UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

United States of American *ex rel.* [UNDER SEAL], Plaintiffs, - against - [UNDER SEAL], Defendants.	Civil Action No. 21-cv-1270 **AMENDED COMPLAINT FOR VIOLATION OF THE FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et. seq.*]** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

DOCUMENT TO BE KEPT UNDER SEAL

DO NOT ENTER INTO PACER

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA *ex rel.*
VERONICA LOPEZ,
139 Melrose Ct.,
Frederick, MD 21702

and

TIMOTHY JOSEPH PERRY,
5810 Farmgate Ct.,
Frederick, MD 21703

and

STATE OF MARYLAND *ex rel.*
VERONICA LOPEZ and TIMOTHY JOSEPH PERRY,

Plaintiffs,

v.

PROGRESSIVE ONCOLOGY AND HEMATOLOGY CENTER LLC,
8 Bankbarn Cir.,
Middleton, MD 21769

and

MOUHAMAD BAZZI,
8 Bankbarn Cir.,
Middleton, MD 21769

Defendants.

Civil Action No. 21-cv-1270

AMENDED COMPLAINT

FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

Qui tam Plaintiff-Relators Veronica Lopez and Timothy Joseph ("T.J.") Perry ("Relators") bring this action on behalf of the United States of America and the State of Maryland against Progressive Oncology and Hematology Center LLC ("Progressive Oncology") and Mouhamad

Bazzi, M.D, under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733, and the Maryland False Claims Act ("Maryland FCA"), Md. Code Ann., Health-Gen. § 2-601 through 2-611.

I. INTRODUCTION

1. Dr. Mouhamad Bazzi is exploiting cancer patients, using them as vehicles to defraud Medicare, Medicaid, and private insurers of potentially millions of dollars. Unbeknownst to the patients, Dr. Bazzi is fraudulently inflating claims for reimbursement by administering less chemotherapy drug to patients than is billed or indicated in the patients' medical records. For most cancer patients receiving costly chemotherapy drugs, it is Dr. Bazzi's routine practice to commit this fraud. Dr. Bazzi also defrauds the Medicare and Medicaid programs by impermissibly billing for chemotherapy drugs that are purchased by the patient, provided by a patient assistance program at no cost, or already paid for by an insurance program. Thus, Dr. Bazzi's oncology practice is engaging in two overbilling schemes. In the first scheme, Defendants bill for drugs that they never provided to patients. In the second scheme, Defendants bill for drugs that they never purchased.

2. Defendants' fraudulent schemes have resulted in false claims to government healthcare programs worth potentially millions of dollars.

3. These claims are false because they misrepresent the quantity of drugs administered and/or represent that the claims are reimbursable.

4. Defendants knew that their claims for payment from government healthcare programs, and the records supporting those claims, were false as a result of these fraudulent schemes, and engaged in many practices to conceal their illegal activities.

5. Had the insurers of Defendants' patients, including government healthcare programs, known of these misrepresentations, they would not have approved or paid Defendants' claims.

6. Accordingly, Defendants' conduct violates the FCA and Maryland FCA, and Relators seek to recover all available damages, civil penalties, and other relief for the violations alleged in this Complaint.

II. PARTIES

7. Plaintiff United States of America is a real party in interest in this action. The United States, acting through the United States Department of Health and Human Services ("HHS"), administers the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* ("Medicare").

8. Plaintiff the State of Maryland is a real party in interest in this action. Maryland, acting through the Maryland Department of Health, administers the Maryland Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* ("Medicaid").

9. Plaintiff-Relator Veronica Lopez is a pharmacy technician residing in Maryland. She has worked at Defendant Progressive Oncology, under the direction of Defendant Bazzi, since September 21, 2015. As a pharmacy technician, she is responsible for inventorying and mixing chemotherapy drugs. Through her counsel, she has voluntarily provided the United States with the information on which the allegations or transactions in this case are based.

10. Plaintiff-Relator T.J. Perry is a pharmacy technician residing in Maryland. He has worked at Defendant Progressive Oncology, under the direction of Defendant Bazzi, since April 5, 2016. As a pharmacy technician, he is responsible for inventorying and mixing chemotherapy drugs. Through his counsel, he has voluntarily provided the United States with the information on which the allegations or transactions in this case are based.

11. Defendant Progressive Oncology and Hematology Center LLC is a Maryland Limited Liability Company that operates a cancer treatment center. It is headquartered at 8

Bankbarn Cir., Middleton, MD 21769, and its registered agent and owner is Defendant Mouhamad Bazzi. The cancer treatment center it operates is located at 2405 Whittier Dr. #100, Frederick, MD 21702. (Before approximately January 2017, the center operated at 915 Toll House Ave., Suite 305, Frederick, MD 21701.) Its National Provider Identifier ("NPI") is 1578959615.

12. Defendant Mouhamad Bazzi, M.D., is a doctor who specializes in Internal Medicine Hematology and Oncology. His NPI is 1265619878. He is the owner of Progressive Oncology and its only doctor. Dr. Bazzi resides at 8 Bank Barn Cir., Middletown, MD 21769. He received his medical degree from Pavlov Medical University in St. Petersburg, Russia.

III. JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

14. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in, reside, and/or transact or have transacted business in this District.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Defendants can be found in and/or transact or have transacted business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business in this District. In addition, statutory violations, as alleged in this Complaint, occurred in this District.

16. Although the issue is no longer jurisdictional, there has been no public disclosure of the "allegations or transactions" in this Complaint within the meaning of 31 U.S.C. § 3730(e) or Md. Code Ann., Health-Gen. § 2-606(d). Even if there had been any such public disclosure, Relators are an original source of the allegations in this Complaint because prior to any relevant public disclosure, they voluntarily disclosed to the government the information upon which the allegations or transactions in the Complaint are based, and/or because they have knowledge that is independent of and materially adds to any publicly-disclosed allegations or transactions relevant to their claims, and voluntarily provided the information to the government before filing this action.

IV. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

17. The FCA imposes civil liability on any person who, inter alia: (1) knowingly presents, or causes to be presented, to an officer or employee of the United States government 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 to get a false or fraudulent claim paid or approved by the government. 31 U.S.C. §§ 3729(a)(l)(A), (B).

18. The FCA defines a "claim" to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that — (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest." § 3729(b)(2).

19. The FCA defines the terms "knowing" and "knowingly" to mean "that a person, with respect to information — (i) has actual knowledge of the information; (ii) acts in deliberate

ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. § 3729(b)(l)(B).

20. The FCA provides that the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." § 3729(b)(4).

21. Any person who violates the FCA is liable for a mandatory civil penalty for each claim, plus three times the damages sustained by the government. § 3729(a)(l).

22. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States and to share in any recovery. The FCA requires the complaint to be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

B. The Medicare Program

23. Medicare is a federally funded health insurance program that primarily benefits the elderly.

24. The Centers for Medicare and Medicaid Services ("CMS"), an agency of the Department of Health and Human Services ("HHS"), directs and manages the Medicare program.

25. The Medicare program has four parts: Part A, which provides insurance for hospital care; Part B, which provides insurance for outpatient care; Part C, or "Medicare Advantage," which provides Part A and Part B benefits via managed care plans; and Part D, which provides prescription drug benefits. The allegations in this case concern outpatient services reimbursed under primarily Part B.

26. Since November 2006, CMS has contracted with Medicare Administrative Contractors ("MACs") to assist in the administration of Medicare Part B. *See* Fed. Reg. 67960, 68181 (Nov. 2006). MACs generally act as CMS's agents in reviewing and paying Part B claims submitted by healthcare providers and perform administrative functions on a regional level. *See* 42 U.S.C. § 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. The MAC overseeing the region in which Defendants practice is Novitas Solutions, Inc.

27. The amount that Medicare authorizes MACs to pay for services under Part B is based on the lesser of the actual charge or the applicable amount in the CMS Physician Fee Schedule ("PFS"). 42 U.S.C. § 1395w–4(a); 42 C.F.R. § 414.21.

28. To participate in the Medicare Program, a healthcare provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with certain requirements that the Secretary deems necessary for participating in the Medicare Program and for receiving reimbursement from Medicare. One such requirement is claims may be submitted only when medical goods and services are: (1) shown to be medically necessary, and (2) are supported by necessary and accurate information. 42 U.S.C. § 1395y(a)(1)(A), (B); 42 C.F.R. § 489.20.

29. In order to get paid from Medicare, providers must complete and submit a claim for payment on CMS Form 1500 or its electronic equivalent. This form contains patient-specific information including the diagnosis and types of services that are assigned or provided to the Medicare patient. The Medicare Program relies upon the accuracy and truthfulness of providers to determine whether and what amounts the provider is owed.

30. CMS 1500 requires medical providers submitting a claim to Medicare to make the following certification:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE ….

31. Medical providers may bill Medicare only in accordance with the medical treatments or services actually performed. *See* 42 U.S.C. § 1395n(a)(2); 42 U.S.C. § 1320c-5(a).

C. Other Federal Healthcare Programs

32. The federal government administers other healthcare programs that include, but are not limited to, TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program ("FEHB").

33. TRICARE is a healthcare program for individuals and dependents affiliated with the armed forces. The United States Department of Defense administers TRICARE.

34. CHAMPVA is a healthcare program for the families of veterans with service-connected disabilities. The United States Department of Veterans Affairs administers CHAMPVA.

35. The FEHB Program provides health insurance for federal employees, retirees, and their survivors. The United States Office of Personnel Management administers the FEHB.

36. TRICARE, CHAMPVA, FEHB, and other federal healthcare programs cover chemotherapy drugs under similar terms and conditions as Medicare.

D. Medicaid

37. The Medicaid program was created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to cover the medically needy, aged, the blind, the disabled, and needy families with dependent children. 42 U.S.C. § 1396 *et seq.* The Medicaid program is funded by both federal and state monies, with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b, 1396d(b). At the federal level, Medicaid is administered by CMS. Each state pays a portion of the Medicaid costs for goods and services provided to the state's Medicaid beneficiaries.

38. Federal regulations require each state to designate a single state agency responsible for the Medicaid program. The agency must create and implement a "plan for medical assistance" that is consistent with Title XIX of the Social Security Act and with the regulations the Secretary of HHS promulgates. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the items and services for which the federal government will pay through its funding of state Medicaid programs.

39. In order to get paid from Maryland Medicaid, including from Maryland Medicaid Managed Care Plans, providers must complete and submit a claim for payment on CMS Form 1500 or its electronic equivalent. This form contains patient-specific information including the diagnosis and types of services that are assigned or provided to the patient. The Medicaid Program relies upon the accuracy and truthfulness of providers to determine whether and what amounts the provider is owed.

E. Medicare and Medicaid Coverage of Chemotherapy Drugs

40. Medicare Part B covers infusible and injectable drugs—including chemotherapy drugs—administered in physician offices and hospital outpatient departments.

41. Chemotherapy drugs are covered only if documentation supports: (1) the drug is safe, effective, and administered for an approved indication; (2) the administration of the drug is medically necessary; and (3) the chemotherapy drug was administered as billed.

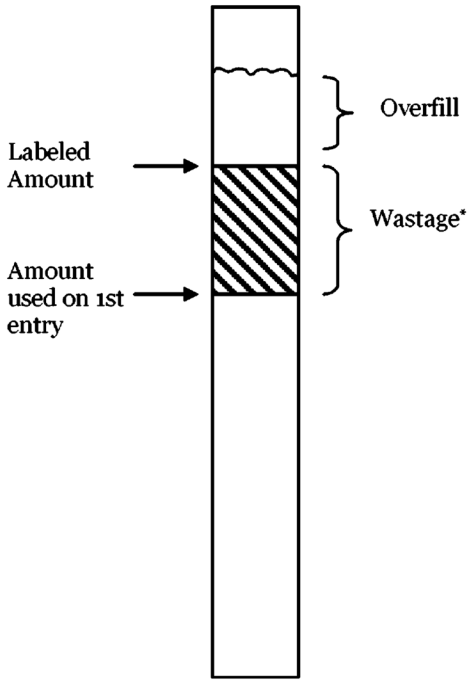
42. Medicare pays for the administration of the drug under the Physician Fee Schedule and separately for the drug itself.

43. Medicare pays physicians and suppliers for most Part B-covered drugs based on 106% of the "average sales price" ("ASP"). 42 U.S.C. § 1395w-3a(b)(1)(B); 42 C.F.R. § 414.904. In simplified terms, a drug's ASP represents the manufacturer's total sales divided by the total number of units of the drug sold in a quarter. The purpose of the ASP methodology is to accurately reflect the costs of drugs to individual providers.

44. Intravenous chemotherapy drugs come in a variety of forms, the most common being single-dose vials. Each vial includes a label approved by the United States Food and Drug Administration ("FDA"). That label will indicate an amount of drug contained in the vial.

45. Vials usually include more drug than what is indicated by the label, however. This excess drug is referred to as "overfill." Overfill ensures that the medical staff administering the drug will be able to extract at least the labeled amount from the vial. The amount of overfill is determined by the manufacturer and can vary, but this amount is not included in the amount appearing on the drug's label.

46. Sometimes, a patient's dosage will require a partial use of a single-dose vial, which results in excess drug that is not needed for the patient's treatment. This excess drug is referred to as "wastage."



One Vial of Medicine

47. Medicare has specific reimbursement rules for overfill and wastage.

48. As to overfill, medical providers may not bill Medicare Part B for drugs harvested as overfill. 42 C.F.R. § 414.904(a)(3)(iii) ("No payment is made for amounts of product in excess of that reflected on the FDA-approved label."); *see* 42 U.S.C. § 1395u(b)(3); § 1395x(v)(1)(A).

49. Although this rule was not effective until January 1, 2011, according to CMS, the prohibition against billing for overfill was not a new policy but a clarification of existing policy—the "longstanding Medicare policy that … services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies…. [P]roviders may only bill for the amount of drug product actually purchased and … the cost of the product must represent an expense to the physician." Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73170-01 (Nov. 29, 2010). When a provider takes excess product (including overfill) harvested from single use containers to create

extra doses, the "[c]laims for drugs and biologicals that do not represent a cost to the provider are not reimbursable." *Id*.

50. One key reason for this prohibition on billing for excess drug is that the current ASP reimbursement methodology disregards overfill, and thus, so should providers when submitting bills to Medicare.[1] *Id*. The Secretary calculates ASP based on the amount of product in the vial as "conspicuously reflected on the FDA[-]approved label," and as such, excludes overfill. *See* 42 C.F.R. § 414.804(a)(6). Because overfill is excluded from the calculation of ASP, CMS does not recognize it as an incurred cost to providers. Indeed, had CMS included overfill in its ASP calculations, the reimbursement amount would have been necessarily lower and providers would receive less reimbursement per vial to account for the overfill. In short, because "[a]dditional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit." § 414.904(a)(3)(ii), "[n]o payment is made for amounts of product in excess of that reflected on the FDA-approved label." § 414.904(a)(3)(iii).

51. In contrast, Medicare does reimburse for wastage but only if it is actually discarded. Medicare requires providers to use the "JW modifier" to identify unused drugs or biologicals from single-use vials that are appropriately discarded. The discarded amount is billed as a separate claim line, and the provider is required to document the discarded amount in the patient's medical record. Medicare Claims Processing Manual, Ch. 17, § 40.

52. Medicare reimburses wastage only if: (1) a single-use vial is used; (2) the units billed correspond to the smallest dose (vial) available for purchase that could provide the

[1] The Secretary considered including overfill in its calculation of ASP as a "price concession," but determined it was infeasible to do so. *See* 75 Fed. Reg. at 73461–73471.

appropriate dose for the patient; and (3) the left-over amount is actually discarded and is not used for another patient. The documentation must include the date, time, amount of medication wasted, and the reason for the wastage.

53. In addition, Medicare will not reimburse a drug that is purchased by a patient or otherwise provided at no cost to the provider ("free drugs"). *See* 42 U.S.C. § 1395u(b)(3); § 1395x(v)(1)(A); *see also* 75 Fed. Reg. 73170-01 ("[P]roviders may only bill for the amount of drug product actually purchased … the cost of the product must represent an expense to the physician."). Free drugs include drugs that are provided by patients or charitable foundations or paid for by other insurance companies.

54. Maryland Medicaid covers chemotherapy drugs under similar terms and conditions as Medicare. For instance, Maryland Medicaid permits providers to bill only their "acquisition cost" for injectable drugs, which precludes billing for excess drug. "Acquisition cost" is defined as the "purchase price of a drug … less any discount, for the amount administered or supplied." *See, e.g.*, 2020 Maryland Medical Assistance Program Professional Services Provider Manual at 19.

55. Providers must submit claims for reimbursement for chemotherapy drugs to Medicare and Medicaid using CPT/HCPCS codes, which in the case of chemotherapy drugs are called "J" codes. Each J code includes a drug in a specified quantity. When submitting claims, providers select an appropriate number of units under the appropriate J code based on the dosage given.

V. ALLEGATIONS

56. The allegations in this Complaint are based on Relators' firsthand knowledge, which they acquired in their employment with Defendants.

57. Dr. Bazzi opened Progressive Oncology in approximately May 2015.

58. Relators joined Progressive Oncology as pharmacy technicians. Ms. Lopez joined in September 2015, and Mr. Perry joined in April 2016.

59. Dr. Bazzi directed both Relators to engage in the two fraudulent schemes alleged in this Complaint in approximately late 2016/early 2017.

60. Dr. Bazzi designed these schemes to maximize Defendants' profits by billing for more drugs than he purchases and provides to the patients and by billing for the same vial of drug more than once.

A. Defendants bill for chemotherapy drugs that they never administered.

61. The chemotherapy drugs that Defendants administer come in single-use vials, each containing a certain volume of drug. The volume of drug is measured in milliliters and the strength in milligrams. Pharmacy technicians mix these vials to provide an appropriate dose to each patient based on the dosage prescribed by the doctor. The technicians then pump that dose into an IV bag filled with saline, which is administered to the patient intravenously.

62. As an example, the drug Rituxan comes in 100 mg single-use vials. If a patient needs a 700 mg dose, the pharmacy technicians must mix seven vials. If the patient needs a 750 mg dose, the pharmacy technician must mix eight vials—discarding half of one vial.

63. Defendants' first overbilling scheme is simple: They bill for drugs that they never administered to the patient. On paper, Dr. Bazzi prescribes his patients a particular dose and the Defendants bill as if that dose, and the number of vials it requires, were administered. In reality, however, Defendants mix *fewer* vials than required by the billed dose—allowing them to bill for drugs that they never administered.

64. Dr. Bazzi carries out this fraud by verbally ordering his pharmacy technicians—the Relators—to mix fewer vials than otherwise required to generate the prescribed and billed dose. He provides specific oral commands for each patient and expects the pharmacy technicians

to follow these commands each time the patient comes in for an infusion. If the Relators do not follow these commands each time the patient comes in, Dr. Bazzi verbally abuses them.

65. In general, Dr. Bazzi engages in this practice for only the more expensive chemotherapy drugs and most of the time when these drugs are administered. These drugs include, among others: Abraxane, Alimta, Avastin, Cyramza, Eribulin, Herceptin, Kadcyla, Lartruvo, Opdivo, Perjeta, Rituxan, and Yervoy.

66. Sometimes the Defendants overbill one vial, sometimes several. The cost of this fraud is substantial. Many of the drugs Defendants administer are enormously expensive—some costing tens of thousands of dollars per infusion—meaning that the cost of even a single missing vial can be thousands. And these vials add up quickly: Defendants routinely overbill for the most expensive drugs they administer, and a significant percentage of their patients are insured by government healthcare programs, mostly Medicare.

67. Defendants have overbilled Medicare for at least hundreds of vials since 2016, as well as additional vials to Medicaid and CHAMPVA.

68. The following list includes representative samples of this overbilling:

a. Patient A.B.1 visited Progressive Oncology on March 1, 2021, to receive Zirabev. Dr. Bazzi prescribed 950 mg based on A.B.1's body-surface area of 1.89 (199.5 lb., 61 in.). That dose requires ten 100 mg vials. Dr. Bazzi instructed Relators, however, to administer only eight vials. Dr. Bazzi billed Medicare as if he administered ten vials, two more than administered to A.B.1.

b. Patient A.B.2 (insured by Medicaid) visited Progressive Oncology on March 8, 2021, to receive Adcetris. Dr. Bazzi prescribed 118 mg. That

dose requires three 50 mg vials. Dr. Bazzi instructed Relators to administer only two vials. Dr. Bazzi billed Medicaid as if he administered three vials, one more than administered to A.B.2.

c. Patient D.C. visited Progressive Oncology on February 23, 2021, to receive Daratumumab. Dr. Bazzi prescribed 1325 mg. That dose requires fourteen 100 mg vials. Dr. Bazzi instructed Relators to administer only eleven vials. Dr. Bazzi billed Medicare as if he administered fourteen vials, three more than administered to D.C.

d. Patient C.G. (insured by CHAMPVA) visited Progressive Oncology on March 18, 2021, to receive Herceptin. Dr. Bazzi prescribed 485 mg. That dose requires four 150 mg vials. Dr. Bazzi instructed Relators to administer only three vials. Dr. Bazzi billed CHAMPVA as if he administered four vials, one more than administered to C.G.

e. Patient J.M. (Medicare) visited Progressive Oncology on March 8, 2021, to receive Zirabev. Dr. Bazzi prescribed 517 mg. That dose requires six 100 mg vials. Dr. Bazzi instructed Relators to administer only five vials. Dr. Bazzi billed Medicare as if he administered six vials, one more than administered to J.M.

f. Patient L.G. visited Progressive Oncology on March 9, 2021, to receive Opdivo and Yervoy. Dr. Bazzi prescribed 240 mg of Opdivo and 65 mg of Yervoy. The Opdivo dose requires six 40 mg vials and the Yervoy dose requires two 50 mg vials. Dr. Bazzi instructed Relators to administer only five vials of Opdivo and one vial of Yervoy. Dr. Bazzi billed Medicare as

if he administered six vials of Opdivo and two vials of Yervoy, one vial of Opdivo and one vial of Yervoy more than administered to L.G.

g. Patient L.M. visited Progressive Oncology on March 10, 2021, to receive Doxil. Dr. Bazzi prescribed 64 mg. That dose requires four 20 mg vials. Dr. Bazzi instructed Relators to administer only three vials. Dr. Bazzi billed Medicare as if he administered four vials, one more than administered to L.M.

h. M.K. visited Progressive Oncology on February 16, 2021, to receive Darzalex. Dr. Bazzi prescribed 436 mg. That dose requires five 100 mg vials. Dr. Bazzi instructed Relators to administer only four vials. Dr. Bazzi billed Medicare as if he administered five vials, one more than administered to M.K.

i. N.H. visited Progressive Oncology on February 9, 2021, to receive Abraxane. Dr. Bazzi prescribed 220 mg. That dose requires three 100 mg vials. Dr. Bazzi instructed Relators to administer only two vials. Dr. Bazzi billed Medicare as if he administered three vials, one more than administered to N.H.

j. P.R. visited Progressive Oncology on March 4, 2021, to receive Darzalex. Dr. Bazzi prescribed 860 mg. That dose requires nine 100 mg vials. Dr. Bazzi instructed Relators to administer only seven vials. Dr. Bazzi billed Medicare as if he administered nine vials, two more than administered to P.R.

69. These representative samples were not isolated instances. Dr. Bazzi overbilled in a similar manner with respect to each of these patients on multiple occasions—sometimes dozens of times—in addition to overbilling for many other government-insured patients.

70. Defendants conceal this fraud in several ways.

71. First, Defendants falsify all of the medical records so that they contain only the prescribed dosage—not the dosage actually administered. Defendants make certain that all records—including the prescriptions, the superbills,[2] and even the IV bag—support the illusion that patients are receiving the prescribed dosage. In contrast, all of Dr. Bazzi's directions to the pharmacy technicians to provide fewer vials than prescribed/billed are made orally, behind closed doors.

72. Second, Defendants have blocked their billing company, Fedora Solutions, from accessing their inventory management system, Nucleus,[3] to prevent the company from discovering that Defendants are billing for more drugs than they are dispensing from inventory. Fedora has repeatedly asked Defendants for access to Nucleus to aid their billing efforts. (Access to the system would enable Fedora to automatize more of the process and avoid some of the labor-intensive practices they must engage in now to accommodate Defendants' refusal to grant access to Nucleus.) On October 1, 2018, for instance, Prateek Murjani at Fedora wrote Ms. Lopez, cc'ing Dr. Bazzi, asking if she could "share the [N]ucleus login info for the practice." Dr. Bazzi instructed Ms. Lopez to deny access and made up an excuse for her to provide. On July 15, 2019, almost a year later, Prateek Murjani asked again, stating: "We bill claims based on

[2] A superbill is an itemized form, used by healthcare providers, which details services provided to a patient. It is the main data source for the creation of a claim for reimbursement.

[3] Nucleus is an inventory management system by Oncology Supply, which is part of the AmerisourceBergen network of companies.

superbills received as we don't have access to Nucleus. We would appreciate if we get the [N]ucleus access so that we can implement a reconciliation process on our end too as a checkmark before submitting the claims."

73. Third, Defendants hide this fraud from all staff besides the Relators and Dr. Bazzi's brother, Jihad "Jay" Bazzi, who joined the practice in May 2018. None of the medical staff members administering the drugs, like the nurses or nurse practitioners, have any idea that they are administering less than the written dose to patients. (Medical staff cannot tell from the IV bag how much drug has been mixed inside—they check the dosage based on only the dosage written on the IV bag, which Defendants cause to be falsified. Some nurses have complained, however, that IV bags run out sooner than expected.)

74. Fourth, Dr. Bazzi or his brother Jay occasionally mix drugs themselves—even though neither is licensed to do so—when Dr. Bazzi wants to hide the extent of his fraud from even the Relators. Relators have caught him doing so on several occasions. For instance, on December 22, 2020, Dr. Bazzi insisted on mixing the drugs for patient C.C. and tried unsuccessfully to hide from Relators that he was mixing fewer vials of Avastin than he had prescribed. Since February 2021, Jay Bazzi has been mixing drugs on a daily basis despite lacking a Maryland license to do so.

75. Since at least 2017, Relators have repeatedly complained to Dr. Bazzi that this scheme is fraudulent. When they do so, Dr. Bazzi verbally abuses them, provides false excuses, and sometimes simply "pulls rank" as a doctor and their boss. Dr. Bazzi also regularly checks the inventory to make sure Relators comply with his instructions. If they fail to do so, he berates them.

76. Dr. Bazzi has repeatedly acknowledged to Relators that he cannot report the dose actually administered to his patients because to do so would draw scrutiny from insurers.

77. As a result of the above practices, Defendants have submitted false claims, supported by false records, to government healthcare programs. These records are factually false because they misstate the quantity of drug actually administered to patients.

B. Defendants bill for chemotherapy drugs that they never paid for.

78. Defendants' second scheme involves improperly billing for three types of excess drugs: overfill, wastage, and free drugs. Medicare rules and regulations prohibit providers from: (1) billing for overfill under any circumstances; (2) billing for wastage if it is not actually discarded; and (3) billing for drugs that do not represent expenses actually incurred.

79. Drug vials usually contain more of a drug than is indicated on the packaging. This excess drug is referred to as "overfill," and it is intentionally included in vials to ensure providers are able to draw up a full dosage. A vial labeled as 100 mg of Rituxan, for instance, might actually contain as much as 110 mg. Medicare and Medicaid prohibit providers from manufacturing and/or billing for additional doses drawn from overfill.

80. "Wastage" is the excess drug that is produced when a patient's dose requires a partially used single-dose vial. For instance, a 750 mg dose of Rituxan, which requires eight 100 mg vials to prepare, results in 50 mg of wastage. Medicare allows providers to bill for wastage as a separate line item identified with the "JW modifier," but only if the provider actually discards the wastage. The provider cannot use that wastage to produce and bill for additional doses, which could result in two payments for the same drug.

81. "Free drugs" occur when a patient brings their own drugs—that they purchased themselves or acquired through a charitable program—to a medical provider for administration. Sometimes, patients for whom these drugs are intended end up not using or needing them, or are

unable to use them before they expire. When that happens, the medical provider must either return the drug or discard it. Medicare rules prohibit providers from billing for drugs they receive for free—Medicare reimburses expenses only if they are actually incurred.

82. Defendants disregard all of these prohibitions and use excess drugs to manufacture and bill for additional doses that they provide to other patients. This practice allows Defendants to squeeze extra doses out of their medication inventory and bill for drugs for which they never paid. In addition, in the case of overfill and wastage, this practice allows Defendants to bill multiple insurers for the same vial of drug or to bill the same insurer multiple times for the same vial of drug.

83. Defendants schedule patients taking the same drugs for the same days when possible to facilitate this practice.

84. Defendants engaged in this practice whenever possible when using the following expensive drugs, among others: Abraxane, Alimta, Avastin, Cyramza, Eribulin, Herceptin, Kadcyla, Lartruvo, Opdivo, Perjeta, Rituxan, and Yervoy.

85. As an example, Dr. Bazzi received free Opdivo for some of his patients, like N.K., R.T., D.M., S.M., and C.M, as part of Bristol Myers Squibb's ("BMS") compassionate use program. At first, the program provided doses through a combination of 100 mg and 40 mg vials—depending on the dose. Accordingly, a 240 mg dose required two 100 mg vials and one 40 mg vial per patient per infusion, or three vials total. At Dr. Bazzi's direction, however, the pharmacy technicians drew as much drug as they could from the 100 mg vials, including the overfill, to save the 40 mg vials for different, non-program patients, including potential Medicare and Medicaid patients.

86. In addition, when a patient passed away and no longer required the Opdivo doses, Dr. Bazzi required the pharmacy technicians to use all the remaining foundation vials on a non-foundation patient and bill his or her insurance. He did not return the drug or obtain approval to provide the drug to another program patient, as required.

87. Defendants engaged in similar practices with respect to drugs provided by specialty pharmacies for G.L. (Avastin), J.G. (Azacitidine), and H.C. (Rituxan), and by charitable foundations for patients A.C. (Darzalex) and M.R. (Rituxan), among others. (However, if a patient has an outstanding balance, Defendants apply the value of these "extra" vials to that patient's outstanding balance.)

88. In the spring of 2018, BMS switched to providing 240 mg vials under the program. This created less overfill, but Dr. Bazzi adapted by instructing the pharmacy technicians to *remove* drug from the larger vials for use with other insured patients.

89. As another example of this excess drug scheme, on March 22, 2021, Dr. Bazzi scheduled two Medicare patients taking Zirabev—L.L. and A.B.—on the same day. Zirabev comes in 100 mg vials. Dr. Bazzi prescribed A.B. 1000 mg of Zirabev and L.L. 820 mg. These prescriptions require 19 vials to produce. Dr. Bazzi, however, mixed only 16 vials, providing each patient eight vials. Defendants billed Medicare as if they administered ten vials to A.B. and nine vials to L.L. For L.L.'s ninth vial, Defendants also billed Medicare for the wastage under the JW modifier.

90. Another example of Defendants' use of excess drug involves the drug Velcade. Defendants had some patients taking Velcade—including M.K., a Medicare patient—whose prescribed dose was much less than the amount contained in one vial, leading to large amounts of excess drug. To maximize his profits, Dr. Bazzi asked Relators to save the excess drug and

store it for up to five days to use for the next patient taking Velcade. This allowed him to bill for the same vial of Velcade more than once.

91. Finally, some patients, like N.K., R.T., and C.M., received Opdivo from charitable foundations for non-FDA-approved uses. For these patients, Defendants mixed fewer vials for each patient than provided by the foundation for those patients. They then used the extra vials from the foundations on non-foundation patients, including Medicare and Medicaid patients.

92. Defendants hide this fraud by using the same methods they use to conceal the first overbilling scheme: They (1) falsify medical records; (2) restrict access to their inventory management system; (3) conceal the fraud from all but a handful of staff; and (4) occasionally limit mixing to Dr. Bazzi and his brother to conceal the fraud from even the pharmacy technicians.

93. In furtherance of this excess drug scheme, Defendants have regularly submitted false claims, supported by false records, for unwarranted reimbursement from government healthcare programs. These claims are false because the administration of excess drugs is not reimbursable: Government healthcare programs like Medicare and Medicaid do not reimburse drugs that providers receive at no expense. In addition, Defendants' claims for reimbursement under the JW modifier are factually false because Defendants do not discard the drug quantities billed as wastage, but instead administer and bill that "wastage" as part of their claims for treating other patients. This results in government healthcare programs paying for the same drug twice.

VI. DEFENDANTS' FCA AND MARYLAND FCA VIOLATIONS

94. Defendants billed and continue to bill government healthcare programs, including Medicare and Medicaid, for drugs that they never administered and/or acquired at no expense.

Each bill that Defendants have submitted for these drugs is a false claim for payment. These claims are false because Defendants are not entitled to reimbursement for drugs that were never administered or that do not constitute an incurred expense. Some of these claims are also false because they violate rules and regulations regarding the use and billing of overfill, wastage, and free drugs.

95. Defendants additionally have submitted and continue to submit false records and statements material to false claims by supporting their claims for reimbursement with false representations and false medical records. These representations and medical records are false because they overstate the quantity of drug actually administered to patients and misstate how drugs were prepared (e.g., lying about the use of overfill and wastage).

96. These false statements were material to government healthcare programs' decisions to pay Defendants' claims. If these government healthcare programs had known of Defendants' fraudulent schemes, they would not have approved their claims for payment or paid any of their claims.

97. Defendants have also falsely certified in their Forms 1500 and its electronic equivalents that the information in their claims is truthful, accurate, and complete, and that their claims comply with all applicable Medicare and Medicaid laws, regulations, and program instructions for payment. Because Defendants' claims were not reimbursable and misstated the quantity of drugs administered, each of those representations is false and fraudulent.

98. Relators cannot now identify each of the false claims for payment that Defendants presented or caused to be presented, or each of the false records or statements that Defendants made or used, or caused to be made or used, in support of such claims because Relators cannot safely access all relevant records in Defendants' possession.

Count I
False Claims Act
31 U.S.C. § 3729(a)(1)(A)–(B)

99. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 98 as though fully set forth herein.

100. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729–3733.

101. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A).

102. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false records or statements to get the United States to pay or approve false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

103. The United States, unaware of the falsity of the claims, records, and statements that Defendants made or caused to be made, paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

104. Defendants have damaged, and continue to damage, the United States in a substantial amount to be determined at trial.

105. Additionally, the United States is entitled to the maximum penalty under 31 U.S.C. § 3729, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, for each and every violation alleged herein.

Count II
Maryland False Claims Act
MD. Code Ann. Health-Gen. § 2-602(a)(1)–(2)

106. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 98 as though fully set forth herein.

107. This is a claim for treble damages and penalties under the Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-601 through 2-611.

108. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment to the State of Maryland, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

109. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false records or statements to get the State of Maryland to pay or approve false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

110. The State of Maryland, unaware of the falsity of the claims, records, and statements that Defendants made or caused to be made, paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

111. Defendants have damaged, and continue to damage, the State of Maryland in a substantial amount to be determined at trial.

112. Additionally, the State of Maryland is entitled to the maximum penalty under the Maryland False Claims Act, for each and every violation alleged herein.

PRAYER

WHEREFORE, Relators pray for judgment against Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. §§ 3729–3733 and Md. Code Ann., Health-Gen. § 2-601 through 2-611.

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States and State of Maryland have sustained because of Defendants' actions, plus the maximum civil penalty permitted for each violation of the FCA and Maryland FCA;

3. That Relators be awarded the maximum amount allowed pursuant to the FCA and Maryland FCA;

4. That Relators be awarded all fees, costs, and expenses incurred in connection with this action, including attorneys' fees, costs, and expenses; and

5. That Relators recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Dated: July 1, 2021

/s/ Peter W. Chatfield
Peter W. Chatfield
peter@phillipsandcohen.com
MD Fed. Bar # 06270
Erika A. Kelton
ekelton@phillipsandcohen.com
(*Pro hac vice* motion to be filed)
Matthew Smith
msmith@phillipsandcohen.com
(*Pro hac vice* motion to be filed)
James Wiseman
jwiseman@phillipsandcohen.com
(*Pro hac vice* motion to be filed)
PHILLIPS & COHEN LLP
2000 Massachusetts Ave., NW
Washington, DC 20036
Tel: (202) 833-4567
Fax: (202) 833-1815

Counsel for Relators Veronica Lopez and Timothy Joseph Perry