States. Acacia's clinic manager, David Dropkin, received a copy of CMS's notice to the state Medicaid programs on or about May 19, 2011. Accordingly, a reasonable person would know that Wisconsin Medicaid would not pay for telemedicine service if it knew that the provider was located outside the United States.

RESPONSE: In response to paragraph 118 of the Complaint, defendants deny all allegations set forth therein.

119. In addition, Optum Health, an insurance company that contracts with Wisconsin Medicaid to provide Medicaid benefits to Medicaid beneficiaries through a health maintenance organization, denied Acacia's claims for telehealth services provided by the physicians located in Israel in November 2012. In the letter to Freund denying those claims, Optum noted that Dr. Nagel resided outside the United States and stated:

> The review of claims submitted under the name of Isaac Nagel MD showed that Dr. Nagel provided services to Medicaid Subscribers during the portion of the audit period January 1, 2011 thru April 11, 2012. CMS Section 6505: "Prohibition of Payments outside the US" states payments may not be made for services provided by a person outside the United States to a Medicaid subscriber. CMS Section 6505 was effective as of January 1, 2011. Claims submitted showing Dr. Nagel as the rendering practitioner during the described time frame were considered an overpayment.

RESPONSE: In response to paragraph 119 of the Complaint, defendants admit that they received a letter on this subject from Optum Health in November 2012; in response to all allegations related to the content of that letter, defendants state that the referenced document speaks for itself and therefore no response is required, and as a result deny any factual allegations set forth in said paragraph.

120. Since July 2011, Acacia and Freund routinely provided psychiatry telemedicine services to its patients through Drs. Nagel and Medwick while they resided in Israel and submitted false claims to the Medicaid program for those services as follows:

Year	Provider Name (Rendering Provider)	Number of Claims	Medicaid Reimbursement
2011	Isaac R Nagel, MD	1,738	$67,232.92
	Matthew B Medwick MD	0	0.00
	Total	1,738	$67,232.92

Year	Provider Name (Rendering Provider)	Number of Claims	Medicaid Reimbursement
2012	Isaac R Nagel, MD	4,322	$258,906.40
	Matthew B Medwick MD	711	$25,716.21
	Total	5,033	$284,622.61
2013	Isaac R Nagel, MD	1,892	$63,695.08
	Matthew B Medwick MD	859	$26,613.86
	Total	2,751	$90,308.94
2014	Isaac R Nagel, MD	717	$38,170.10
	Matthew B Medwick MD	151	$8,717.50
	Total	868	$46,887.60
2011-2014	**Total**	**10,390**	**$489,052.07**

RESPONSE: In response to paragraph 121 of the Complaint, defendants deny the allegations set forth therein.

121. In addition, over 60% of the claims submitted by Acacia to Wisconsin Medicaid for the services rendered by Drs. Nagel and Medwick falsely represented that the services were provided in-person because the claims did not include the GT modifier to indicate that the services were provided via telemedicine.

RESPONSE: In response to paragraph 121 of the Complaint, defendants deny the allegations set forth therein.

122. Since July 2011, Freund and Acacia submitted false claims to Wisconsin Medicaid for group therapy provided by Drs. Nagel and Medwick while they were outside the United States and did not in fact provide the services.

RESPONSE: In response to paragraph 122 of the Complaint, defendants deny the allegations set forth therein.

123. Freund and Acacia knew that Nagel and Medwick were located outside the United States when providing services to Acacia's patients and that the presence of a provider outside the United States was material to Wisconsin Medicaid's payment determination and that Wisconsin Medicaid would not pay for services rendered by a provider located outside the United States.

RESPONSE: In response to paragraph 123 of the Complaint, defendants deny the allegations set forth therein.

124. Because Acacia submitted claims to Wisconsin Medicaid that did not disclose that many services provided by Nagel and Medwick were provided by telemedicine or that Nagel and Medwick were in Israel at the time services were provided, Wisconsin Medicaid paid Acacia for claims for services rendered by Nagel and Medwick that it would not have otherwise paid.

RESPONSE: In response to paragraph 124 of the Complaint, defendants deny the allegations set forth therein.

A. Patient C

125. Patient C received health care and mental health services from Drs. Nagel and Medwick between November 5, 2012 and December 19, 2013.

RESPONSE: In response to paragraph 125 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

126. From November 5, 2012 through December 19, 2013, Acacia submitted 15 claims for services provided to Patient C purportedly by Drs. Nagel and Medwick, including the following:

- An office consultation with Dr. Nagel on November 5, 2012;
- An office consultation with Dr. Medwick on November 6, 2012;
- Three group psychotherapy sessions on November 13, 20, and December 5, 2012; and
- Eight office visits on November 20 and 27, 2012; December 5 and 11, 2012; January 8 and 22, 2013; and February 5 and 19, 2013.

RESPONSE: In response to paragraph 85 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

127. Drs. Nagel and Medwick were in Israel when these services were provided via telemedicine.

RESPONSE: In response to paragraph 127 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

128. While these services were provided by telemedicine, the "GT" modifier was not appended to any of the codes used to bill these services.

RESPONSE: In response to paragraph 128 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

129. In addition, the group psychotherapy services billed by Dr. Nagel and as specified above, were not, in fact, provided by Dr. Nagel but were provided by counselors-in-training who were employed by Acacia.

RESPONSE: In response to paragraph 129 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

130. Acacia submitted claims to Wisconsin Medicaid for the services in Paragraph 126, above, and was reimbursed $853.76.

RESPONSE: In response to paragraph 130 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

131. The claims submitted by Acacia were false because the Wisconsin Medicaid rules prohibit payment for telemedicine services provided by providers located outside the United States and because the claims for the group therapy services misrepresent who provided the therapy services.

RESPONSE: In response to paragraph 131 of the Complaint, defendants deny the allegations set forth therein.

B. Patient D

132. Patient D received health care and mental health services from Dr. Nagel between December 12, 2012 and July 7, 2014.

RESPONSE: In response to paragraph 132 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

133. From December 12, 2012 to July 7, 2014, Acacia submitted 21 claims for services provided by Dr. Nagel to Patient D, including the following:

- One psychotherapy visit on December 7, 2012;
- One medication management visit on December 20, 2012; and
- Nineteen office visits on January 28, February 25, April 22, May 1, May 29, June 26, July 24, August 21, October 3, October 23, and November 25, 2013; and January 9, February 6, February 20, March 3, March 18, May 13, June 9, and July 7, 2014.

RESPONSE: In response to paragraph 133 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

134. Dr. Nagel was in Israel while providing these services via telemedicine.

RESPONSE: In response to paragraph 134 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

135. While these services were provided by telemedicine, the "GT" modifier was appended to only 9 of the claims for these 21 services, thereby misrepresenting that these services were provided in Acacia's clinic in Milwaukee, Wisconsin.

RESPONSE: In response to paragraph 135 of the Complaint, defendants deny the allegations set forth therein.

136. Acacia submitted claims to Wisconsin Medicaid for the services in Paragraph 133, above, and was reimbursed $1,033.54.

RESPONSE: In response to paragraph 136 of the Complaint, defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

137. The claims submitted by Acacia were false because the Wisconsin Medicaid rules prohibit payment for telemedicine services provided by providers located outside the United States.

RESPONSE: In response to paragraph 137 of the Complaint, defendants deny the allegations set forth therein.

VIII. CLAIMS FOR RELIEF

A. Count One: False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

138. Plaintiff United States repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

RESPONSE: In response to paragraph 138 of the Complaint, defendants reassert their responses to each of the preceding paragraphs of this Answer.

139. Freund and Acacia submitted and/or caused to be submitted false claims for payment to Wisconsin Medicaid seeking reimbursement for (1) drug tests performed with point-of-care cups but billed as if they were performed with more complex equipment; (2) duplicative drug tests; (3) medically unnecessary urine drug tests, (4) drug tests for which there is no clinical document of the test, and (4) psychiatric services provided by physicians located outside the United States. Freund and Acacia knowingly submitted or caused the submission of false and ineligible claims to Wisconsin Medicaid in violation of the False Claims Act.

RESPONSE: In response to paragraph 139 of the Complaint, defendants deny the allegations set forth therein.

140. By virtue of the false or fraudulent claims that Freund and Acacia submitted or caused to be submitted, the United States and the State of Wisconsin have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

RESPONSE: In response to paragraph 140 of the Complaint, defendants deny the allegations set forth therein.

B. Count Two: False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

141. Plaintiff United States repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

RESPONSE: In response to paragraph 141 of the Complaint, defendants reassert their responses to each of the preceding paragraphs of this Answer.

142. Freund and Acacia knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to Wisconsin Medicaid. Specifically, Freund and Acacia knowingly created false billing records that (1) misrepresented the drug tests that were performed, (2) misrepresented that psychiatry services had been provided in Acacia's clinic and not by telehealth; and (3) misrepresented that other telehealth services had been appropriately provided by physicians located inside the United States.

RESPONSE: In response to paragraph 142 of the Complaint, defendants deny the allegations set forth therein.

C. Count Three: Unjust Enrichment

143. Plaintiff United States repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

RESPONSE: In response to paragraph 143 of the Complaint, defendants reassert their responses to each of the preceding paragraphs of this Answer.

144. The United States claims the recovery of all monies by which Freund and Acacia have been unjustly enriched, including profits earned by Freund and Acacia because of the conduct described herein.

RESPONSE: In response to paragraph 144 of the Complaint, defendants deny the allegations set forth therein.

145. By retaining the monies received for the conduct described herein, Freund and Acacia were unjustly enriched at the expense of the United States and the State of Wisconsin in an amount to be determined and, which in equity and good conscience, should be returned to the United States and the State of Wisconsin.

RESPONSE: In response to paragraph 145 of the Complaint, defendants deny the allegations set forth therein.

AFFIRMATIVE DEFENSES

1. Some or all of the United States' claims may be barred, either in whole or in part, by the applicable statutes of limitations and/or repose.

2. To the extent that the United States intends to extrapolate any claims and/or damages over a population of patients, without unique and individualized proof, defendants' rights under all applicable provisions of the United States Constitution, including but not limited to their rights to procedural and substantive due process provided by the Fifth and Fourteenth Amendments to the United States Constitution, and all applicable provisions of the Constitution of the State of Wisconsin have been violated.

3. Any claim by the United States for treble damages and civil penalties violate defendants' rights under all applicable provisions of the United States Constitution, including but not limited to their rights to procedural and substantive due process provided in the Fifth and Fourteenth Amendments of the United States Constitution, and all applicable provisions of the Constitution of the State of Wisconsin.

4. Penalties and treble damages are a form of quasi-criminal sanctions. Therefore, the United States' claim for penalties and treble damages cannot be sustained, because an award of penalties and treble damages without the same protections that are accorded criminal defendants, including, but not limited to, protection against searches and seizures, double jeopardy and self-incrimination and the rights to confront adverse witnesses, to proof by evidence beyond a reasonable doubt, and to a speedy trial would violate defendants' rights under the Fourth, Fifth, Sixth, and Fourteenth Amendments to the United States Constitution. These rights will be violated unless defendants are afforded the safeguards guaranteed by these

provisions, including, but not limited to, the right to separate trials if requested by defendants for the determination of liability for treble damages and penalties, as well as for the determination of the amount of penalties and treble damages, if any.

5. The award of penalties and treble damages to the United States would be an unconstitutionally excessive fine under the Eighth Amendment to the United States Constitution because any award would be grossly disproportional to the gravity of defendants' offense, if any.

6. The United States' claim for penalties and treble damages cannot be sustained to the extent it violates or contravenes the holding of the United States Supreme Court in *BMW v. Gore*, 517 U.S. 559 (1996).

7. Any recovery by the United States, and/or the State of Wisconsin, should be offset by their gain.

8. The United States' claims may be barred by the doctrines of recoupment and set-off.

9. Because, at the time this Answer is filed, discovery has not been completed, defendants reserve the right to assert any and all further, supplemental, or other affirmative defenses which become available during the course of discovery or trial.

10. Any allegation in the Complaint not expressly admitted nor denied herein is denied.

JURY DEMAND

Defendants, pursuant to Fed. R. Civ. P. 38(b), demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, defendants demand judgment dismissing the Complaint against them on its merits and with prejudice and an order granting them their costs and disbursements in

defending this litigation, together with such other and further relief as this Court deems just and appropriate.

Dated this 3rd day of April, 2017.

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