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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, And THE STATE OF NEW YORK, *ex rel.* PANNA NAHAR Plaintiffs, vs. SORKIN'S RX LTD., t/a and/or d/b/a CAREMED PHARMACEUTICAL SERVICES Defendant.	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730** CIVIL ACTION NO. COMPLAINT JURY TRIAL DEMANDED

On behalf of the United States of America pursuant to the United States False Claims Act, 31 U.S.C. §§ 3729 et seq., and on behalf of the State of New York pursuant to the New York False Claims Act, N.Y. State Finance Law §§ 187 et seq., Plaintiff-Relator Panna Nahar ("Relator") files this *qui tam* Complaint for treble damages and civil money penalties against defendant Sorkin's Rx Ltd., d/b/a and/or t/a CareMed Pharmaceutical Services ("CareMed"). These claims arise out of the defendant's knowing submission of false and fraudulent claims for payment to the Medicare and Medicaid programs as set forth below. In support of these claims, Relator alleges as follows:

The Parties

1. Plaintiff-Relator Panna Nahar is an individual citizen of the State of New York. Relator was employed by the defendant from July 2008 until February 2011 as a "Clinical Care Coordinator." Ms. Nahar's regular duties and responsibilities included obtaining prior authorizations for prescription drugs and training other employees of the defendant in prior authorization procedures.

2. Defendant Sorkin's Rx Ltd., d/b/a and/or t/a CareMed Pharmaceutical Services ("CareMed"), is a private limited company organized under the laws of the State of New York with its principal place of business at 1981 Marcus Avenue, Lake Success, New York 11042. CareMed is a "specialty pharmacy," so-called because it primarily sells and distributes pharmaceuticals that are high-cost and are prescribed for conditions that are chronic and/or require complex care, such as cancer, HIV/AIDS, hemophilia, hepatitis C, infertility and multiple sclerosis. Most of CareMed's business is mail order, and it has customers throughout the State of New York, including in the Southern District of New York, and around the country. CareMed is licensed as a wholesaler and pharmacy in the State of New York, and it is a "Provider" under the Medicare and New York Medicaid programs, as defined below. CareMed fills approximately 200 to 250 prescriptions per day, a substantial percentage of which are for patients covered by Medicare Part D or Medicaid.

3. Relator has direct and independent knowledge on which the allegations are based, is an original source of this information to the United States and the State of New York, and has voluntarily provided the information to the United States and to the State of New York before filing this action based on the information.

4. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relator, she is an original source under 31 U.S.C. § 3730(e)(4) and N.Y. State Finance Law § 190(9)(b).

5. The Court has subject matter jurisdiction over this case pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over this case for the claims brought on behalf of the State of New York pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, as recovery is sought on behalf of the State of New York arising from the same transactions and occurrences as the claims brought on behalf of the United States.

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

7. This Court has personal jurisdiction over the defendant under 31 U.S.C. § 3732(a) because it is located in New York and it submitted false or fraudulent claims directly or indirectly to the federal and state governments in New York.

Statutory and Regulatory Background

Medicare

8. Medicare is a federal health insurance system for people 65 and older and for people under 65 with certain disabilities. Medicare Part A provides hospital insurance for eligible individuals. See 42 U.S.C. §§1395c-1395i. Medicare Part B is a voluntary subscription

program of supplementary medical insurance covering items and services other than hospitalization expenses. See 42 U.S.C. § 1395k(a)(2)(B).

9. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA," P.L. 108-173) established a voluntary prescription drug benefit under a new Medicare Part D. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. The United States Department of Health and Human Services ("HHS"), through its component agency, the Centers for Medicare and Medicaid Services (CMS), contracts with private companies (or "sponsors") authorized to sell Part D insurance coverage. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts.

10. There are two types of Part D coverage: stand-alone prescription drug plans ("PDPs") and plans that offer hospital, medical and prescription drug plans under a single policy (Medicare Advantage Prescription Drug Plans or ("MA-PDs"). Plans list the covered drugs and prices on "formularies," which vary from plan to plan (and change periodically even during the plan year) subject to minimum regulatory requirements.

11. Plan sponsors must offer a minimum standard benefit package, which consist of a four-stage benefit structure. In 2012, the standard benefit is as follows:

- Annual deductible of $320 (Stage 1);
- "Initial coverage period" (Stage 2): After meeting the deductible, the beneficiary pays 25% of the next $2610 (or $632.50);
- "Donut Hole" (Stage 3): Once the beneficiary and plan have paid a total of $2930 (the initial deductible plus the initial coverage limit), the beneficiary pays 100% of the next $3725.50.

- "Catastrophic coverage period" (Stage 4): Once the beneficiary has paid a total of $4700 -- the initial deductible of $320 plus the beneficiary's portion of the initial coverage limit ($632.50) plus the $3725.50 "Donut Hole" – the beneficiary pays 5% of the cost of formulary drugs, or $2.50 for generics and $6.30 for brand name drugs, whichever is greater.

12. Medicare subsidizes 80% of the costs for catastrophic coverage. See 42 C.F.R. § 423.329(c)(1). CMS makes reinsurance subsidy payments to plans for those individuals who have actually incurred such costs.

13. CMS makes three additional types of payments to Part D plans: (1) monthly direct subsidy payments on a per capita basis for each Part D enrollee, (2) low-income subsidy payments for premium and cost-sharing charges that would otherwise by paid by the beneficiary, and (3) risk-sharing payments, which limit a sponsor's overall risks and profits in offering Part coverage.

14. Part D plan sponsors negotiate prices with drug manufacturers, wholesalers and pharmacies. Sponsors sometimes hire pharmaceutical benefit managers ("PBMs") for this purpose. Plan sponsors negotiate with pharmacies in order to include a sufficient number and geographic distribution of pharmacies in their networks. The plan reimburses the pharmacy for the cost of the drug plus a dispensing fee.

15. A pharmacy is a "provider" or "downstream entity" under Medicare regulations. 42 C.F.R. §§ 423.4, 423.501; see Centers for Medicare and Medicaid Services, *Prescription Drug Benefit Manual*, Pub. 100-18 (2006), Ch. 9 § 10.1 (hereinafter "PDBM").

16. Sponsors are permitted to employ utilization management rules requiring "prior authorization" for certain prescription drugs. This means that before the plan will pay the cost of the drug, the prescribing physician must demonstrate that the beneficiary has a medically-

necessary need for the drug. Requests for prior authorization may be made either verbally over the telephone or in writing on standard forms prepared by the PDP or MA-PD sponsor.

Statutes and regulations prohibiting fraudulent conduct

17. Medicare does not pay for any and all services furnished to Medicare beneficiaries but only those services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Medicare requires that Part D plan providers not participate in "false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data." 42 C.F.R. § 423.509(a)(4).

18. The PDBM further identifies examples of Pharmacy Fraud, Waste and Abuse, including:

> *Inappropriate billing practices*: Inappropriate billing practices at the pharmacy level occur when pharmacies engage in the following types of billing practices:
>
> > Billing for prescriptions that are never picked up (i.e., not reversing claims that are processed when prescriptions are filled but never picked up).
>
> *Dispensing expired or adulterated prescription drugs:* Pharmacies dispense drugs that are expired, or have not been stored or handled in accordance with manufacturer and FDA requirements.

See PDBM, Ch. 9 § 70.1.3; see also 18 U.S.C. §§ 1035, 1347.

19. To obtain reimbursement for prescription drug coverage, the provider must submit and certify to details establishing that Medicare's medical necessity requirements are met. See 42 C.F.R. § 423.505(i)(3)(v). When submitting claims data to CMS for payment, sponsors and their subcontractors must certify that the claims data is true and accurate to the best of their knowledge and belief. 42 C.F.R. § 423.505(k)(3).

20. In addition, parties have a continuing obligation to disclose to the government any new information indicating the falsity of the original statement. See PDBM, Ch. 9 § 80.1.

Medicaid

Statutory and regulatory background

21. Medicaid is a federal health insurance system that is administered by the states and is available to low-income individuals and families who meet eligibility requirements determined by federal and state law. Medicaid pays for items and services, including prescription drugs, pursuant to plans developed by the states and approved by HHS through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay health care providers, including pharmacies, according to established rates, and the federal government then pays a statutorily established share of "the total amount expended … as medical assistance under the State plan." See 42 U.S.C. §§ 1396b(a)(1).

22. At all times relevant hereto, the United States has provided funds to New York for its Medicaid program, which New York administers through the New York State Department of Health, and HHS, through CMS, has ensured that New York has complied with minimum federal standards in its administration of the Medicaid program.

23. New York Medicaid provides a prescription drug benefit to its beneficiaries. New York Medicaid regulations determine how much a pharmacy is reimbursed for a particular prescription. New York Medicaid also pays participating pharmacies a dispensing fee for each prescription drug claim and an additional compounding fee for each compounded prescription drug claim. 18 NYCRR § 505.3(f)(3).

24. The Medicaid Program requires prior authorization for certain drugs. Prescribers ordering a drug that requires prior authorization must complete the approval process. See New

York State Medicaid Program, *Pharmacy Manual Policy Guidelines*, Version 2010-2, December 15, 2010 (hereinafter, "NY PMPG"), at 8-9. Prescribers are required to initiate the prior authorization process by responding to questions related to the patient's condition, justifying the use of a drug. Id.

25. For dual Medicare Part D and New York Medicaid beneficiaries, Medicare supplants Medicaid for most prescription drug costs.

Statutes and regulations prohibiting fraudulent conduct

26. In order to furnish supplies including prescription drugs for which payments are claimed, a person must enroll with the New York State Department of Health as a provider. By enrolling, the provider agrees "that the information provided in relation to any claim for payment shall be true, accurate and complete." 18 NYCRR § 504.3.

27. The NY General Policy for All Providers states, *inter alia*, that payment will not be made for medical care and services "which are fraudulently claimed." See New York State Medicaid Program, *Information for All Providers – General Policy*, Version 2011-2 (October 20, 2011) (hereinafter, "NY GP"), at 23 of 65.

28. The Policy states that an example of fraud is when a person "knowingly submits false information for the purpose of obtaining authorization for the provision of services or merchandise." Id. at 31. See 18 NYCRR § 515.5(b); see also N.Y. Soc. Serv. Law § 366-b; 18 NYCRR § 515.3.

29. Since 2003, pharmacies have been required to submit most of their claims to the New York State Medicaid program electronically. The New York State Electronic Medicaid

System eMedNY 000301 Pharmacy Billing Guidelines, September 21, 2010 at p. 5 (hereinafter "eMedNY Pharmacy Billing Guidelines").

30. For paper submissions, pharmacies must use the New York State eMedNY-000301 claim form. Id. at 6. The eMedNY Pharmacy Billing Guidelines provide that before submitting electronic or paper claims to the New York Medicaid program, pharmacies are required to submit (1) an Electronic Transmitter Identification Number (ETIN); and (2) a Certification Statement. Id.

31. By submitting the certification statement, the pharmacy is certifying that it has complied with all applicable laws and regulations, including those set forth above, and has not engaged in any prohibited conduct in connection with the claim. See New York State Medicaid Program, *Information for All Providers -- General Billing*, Version 2011-3 (July 15, 2011), at 6-7.

32. On information and belief, CareMed entered into one or more agreements, either directly or indirectly through sponsors, with the United States and/or New York in order to become a participant in Medicare and Medicaid, including enrolling as a provider as stated above. Pursuant to these agreements, CareMed agreed to bill for monies for medications provided to Medicare and Medicaid beneficiaries, and these payments were made to the defendant entity. Furthermore, the defendant entity agreed to submit only truthful and accurate claims for reimbursement.

The United States False Claims Act

33. The False Claims Act prohibits, *inter alia*, the following:

> knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval;

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

31 U.S.C. §§ 3729(a)(1)(A), (B) and (G).

The New York False Claims Act

34. The New York False Claims Act prohibits, *inter alia*, the following:

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

New York State Finance Law § 189(1)(a), (b), and (g).

Defendant's Fraudulent Conduct

False and fraudulent prior authorization requests

35. CareMed routinely makes false and fraudulent statements to PDPs and MA-PDs during both verbal telephone requests for prior authorizations and on written prior authorization forms. These statements are made as a matter of company policy and at the express direction of company management. CareMed employees are trained in how to make the false and fraudulent statements in order to obtain prior authorization by telephone, in particular, and they are chastised if they are not successful in doing so.

36. Since at least July 2008 when Nahar joined CareMed, CareMed has trained its clinical care coordinators to obtain prior authorizations by telephone wherever possible in order

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The Parties

1. Plaintiff-Relator Panna Nahar is an individual citizen of the State of New York. Relator was employed by the defendant from July 2008 until February 2011 as a "Clinical Care Coordinator." Ms. Nahar's regular duties and responsibilities included obtaining prior authorizations for prescription drugs and training other employees of the defendant in prior authorization procedures.

2. Defendant Sorkin's Rx Ltd., d/b/a and/or t/a CareMed Pharmaceutical Services ("CareMed"), is a private limited company organized under the laws of the State of New York with its principal place of business at 1981 Marcus Avenue, Lake Success, New York 11042. CareMed is a "specialty pharmacy," so-called because it primarily sells and distributes pharmaceuticals that are high-cost and are prescribed for conditions that are chronic and/or require complex care, such as cancer, HIV/AIDS, hemophilia, hepatitis C, infertility and multiple sclerosis. Most of CareMed's business is mail order, and it has customers throughout the State of New York, including in the Southern District of New York, and around the country. CareMed is licensed as a wholesaler and pharmacy in the State of New York, and it is a "Provider" under the Medicare and New York Medicaid programs, as defined below. CareMed fills approximately 200 to 250 prescriptions per day, a substantial percentage of which are for patients covered by Medicare Part D or Medicaid.

3. Relator has direct and independent knowledge on which the allegations are based, is an original source of this information to the United States and the State of New York, and has voluntarily provided the information to the United States and to the State of New York before filing this action based on the information.

4. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relator, she is an original source under 31 U.S.C. § 3730(e)(4) and N.Y. State Finance Law § 190(9)(b).

5. The Court has subject matter jurisdiction over this case pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over this case for the claims brought on behalf of the State of New York pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, as recovery is sought on behalf of the State of New York arising from the same transactions and occurrences as the claims brought on behalf of the United States.

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Statutory and Regulatory Background

Medicare

8. Medicare is a federal health insurance system for people 65 and older and for people under 65 with certain disabilities. Medicare Part A provides hospital insurance for eligible individuals. See 42 U.S.C. §§1395c-1395i. Medicare Part B is a voluntary subscription

program of supplementary medical insurance covering items and services other than hospitalization expenses. See 42 U.S.C. § 1395k(a)(2)(B).

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13. CMS makes three additional types of payments to Part D plans: (1) monthly direct subsidy payments on a per capita basis for each Part D enrollee, (2) low-income subsidy payments for premium and cost-sharing charges that would otherwise by paid by the beneficiary, and (3) risk-sharing payments, which limit a sponsor's overall risks and profits in offering Part coverage.

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15. A pharmacy is a "provider" or "downstream entity" under Medicare regulations. 42 C.F.R. §§ 423.4, 423.501; see Centers for Medicare and Medicaid Services, *Prescription Drug Benefit Manual*, Pub. 100-18 (2006), Ch. 9 § 10.1 (hereinafter "PDBM").

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necessary need for the drug. Requests for prior authorization may be made either verbally over the telephone or in writing on standard forms prepared by the PDP or MA-PD sponsor.

Statutes and regulations prohibiting fraudulent conduct

17. Medicare does not pay for any and all services furnished to Medicare beneficiaries but only those services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Medicare requires that Part D plan providers not participate in "false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data." 42 C.F.R. § 423.509(a)(4).

18. The PDBM further identifies examples of Pharmacy Fraud, Waste and Abuse, including:

> *Inappropriate billing practices*: Inappropriate billing practices at the pharmacy level occur when pharmacies engage in the following types of billing practices:
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> > Billing for prescriptions that are never picked up (i.e., not reversing claims that are processed when prescriptions are filled but never picked up).
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> *Dispensing expired or adulterated prescription drugs:* Pharmacies dispense drugs that are expired, or have not been stored or handled in accordance with manufacturer and FDA requirements.

See PDBM, Ch. 9 § 70.1.3; see also 18 U.S.C. §§ 1035, 1347.

19. To obtain reimbursement for prescription drug coverage, the provider must submit and certify to details establishing that Medicare's medical necessity requirements are met. See 42 C.F.R. § 423.505(i)(3)(v). When submitting claims data to CMS for payment, sponsors and their subcontractors must certify that the claims data is true and accurate to the best of their knowledge and belief. 42 C.F.R. § 423.505(k)(3).

20. In addition, parties have a continuing obligation to disclose to the government any new information indicating the falsity of the original statement. See PDBM, Ch. 9 § 80.1.

Medicaid

Statutory and regulatory background

21. Medicaid is a federal health insurance system that is administered by the states and is available to low-income individuals and families who meet eligibility requirements determined by federal and state law. Medicaid pays for items and services, including prescription drugs, pursuant to plans developed by the states and approved by HHS through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay health care providers, including pharmacies, according to established rates, and the federal government then pays a statutorily established share of "the total amount expended ... as medical assistance under the State plan." See 42 U.S.C. §§ 1396b(a)(1).

22. At all times relevant hereto, the United States has provided funds to New York for its Medicaid program, which New York administers through the New York State Department of Health, and HHS, through CMS, has ensured that New York has complied with minimum federal standards in its administration of the Medicaid program.

23. New York Medicaid provides a prescription drug benefit to its beneficiaries. New York Medicaid regulations determine how much a pharmacy is reimbursed for a particular prescription. New York Medicaid also pays participating pharmacies a dispensing fee for each prescription drug claim and an additional compounding fee for each compounded prescription drug claim. 18 NYCRR § 505.3(f)(3).

24. The Medicaid Program requires prior authorization for certain drugs. Prescribers ordering a drug that requires prior authorization must complete the approval process. See New

York State Medicaid Program, *Pharmacy Manual Policy Guidelines*, Version 2010-2, December 15, 2010 (hereinafter, "NY PMPG"), at 8-9. Prescribers are required to initiate the prior authorization process by responding to questions related to the patient's condition, justifying the use of a drug. Id.

25. For dual Medicare Part D and New York Medicaid beneficiaries, Medicare supplants Medicaid for most prescription drug costs.

Statutes and regulations prohibiting fraudulent conduct

26. In order to furnish supplies including prescription drugs for which payments are claimed, a person must enroll with the New York State Department of Health as a provider. By enrolling, the provider agrees "that the information provided in relation to any claim for payment shall be true, accurate and complete." 18 NYCRR § 504.3.

27. The NY General Policy for All Providers states, *inter alia*, that payment will not be made for medical care and services "which are fraudulently claimed." See New York State Medicaid Program, *Information for All Providers – General Policy*, Version 2011-2 (October 20, 2011) (hereinafter, "NY GP"), at 23 of 65.

28. The Policy states that an example of fraud is when a person "knowingly submits false information for the purpose of obtaining authorization for the provision of services or merchandise." Id. at 31. See 18 NYCRR § 515.5(b); see also N.Y. Soc. Serv. Law § 366-b; 18 NYCRR § 515.3.

29. Since 2003, pharmacies have been required to submit most of their claims to the New York State Medicaid program electronically. The New York State Electronic Medicaid

System eMedNY 000301 Pharmacy Billing Guidelines, September 21, 2010 at p. 5 (hereinafter "eMedNY Pharmacy Billing Guidelines").

30. For paper submissions, pharmacies must use the New York State eMedNY-000301 claim form. Id. at 6. The eMedNY Pharmacy Billing Guidelines provide that before submitting electronic or paper claims to the New York Medicaid program, pharmacies are required to submit (1) an Electronic Transmitter Identification Number (ETIN); and (2) a Certification Statement. Id.

31. By submitting the certification statement, the pharmacy is certifying that it has complied with all applicable laws and regulations, including those set forth above, and has not engaged in any prohibited conduct in connection with the claim. See New York State Medicaid Program, *Information for All Providers -- General Billing*, Version 2011-3 (July 15, 2011), at 6-7.

32. On information and belief, CareMed entered into one or more agreements, either directly or indirectly through sponsors, with the United States and/or New York in order to become a participant in Medicare and Medicaid, including enrolling as a provider as stated above. Pursuant to these agreements, CareMed agreed to bill for monies for medications provided to Medicare and Medicaid beneficiaries, and these payments were made to the defendant entity. Furthermore, the defendant entity agreed to submit only truthful and accurate claims for reimbursement.

The United States False Claims Act

33. The False Claims Act prohibits, *inter alia*, the following:

> knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval;

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

31 U.S.C. §§ 3729(a)(1)(A), (B) and (G).

The New York False Claims Act

34. The New York False Claims Act prohibits, *inter alia*, the following:

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

New York State Finance Law § 189(1)(a), (b), and (g).

Defendant's Fraudulent Conduct

False and fraudulent prior authorization requests

35. CareMed routinely makes false and fraudulent statements to PDPs and MA-PDs during both verbal telephone requests for prior authorizations and on written prior authorization forms. These statements are made as a matter of company policy and at the express direction of company management. CareMed employees are trained in how to make the false and fraudulent statements in order to obtain prior authorization by telephone, in particular, and they are chastised if they are not successful in doing so.

36. Since at least July 2008 when Nahar joined CareMed, CareMed has trained its clinical care coordinators to obtain prior authorizations by telephone wherever possible in order

to avoid submitting fraudulent documentation; to pose as if they are calling from physicians' offices when making these telephone calls; and to provide false medical history and information in order to secure prior authorization for the prescription.

37. This training occurs at the direction of company management and, in particular, Senior Vice President John Witkowsky. Former CareMed employee Javeria Sheikh trained Nahar in how to make these fraudulent telephone requests, and Nahar's training included shadowing other clinical care coordinators for several days to watch them make such fraudulent calls. After Nahar became skilled in the process, she was asked to (and did) train new CareMed employees in how to make these calls, including employees in Pakistan via Skype. The employees in Pakistan had previously performed only data entry and, upon information and belief, are not certified by HIPAA.

38. Consistent with their training and direction, CareMed employees routinely falsely identify themselves to PDPs or MA-PDs as nurses or other employees of the prescribing physicians' offices, using fake names when doing so. CareMed uses Caller ID blocker to prevent its outgoing calls from identifying CareMed as the caller. Alternatively, CareMed uses a website that enables employees to make calls appear on Caller ID as if they are originating from a physician's number.

39. Occasionally, PDPs and MA-PDs become suspicious and catch on to CareMed's deceptive methods. For example, a CareMed employee might be on the phone with a PDP or MA-PD representative posing as "Lisa" from a physician's office when the representative would overhear another CareMed employee in the background answering the phone "Thank you for calling CareMed." The PDP or MA-PD representative would then end the call and dial the

physician's office directly and ask to speak with Lisa, only to be told that no one by that name worked there.

40. CareMed employees are also trained to falsely state that the request is urgent in order to avoid having to submit a written form and in an effort to minimize the PDP or MA-PD's time to review patient history.

41. Most significantly, CareMed employees provide false medical information about CareMed customers in order to secure prior authorization. Typically, CareMed only has access to their customers' demographics, not to the medical history or information that is necessary to obtain prior authorization for a prescription drug. Lacking access to the necessary medical information, CareMed provides false information based not on the customer's actual medical history but based on the requirements for obtaining prior authorization for that prescription. CareMed employees are able to determine the PDP or MA-PD's prior authorization criteria for a particular prescription drug by using websites such as rxlist.com and webmd.com. CareMed then provides fictional information that meet the criteria.

42. For example, if CareMed determines from the available on-line sources that prior authorization would be denied if a particular lab test did not fall within a certain range, CareMed employees provide fictional lab test results within the qualifying range in order to secure prior authorization.

43. CareMed employees engaged in the same scheme with respect to NY Medicaid. Consistent with her training and supervision, Nahar personally obtained prior authorization in this way from NY Medicaid for enteral nutritional formulas such as Pediasure, Ensure, and other items that Medicaid covers with prior authorization.

44. If a sponsor's questions are all answered correctly, medications are instantly approved. If CareMed employees are not successful in obtaining prior authorization, Mr. Witkowsky reprimands them and then calls the sponsor back himself to try again. CareMed also had a monthly bonus program to reward the employee who secured the most prior authorizations, providing a further incentive for this illegal conduct.

45. In addition to being false and fraudulent, this practice creates a patient safety risk where accurate medical information might reveal that a particular prescription drug is contraindicated either standing alone or in combination with another prescription. The example of the multiple myeloma drugs, Revlimid/Thalimid, which are contraindicated for pregnant women because of the risk of birth defects, is discussed below. The practice also created the potential to interfere with a physician's treatment of a patient.

46. When a prior authorization could not be obtained by telephone and a form had to be submitted to the PDP or MA-PD, CareMed employees completed the forms as if they were being completed by physicians' offices, including providing Drug Enforcement Agency registration numbers and medical license numbers and forging physicians' signatures. Nahar was personally trained to do this by Javeria Sheikh and other co-workers during her training. Nick Slobodskoy performed the training after Ms. Sheikh left. Nahar never attempted to forge an actual physician signature but signed the forms "sig on file." Nahar estimates that she did this on average three to four times per week. Other employees would sign the physician's actual name, attempting to replicate the exact signature if it appeared on the prescription. Certain insurance companies, including Humana, Rx America, Healthnet and Rx Solutions, always required a written form.

Fraudulent practices regarding Revlimid and Thalomid

47. Revlimid (Celgene's trade name for lenalidomide) is indicated for patients with certain forms of transfusion dependent anemia and, in combination with dexamethasone, for treatment of multiple myeloma patients with at least one prior therapy. One 28-day prescription costs approximately $8,500 and patients typically are prescribed multiple courses of the drug.

48. Thalomid (Celgene's trade name for thalidomide) is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL), as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence, and, in combination with dexamethasone, for the treatment of patients with newly diagnosed multiple myeloma. One 28-day prescription costs approximately $7,500 and patients typically are prescribed multiple courses of the drug.

49. Because Revlimid and Thalomid both carry significant risks for birth defects, they are contraindicated for women who are pregnant or capable of becoming pregnant, and all men taking the drugs (even those who have had vasectomies) are warned to wear a latex condom during sexual activity with a woman of child bearing age.

50. In order to avoid fetal exposure to the drugs, they are only available from Celgene pursuant to a restricted distribution program. The Revlimid program is called "RevAssist" and the Thalomid program is called "S.T.E.P.S." (an acronym for "System for Thalidomide Education and Patient Safety"). Prescribers and pharmacists who are registered with these programs can prescribe and dispense the drugs to patients who are registered with and meet all the conditions of the programs. The programs require both the prescribing physician and the patient to complete surveys ensuring that the conditions are met and that the patient is adequately informed of the birth defect risks and the precautions necessary to prevent pregnancy. Once the

surveys are completed, each prescription is assigned a specific authorization number which is valid for a limited time. A registered pharmacist must also complete a patient consultation.

51. CareMed routinely completes the surveys for physicians and patients in order to expedite ordering and payment and qualify for manufacturer incentives based on turnaround time. In so doing, CareMed employees engage in the same type of conduct as described above, i.e., falsely representing themselves as employees of physicians' offices and patients and providing false medical information. The required patient consultation by a registered pharmacist also does not occur.

52. In addition, CareMed provided physicians with Revlimid order forms which replaced the Celgene fax number with CareMed's fax number. Thus, physicians believed that they were faxing the order forms to RevAssist but were in fact faxing them to CareMed. Upon receipt of the faxed order form, CareMed then initiates the process with RevAssist, including completing surveys on behalf of physicians and patients.

53. The restricted distribution systems for Revlimid and Thalomid are intended to ensure that patients are adequately informed of the birth defect risks and the precautions necessary to prevent pregnancy. In addition to defrauding government health care programs, CareMed is creating a grave safety risk by subverting the systems with its false and fraudulent practices.

Re-stocking and re-selling unused specialty medications

54. On occasion, individuals contact CareMed to ask how they should dispose of drugs that are no longer needed, either because a customer's prescription has changed or because a customer has died. CareMed instructs its employees to inquire whether the medications have

been opened or used and, if the answer is no, to make arrangements to retrieve the medications under the pretext that the materials are toxic and hazardous and CareMed will ensure that they are properly discarded. If the patient is within short driving distance of CareMed's location, CareMed sends a driver to pick up the drugs and return them to CareMed for re-stocking.

55. If the patient is not within short driving distance of CareMed's location, CareMed sends a self-addressed Federal Express envelope to the individual to use to return the drugs. CareMed then re-stocks and re-sells the drugs without crediting the PDP, MA-PD or other third-party payor for the amount that it has already paid.

56. In addition to constituting fraudulent double-billing for prescription drugs, this conduct creates a safety risk because CareMed is unsure whether the medications have been properly stored by the customer. Some chemotherapy drugs, for example, must be refrigerated in order to remain safe and effective for their intended uses. Others may crystallize if they are stored at a temperature that is too low. One drug that was re-stocked particularly often was Revlimid.

Automatic refills

57. CareMed's ordering system (Cerner Etreby) generates automatic refill orders on a daily basis, including billing the PDP, MA-PD or other private payor.

58. For example, if a patient is prescribed a 28-day course of a chemotherapy drug, CareMed's system generated an automatic refill for the medication after 21 days. CareMed notifies its customer that its refill is ready to be picked up. If the customer does not require the refill for any reason, CareMed does not reverse the claim to the PDP, MA-PD or other private payor. A manager, Raiju Chacko, marks the refill as "Delivered" in CareMed's system but the

medications remain on CareMed's shelves to be sold to another customer. This cycle continues until there is a complaint from the patient or payor, at which point CareMed falsely attributes the issue to a glitch in its system that it will correct immediately.

59. Nahar was specifically instructed by Neuman Tyyeb, Raiju Chacko and Nick Slobodsky not to reverse a claim for an automatically refilled prescription that was never provided to a customer. In order to prevent auto refills, a CareMed employee has to manually enter into the system "not to autorefill."

Forging signatures on co-pay assistance applications

60. CareMed offers co-pay assistance for patients who have high co-pays for prescriptions and cannot afford the payments. Whenever patients cannot afford their co-pay, CareMed assists them in obtaining co-pay assistance from agencies or organizations such as New York State Epic, Healthwell Foundation, Patient Access Network Foundation, Patient Services Inc., Chronic Disease Fund, or Patient Advocate Foundation.

61. CareMed's efforts included making false and fraudulent misrepresentations such as underreporting the patient's income. Again, where possible, CareMed would attempt to secure approval via phone, but where submitting a written application was necessary, technicians were trained to how complete the forms with false and fraudulent misrepresentations about a patient's income and forged physician and patient signatures. Applications were faxed with "Urgent" status, and patients were usually approved within 24 to 48 hours. In this way, CareMed fraudulently secured payment for at least one cycle of expensive specialty medications.

62. In addition, CareMed routinely waived co-pays for all Express Scripts patients who filled their retail drug prescriptions at CareMed and only filled specialty medication

prescriptions of patients who also filled their retail prescriptions at CareMed. CareMed engaged in this practice in order to keep its contract with Express Scripts, which required that a sufficient percentage of CareMed's business be retail prescriptions. CareMed also had a practice of waiving co-pays for patients of certain physicians' offices, in order to encourage those physicians to refer their patients to CareMed. CareMed provided other benefits directly to the physicians themselves, such as meals, gifts, and tickets to events.

Fraudulent statements to Fox Insurance Medicare Part D plan beneficiaries

63. CareMed customers who were covered by Fox Insurance's Medicare Part D plan were fraudulently required to purchase all of their specialty medications from Caremed. Fox insurance automatically faxed the order forms for any specialty medication to Caremed and granted an initial three months authorization and "locked it" (meaning that if the patient tried to fill the prescription at any other pharmacy, the claim will not be paid and the customer will be directed to CareMed). Therefore, when patients went to their local pharmacy to pick up their medication, they were told to contact Caremed. Patients then contacted Caremed and clinical care coordinators were trained to tell the patients that Caremed has a contract with Fox requiring them to purchase their medications from Caremed. There was no such contract, and any such contract would have violated Medicare Part D in any event.

64. In March 2010, CMS terminated Fox Insurance's Medicare Part D contract as a result of Fox's violations of various CMS rules. See http://www.healthleadersmedia.com/content/HEP-247772/CMS-Drops-Fox-Insurance-from-Medicare-Part-D.html CareMed advised Fox Insurance beneficiaries to switch to Medco or

Prescription Solution as their PDP because they were the easiest to obtain pre-authorizations from and granted them over the phone.

Medications covered by Medicare Part B

65. Medicare Part B covers a limited number of oral medications that are usually administered in a hospital out-patient setting or physician's office. If these medications were not dispensed within 24 hours of billing and not reversed electronically during that time, a form had to be completed and manually faxed to CMS in order to reverse the billing. CareMed's practice was never to complete or submit the reversal form and never to reimburse Medicare for any prescriptions of Part B drugs that were not dispensed. CareMed also routinely provided diagnoses that would ensure that Medicare Part B paid for the medications regardless of whether that diagnosis was correct and was the reason that the drug had been prescribed.

66. Part B drugs that CareMed billed most frequently were Xeloda, Temodar, Alkeran, Cytoxan Tabs, Vepesid, Leucovorin Tabs, and Methotrexate Tabs. Medicare paid 80% of the cost of the medication and the remaining 20% would be covered by supplemental coverage, where the customer had it.

67. Defendant's certifications submitted to Medicare, CMS or any of its intermediaries in connection with the claims described in paragraphs 35 through 66 above were knowingly and materially false and fraudulent.

68. Defendant's certifications submitted to New York Medicaid, including any of its intermediaries and the New York State Electronic Medicaid System, in connection with these claims were knowingly and materially false and fraudulent.

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

70. The State of New York, through its carriers and intermediaries, has made payments to the defendant and has been damaged in an amount to be determined. The State of New York is entitled to treble its actual damages and to civil penalties in the amount of $6,000 to $12,000 for each of the false claims submitted.

COUNT I

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

71. Relator incorporates by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

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

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

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

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

COUNT II

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

76. Relator incorporates by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

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

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

79. Defendant's materially false records or false statements are set forth above and include, but are not limited to, fictional patient data, physician signatures, and participation in "false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data." 42 C.F.R. § 423.509(a)(4).

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

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

COUNT III

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

82. Relator incorporates by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

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

84. As a direct and proximate result of the above conduct by defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the False Claims Act of an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation of the False Claims Act.

COUNT IV

(VIOLATION OF THE NEW YORK FALSE CLAIMS ACT – N.Y. State Finance Law § 189(1)(a))

85. Relator incorporates by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

86. Defendant knowingly presented, or caused to be presented, and continues to present or cause to be presented, false and fraudulent claims for payment or approval to the State of New York – i.e., the foregoing false and fraudulent claims for payments from Medicaid – in violation of N.Y. Finance Law § 189(1)(a).

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

88. The State of New York relied on these false and fraudulent claims, was ignorant of the truth regarding these claims, and would not have paid defendant for these false and fraudulent claims had it known the falsity of the said Medicaid claims by defendants.

89. By virtue of the false or fraudulent claims, the State of New York suffered damages and therefore is entitled to recover from Defendant treble damages under the NYFCA, in an amount to be proved at trial, plus a civil penalty of at least $6,000 for each violation.

COUNT V

(VIOLATION OF THE NEW YORK FALSE CLAIMS ACT – N.Y. State Finance Law § 189(1)(b))

90. Relator incorporates by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

91. Defendant knowingly made, used or caused to be made or used, and continues to make, use and cause to be made or used, false records or false statements material to the foregoing false or fraudulent claims to get these false or fraudulent claims paid and approved by the State of New York, in violation of N.Y. Finance Law § 189(1)(b).

92. Defendant's knowingly false records or false statements were material, and upon information and belief continue to be material, to the false and fraudulent claims for payments they made and continue to make to the State of New York for Medicaid reimbursements and benefits.

93. Defendant's materially false records or false statements are set forth above and include, but are not limited to, fictional patient data, physician signatures and participation in other "false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data." 42 C.F.R. § 423.509(a)(4).

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

95. As a direct and proximate result of these materially false records or false statements, and the related false or fraudulent claims made by defendant, the State of New York suffered damages and therefore is entitled to recover from Defendant treble damages under the NYFCA, in an amount to be proved at trial, plus a civil penalty of at least $6,000 for each violation.

COUNT VI

(VIOLATION OF NEW YORK FALSE CLAIMS ACT – N.Y. State Finance Law § 189(1)(g))

96. Relator incorporates by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

97. Upon information and belief, defendant knowingly made or used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State of New York, in violation of N.Y. Finance Law § 189(1)(g).

98. As a direct and proximate result of the above conduct by defendant, the State of New York suffered damages and therefore is entitled to recover from Defendant treble damages under the NYFCA, in an amount to be proved at trial, plus a civil penalty of at least $6,000 for each violation.

CLAIM FOR RELIEF

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

Dated: New York, New York
May 30, 2012

Respectfully submitted,

KLINE & SPECTER
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BY: _____

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