UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES, ex rel. DR. SUSAN NEDZA, Relator, v. AMERICAN IMAGING MANAGEMENT, INC., Defendant.	Case No. 15-cv-6937 Judge Alonso Magistrate Judge Cox

DEFENDANT'S ANSWER TO THIRD AMENDED COMPLAINT

Defendant American Imaging Management, Inc. d/b/a AIM ("AIM" or "Defendant"), by and through its attorneys, Foley and Lardner LLP, states as follows for its Answer to Relator's Third Amended Complaint ("Complaint") (Dkt. 220), and pleads the affirmative defenses set forth herein. The allegations in the Complaint are denied except to the extent they are expressly admitted below.[1]

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements and claims Defendants and/or their agents or employees caused to be made in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq. ("FCA").

ANSWER: Defendant admits this is a False Claims Act ("FCA") action seeking damages and civil penalties on behalf of the United States of America. Defendant denies the remaining allegations in Paragraph 1.

[1] The Court dismissed Anthem, Inc. from this case on March 26, 2020 (Dkt. 238). Accordingly, the only answering entity is AIM.

2. This *qui tam* case is brought against Defendants AIM and Anthem for knowingly devising and implementing a scheme with the intent and effect of defrauding the federal government in connection with the federally funded Medicare Advantage ("MA") healthcare program, 42 U.S.C. § 1395w-21 *et seq*. Medicare Advantage is a federal government program pursuant to which private health insurance companies ("insurers") contract with the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") to provide health insurance plans ("MA plans"), under a managed care model to Medicare beneficiaries.

ANSWER: Defendant admits Relator brought this action, and that Relator's claims are related to a Medicare Advantage ("MA") healthcare program. Defendant further admits that MA is a federal government program pursuant to which private health insurance companies contract with the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") to provide health insurance plans ("MA plans"), under a managed care model to Medicare beneficiaries. Defendant denies the remainder of the allegations in Paragraph 2.

3. The defining features of MA insurance, and the fundamental requirements for the government MA contract and payment, are (1) that the MA plan provides at least the same scope of coverage Medicare beneficiaries would receive if they were original Medicare participants, and (2) that the insurer makes individualized coverage determinations for the MA plan based on Medicare coverage rules. 42 U.S.C. §§ 1395w-22(a)(1)(A) and (g)(1)(A); 42 C.F.R. § 422.101(a); 42 C.F.R. § 422.112(a)(6)(ii); Medicare Managed Care Manual § 4.10.16. In other words, as a mandatory legal prerequisite to the government entering into contracts with private insurers for MA contracts and payments, the private insurers must certify that they will provide Medicare beneficiaries with at least the same level of coverage as they would receive under the original Medicare fee-for-service program and do so by applying the same rules as would apply in original Medicare.

ANSWER: Defendant denies the allegations contained in Paragraph 3, particularly those regarding Relator's application and characterization of legal terminology, including Relator's characterizations of "defining features" and "mandatory legal prerequisites." The remaining allegations in Paragraph 3 are legal conclusions to which no response is required.

4. AIM and Anthem designed, marketed and implemented a fraudulent scheme that circumvented federal law and provided Medicare beneficiaries in MA plans fewer benefits than they would have received under the original Medicare fee-for-service program.

ANSWER: Denied.

5. As a result of this scheme, dozens of insurers enrolled Medicare beneficiaries in MA plans that provided defective and incomplete Medicare insurance coverage and fraudulently collected the full price for less medical care than required by the Medicare statute. The plans provided less coverage than the United States government contracted and paid for, and less coverage than promised to the more than one million seniors who entrusted their Medicare coverage to the MA plans tainted by this fraud.

ANSWER: Denied.

6. AIM's and Anthem's scheme caused the Government to pay for defective insurance coverage and insurers to wrongly deny over $100 million in necessary medical care for tens of thousands of Medicare beneficiaries. Defendants' fraudulent scheme also caused beneficiaries to be denied potentially life-saving medical procedures that were deemed necessary and ordered by their treating physician. AIM and Anthem did so for no medical reason, but rather, solely to illegally line their own pockets by fraudulently inflating the profits of the insurers who participated in their scheme.

ANSWER: Denied.

7. Defendant American Imaging Management, Inc. (which does business as AIM Specialty Health) ("AIM") contracts with its client insurers to provide what is referred to as "utilization management," a pre-authorization review of requests for coverage of many services requested by medical providers. If AIM denies pre-authorization for a medical procedure, the insurers will not pay for it and the patient then does not receive the medical care in question (or wrongly must pay out of pocket for procedures that can cost thousands of dollars).

ANSWER: Defendant admits that AIM provides utilization management ("UM") services for its clients, and further admits that UM involves a pre-authorization review of requests for coverage before certain services are provided. Defendant denies the remaining allegations in Paragraph 7.

8. Dozens of insurers offering MA plans contracted with AIM for its fraudulently rigged pre-authorization review process. AIM promised the insurers that it would deny requests for coverage of medical care at specific high rates to hit cost savings goals. AIM fulfilled that promise by intentionally structuring its pre-authorization review process to avoid compliance with Medicare's rules and safeguards for beneficiaries. The deal here was simple: the insurers, in effect, paid AIM $5 to deny $15 in care to MA plan beneficiaries. Defendants and the insurers profited, and the patients and the government lost.

ANSWER: Defendant admits that AIM contracts with MA plans to provide UM services. Defendant denies the remaining allegations in Paragraph 8.

9. A lawful pre-authorization review process for MA plans, which properly considers each individual patient and implements Medicare's coverage rules, would result in denial rates for certain services (*i.e.* diagnostic imaging services) between approximately 0.5% and 1.5%. In contrast, according to AIM's internal documentation, the rigged AIM review process resulted in denial rates for those services as high as 5% to 9%.

ANSWER: Denied.

10. AIM used its rigged review process to cheat the federal Government and to deny Medicare beneficiaries benefits equivalent to those under the original Medicare fee-for-service program. The scheme limited benefits without regard to medical judgment or merit and in violation of Medicare coverage rules. AIM employed baseless and wrongful ploys that included the following:

a. Designing and applying intentionally flawed computer algorithms that imposed coverage rules with no medical basis to improperly refuse to approve care.

b. Turning off the computer algorithms entirely for periods of time, resulting in initial denials of all requests for a certain service for a particular MA plan, for *no reason* other than boosting denial rates ("turning off algorithms").

c. Denying care with no medical justification when a provider failed to return a call from AIM within a business day ("case aging").

d. Secretly blocking the receipt of, and thus refusing to review, the full medical information submitted by medical providers by setting AIM fax machines to stop printing medical records after the first 10 pages.

e. Prohibiting AIM staff from making more than one attempt to contact a medical provider for information related to requests for coverage, in clear violation of CMS requirements.

f. **Training and incentivizing AIM employees to improperly deny requests for coverage.**

g. Covering up wrongful denials by falsely representing in written denial letters that Medicare rules had been applied to the determination of coverage, rather than AIM's more restrictive rules, or that the request had been denied on one of AIM's rigged procedural technicalities and not for any medical reason.

ANSWER: Denied.

11. Anthem, the parent company of AIM, was intimately involved in the design and direct approval of AIM's rigged review process. Top Anthem executives decided to perpetrate this fraud to reap the profits not only from AIM's operations, but also from the numerous Anthem-owned insurance companies that operate MA plans.

ANSWER: Denied.

12. As a result of AIM's and Anthem's rigged review process, each insurer provided to the government and Medicare beneficiaries defective and deficient insurance benefits designed to be less than what was available under the original Medicare fee-for-service program.

ANSWER: Denied.

13. Each insurer that used AIM's and Anthem's rigged review process submitted false and fraudulent certification statements to CMS to obtain MA contracts and payments. Each insurer certified to CMS at least annually in the MA contract or "bid" document, and at least monthly with each request for payment, that they provided the same coverage to Medicare beneficiaries as the beneficiaries would receive if they were participants under the original Medicare fee-for-service program. They further certified that they complied with Medicare requirements for making individual coverage determinations. Due to Defendants' rigged review process, these statements and certifications, which were material and necessary prerequisites to obtaining MA contracts and payments, were false and fraudulent.

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 13.

14. Collectively, the insurers that used AIM's fraudulent review process for their MA plans falsely and fraudulently obtained billions of dollars of government premium payments. The government paid for coverage the Medicare beneficiaries did not and could not receive under the AIM pre-authorization review scheme; the Medicare beneficiaries received less medical care than they were legally entitled to; the beneficiaries suffered delay and denial of medical procedures, increased financial costs, inferior medical care, and in many instances, physical and mental suffering; while AIM and its parent company Anthem, and AIM's clients, the insurers offering MA plans, all enjoyed excess and illegal profits.

ANSWER: Denied.

15. The False Claims Act (the "FCA") was originally enacted during the Civil War. Congress substantially amended the Act in 1986 – and, again, in 2009 and 2010 – to enhance the ability of the United States Government to fight fraud. The FCA was amended after Congress found that fraud in federal programs was pervasive and that the FCA, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments would create incentives for individual whistleblowers with knowledge of fraud against the Government (called relators) to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on Government's.

ANSWER: The allegations in Paragraph 15 are legal conclusions and characterizations by Relator to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 15 to the extent they are inconsistent with, or are the Relator's interpretation of, the False Claims Act.

16. The FCA prohibits, inter alia: (a) knowingly presenting or *causing* to be presented to the federal government a false or fraudulent claim for payment or approval; (b) knowingly making or using, *or causing to be made or used,* a false or fraudulent record or statement material to a false or fraudulent claim; (c) *conspiring* to knowingly present or cause to be presented to the federal government a false or fraudulent claim for payment or approval; and (d) knowingly making, using, or *causing to be made or used,* a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government. 31 U.S.C. §§ 3729(a)(1)(A)-(C), and (G). Any person who violates the FCA is liable for a civil penalty of up to $11,000 for each violation

committed on November 2, 2015 or before (and up to $22,927 for each violation committed after November 2, 2015), plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1).

ANSWER: The allegations in Paragraph 16 are legal conclusions and characterizations by Relator to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 16 to the extent they are inconsistent with, or are Relator's interpretation of, the False Claims Act.

17. **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.**

ANSWER: The allegations in Paragraph 17 are legal conclusions and characterizations by Relator to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 17 to the extent they are inconsistent with, or are the Relator's interpretation of, the False Claims Act.

18. **Plaintiff-Relator Dr. Susan Nedza seeks through this action to recover all available damages, civil penalties, and other relief for the FCA violations alleged herein in every jurisdiction to which Defendants' misconduct has extended.**

ANSWER: Defendant admits that Relator seeks to recover damages in this matter, but denies that she is entitled to any. Defendant denies the remaining allegations in Paragraph 18.

II. PARTIES

19. **The Relator, Dr. Nedza, served as Chief Medical Officer and a member of the executive team at AIM from July 2012 until January 2015.[2]Among her other duties, Dr. Nedza oversaw the AIM Clinical Affairs Group and was responsible for development of clinical guidelines and regulatory compliance for Medicare programs, including compliance with Medicare policies and**

[2]Dr. Nedza's allegations describe AIM's and Anthem's fraud as it continued at least through the period of her employment. She does not have knowledge of whether or how the fraudulent practices complained of herein continued thereafter, or were discontinued or changed by AIM and Anthem, either on their own or as a result of detection by and directions from the government.

regulations. Though her position did not involve the day-to-day review of pre-authorization requests, she witnessed firsthand the design of rules, policies and practices calculated to deny care with no medical basis and in violation of the core Medicare requirements. She also personally witnessed the repeated admissions of AIM executives that Defendants were fully aware of the fact that they were illegally violating Medicare coverage rules, and that they did so in search of profits.

ANSWER: Defendant admits that Relator served as AIM's Chief Medical Officer ("CMO") from July 2012 through January 2015. Defendant further admits that Paragraph 19 summarizes some of Relator's responsibilities as CMO. Defendant lacks information sufficient to form a belief about the truth of the remaining allegations in Paragraph 19 or footnote 2, and therefore denies them.

20. Dr. Nedza repeatedly attempted to get AIM to cease these fraudulent practices, and voluntarily terminated her employment with AIM after it became apparent to her that in spite of her efforts, AIM was refusing to stop the systematic fraud on Medicare.

ANSWER: Defendant admits that Nedza resigned from her position at AIM. Defendant denies the remaining allegations in Paragraph 20.

21. Prior to her employment at AIM, Dr. Nedza was Vice President of Strategic Clinical Solutions at Health Circles, LLC, where she served as a member of the executive team and led the clinical team that built evidence-based clinical tools for healthcare providers.[3]From 2008 to 2010, she was Vice President of Clinical Quality and Patient Safety Strategy, and Medical Director, Clinical Practice Solutions, at the American Medical Association.

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 21 or footnote 3.

22. From 2003 to 2008, Dr. Nedza served as the Chief Medical Officer for Region V and as a Medical Officer in the Special Program Office in the United States Department of Health and Human Services ("HHS") at the Centers for

[3]Evidence-based clinical tools are clinical algorithms that enable doctors to effectively and efficiently manage patient care.

Medicare and Medicaid Services ("CMS"). Among her duties was working with insurance companies on Medicare coverage policies.

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 22.

23. Dr. Nedza holds an M.B.A. from the Kellogg Graduate School of Management of Northwestern University and an M.D. from the Stritch School of Medicine at Loyola University.

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 23.

24. Plaintiff the United States of America is the real party in interest in this matter. The United States through HHS administers the Medicare program. Title XVIII of the Social Security Act, 42 U.S.C. §1395-1395lll.

ANSWER: Defendant admits Relator brought this case on behalf of herself and the United States. The remaining allegations in Paragraph 24 are legal conclusions to which no response is required.

25. Defendant AIM is a specialty health benefits management corporation organized under the laws of the state of Illinois. AIM is a wholly-owned subsidiary of Defendant Anthem. AIM makes health insurance coverage determinations in the areas of radiology, cardiology, oncology, specialty drugs, and sleep medicine for over 48 health plans with approximately 38 million covered members.

ANSWER: Defendant admits that AIM is a specialty health benefits management corporation organized under the laws of the state of Illinois. Defendant denies the remaining allegations in Paragraph 25.

26. Defendant Anthem is a health benefits company organized under the laws of the state of Indiana. Anthem is AIM's parent company (since 2007) and is the parent company of National Government Services, a Medicare Administrative Contractor ("MAC") hired by CMS to perform certain services, including writing regional guidelines for Medicare coverage called Local Coverage Determinations ("LCDs"). Anthem serves approximately 73 million

individuals through its affiliated companies, including more than 40 million individuals enrolled in one of its health insurance plans. One in eight Americans receives coverage for their medical care through Anthem's affiliated plans.

ANSWER: Defendant admits that Anthem is a health benefits company organized under the laws of the state of Indiana, and that Anthem is AIM's parent company. Defendant lacks information sufficient to form a belief about the truth of the remaining allegations in Paragraph 26.

27. **Anthem is also the parent company of the following insurers that hired AIM to increase profits in MA plans by utilizing the rigged AIM review process: Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Health Plans, Inc. (serving Connecticut), Anthem Insurance Companies, Inc. (serving Indiana), Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross and Blue Shield Healthcare Plan of Georgia, Community Insurance Co. (serving Ohio), Compcare Health Service Insurance Corp. (serving Wisconsin), Empire Healthchoice HMO, Inc., Empire Healthchoice Assurance, Inc., HMO Colorado, Inc., and HMO Missouri, Inc. Insurers that used AIM's rigged review process for their MA plans also include non-Anthem insurers such as Blue Cross of Idaho Care Plus, Inc., Blue Cross Blue Shield of Michigan Mutual Insurance Company ("BCBS Michigan"), Blue Cross and Blue Shield of North Carolina ("BCBS North Carolina"), Health First Health Plans, Inc., Moda Health Plan, Inc., Priority Health, Providence Health Plan, Providence Health Assurance, Regence Bluecross Blueshield of Oregon, Regence Bluecross Blueshield of Utah, Regence Blueshield, Regence Blue Shield of Idaho, Asuris Northwest Health, and Pacificsource [sic] Community Health Plans.**

ANSWER: Denied.

28. **The insurers engage in the business of participating in the Medicare Advantage program and selling MA insurance plans to persons eligible for Medicare. The overwhelming majority of revenue, if not the entire revenue, generated by each MA plan is from federal government payments from CMS and premiums paid by Medicare beneficiaries. Every insurer annually certifies that its MA plan is in compliance with Medicare coverage requirements and, based upon that certification, requests payment from the government in an amount set for each beneficiary, each month (called a "capitation payment").**

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 28.

III. JURISDICTION AND VENUE

29. 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 specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

ANSWER: Paragraph 29 consists of legal conclusions to which no response is required. To the extent a response is required, Defendant admits this Court has jurisdiction over this action.

30. Venue is proper in this district under 31 U.S.C. § 3732(a) because AIM transacts business in this district and committed a number of the acts complained of in this district.

ANSWER: Paragraph 30 consists of legal conclusions to which no response is required. To the extent a response is required, Defendant admits this Court has venue over this action. Defendant denies the remainder of Paragraph 30.

31. Although the issue is no longer jurisdictional after the 2009 amendments to the FCA, to Relator's knowledge, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e). To the extent there may have been a public disclosure under 31 U.S.C. § 3730(e), Relator is the original source of the allegations herein because: (1) prior to any public disclosure, she voluntarily disclosed to the government the information on which her allegations are based; and (2) she has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions, and she voluntarily disclosed that information to the United States Attorney for the Northern District of Illinois before filing, in accordance with 31 U.S.C. § 3730(b)(2).

ANSWER: Denied.

IV. LEGAL FRAMEWORK

A. The Medicare Program[4]

32. Medicare is a federally-funded health insurance program that covers certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

ANSWER: Admitted.

33. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

ANSWER: Admitted, except Defendant denies that any Part of Medicare covers all medical costs or services.

34. "Original Medicare" (Parts A and B) operates on a "fee-for-service" basis, meaning CMS pays hospitals and physicians for each covered service they provide to a Medicare beneficiary.

ANSWER: Admitted.

35. Medicare Part C provides the same benefits to Medicare beneficiaries as original Medicare, but does so under a managed care model, rather than the traditional fee-for-service model. Under Part C, rather than pay providers for each medical service or procedure, Medicare pays private managed care insurance plans (known as "Medicare Advantage" or "MA" plans) a capitation payment (a fixed amount per member per month) and those plans are responsible for paying providers for services. The monthly capitation rate is based on the beneficiary's geographic location, income status, gender, age, and health status.

[4] Defendant provides no responses to headings throughout its Answer as it does not construe headings as numbered allegations but rather mere organization.

ANSWER: Admitted, except Defendant denies Paragraph 35 to the extent it alleges Medicare Part C provides benefits without first applying UM, or that Medicare Part C provides the same benefits to Medicare beneficiaries as original Medicare.

B. Medicare Advantage Program Requirements, Contracts, and Payments

36. Insurers profit from MA plans by keeping the healthcare costs they pay lower than the amount the government pays. Under Medicare Advantage, insurers are required to "assume the full financial risk" for the cost of required care. 42 U.S.C. §1395w-25(b). Accordingly, the more medical care that is denied, the greater the profit realized by the plan.

ANSWER: The allegations in Paragraph 36 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations. Defendant further denies Relator's allegation that the more medical care that is denied, the greater the profit realized by the plan.

37. To prevent the insurers from engaging in improper denial of care for the sake of profits, all MA plans must (1) pay for all the medical care that would be covered under original Medicare, and (2) make fair individualized coverage determinations based on Medicare's own coverage rules. These twin requirements are the core of the MA program.

ANSWER: The allegations in Paragraph 37 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

38. Accordingly, CMS assures Medicare beneficiaries that they are not trading away their valuable Medicare rights by signing up for Medicare Advantage. CMS promises Medicare Advantage participants that "1. You're still in the Medicare Program; 2. You still have Medicare rights and protections; 3. You still get complete Part A and Part B coverage through the plan." CMS also assures seniors and other Medicare beneficiaries that "Medicare Advantage

Plans cover all Medicare services" and the MA "companies must follow rules set by Medicare."[5]

ANSWER: Defendant admits that Relator quotes selections from Medicare.gov as referenced in Footnote 3. The remaining allegations in Paragraph 38 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 36 and footnote 5, including to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

39. Further, as discussed in detail below, to get an MA contract, participate in the MA program each year, or claim a single monthly MA payment, each insurer certifies to CMS that it will act in compliance with the twin core requirements of MA.

ANSWER: Defendant admits that MA plans must certify their compliance with certain CMS guidelines in order to participate in the MA system. The remaining allegations in Paragraph 39 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

40. MA plans thus, by definition, must provide full coverage of Medicare benefits according to the "Basic Benefit Requirement" of Medicare and make individualized coverage determinations. These two requirements define an MA plan; they are what the insurers certify to CMS; and what CMS promises to MA beneficiaries.

ANSWER: Denied.

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[5]Medicare.gov, Things to know about Medicare Advantage Plans, *available at* www.medicare.gov/sign-up-change- plans/types-of-medicare-health-plans/things-to-know-about-medicare-advantage-plans and Medicare.gov, How do Medicare Advantage Plans work?, *available at*, www.medicare.gov/sign-up-change-plans/types-of-medicare-health- plans/medicare-advantage-plans/how-do-medicare-advantage-plans-work. *See also* Medicare.gov, What's a Medicare Advantage Plan? at 2 ("Medicare Advantage Plans must cover all of the services that Original Medicare covers except hospice care."), *available at*www.medicare.gov/Pubs/pdf/11474.pdf.

2. Requirement 1: MA plans must provide the benefits provided by original Medicare.

41. The Basic Benefit Requirement of the Medicare Advantage program is that MA plans must provide beneficiaries with all of the services and benefits provided under original Medicare. 42 U.S.C. § 1395w–22(a)(1)(A). Thus, MA plans, like original Medicare, must provide all services and benefits that are "medically necessary" as defined by Medicare. 42 U.S.C. § 1395w–27(g)(1). Medicare beneficiaries are entitled to health care services that are "reasonable and necessary for the diagnosis or treatment of illness or injury" and some preventive services. 42 U.S.C. § 1395y(a)(1); CMS, Medicare Managed Care Manual § 4.10.2. This includes diagnostic imaging services. 42 U.S.C. § 1395x(s)(2)(C).

ANSWER: The allegations in Paragraph 41 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

42. CMS further defines what is "reasonable and necessary" healthcare for Medicare coverage through national rules—called National Coverage Determinations ("NCDs"), 42 U.S.C. §§ 1395y(l), 1395ff(f)(1)(B); 42 C.F.R. § 422.101(b)(1)—and regional rules called Local Coverage Determinations ("LCDs"), 42 U.S.C. § 1395ff(f)(2)(B); 42 C.F.R. § 422.101(b)(3). CMS hires Medicare Administrator Contractors, including one of Anthem's subsidiaries, to perform a number of services, including writing LCDs.

ANSWER: The allegations in Paragraph 42 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

43. An MA plan must make coverage decisions in compliance with NCDs, LCDs, and all "Medicare manuals and instructions." 42 U.S.C. § 1395y(l); 42 C.F.R. § 422.101(b)(1) - (b)(3); 42 C.F.R. § 422.109. See also CMS, Medicare Program Integrity Manual, Ch. 13.

ANSWER: The allegations in Paragraph 43 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

44. MA plan coverage decisions thus must be based on "coverage criteria no more restrictive than original Medicare's national and local coverage policies" and must consider "the enrollee's medical history." CMS, Medicare Managed Care Manual, § 4.10.16. Any service "must be covered by every MA plan" if "coverage is consistent with general coverage guidelines included in original Medicare regulations, manuals and instructions." CMS, Medicare Managed Care Manual, § 4.90.1.

ANSWER: The allegations in Paragraph 44 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

3. Requirement 2: Insurers and pre-authorization review programs must process MA plan coverage requests based on complete information about an individual's medical situation and Medicare coverage rules.

45. Insurers must make appropriate individualized determinations of MA coverage based on Medicare coverage rules. 42 C.F.R. § 422.566(a); 42 U.S.C. § 1395w-22(g). Procedures for MA plans must provide "individual medical necessity determinations." CMS, Medicare Managed Care Manual, § 4.10.16; 42 C.F.R. § 422.112(a)(6)(ii) (The written standards for an MA plan, including for "utilization management," must "allow for individual medical necessity determinations"). Coverage decisions must also fully consider "the enrollee's medical history." CMS, Medicare Managed Care Manual, § 4.10.16.

ANSWER: The allegations in Paragraph 45 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

46. While CMS does not forbid pre-authorization reviews in the MA program, Medicare requirements prohibit a rigged pre-authorization process (*i.e.*, the type of pre- authorization system Defendant AIM provides) that is intended to limit or be a barrier to care. MA "plans may not implement utilization management protocols that create inappropriate barriers to needed care." CMS, Medicare Managed Care Manual, § 4.110.1.1. See also 42 C.F.R. § 422.112(a)(6)(ii).

ANSWER: Defendant admits that CMS authorizes the use of UM and pre-authorization reviews in the MA program. The remaining allegations in Paragraph 46 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations, including to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

47. Further, whenever an insurer "expects to issue a partially or fully adverse medical necessity … decision," Medicare's coverage guidelines require that the decision "must be reviewed by a physician or other appropriate health care professional" familiar with "Medicare coverage criteria" before such a decision is issued. 42 C.F.R. § 422.566(d). In other words, prior to any denial of care to an MA beneficiary, an approved medical professional must make sure that the individual denial is appropriate under Medicare rules.

ANSWER: The allegations in Paragraph 47 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

4. Medicare Advantage contracts and payments.

48. To obtain an MA contract with CMS—and to participate in the MA program— each insurer must certify to CMS as material terms of their agreement that the proposed MA plan complies with the Basic Benefit Requirement of the Medicare Advantage program, 42 U.S.C. § 1395w–22(a)(1)(A), and that they make proper individualized determinations of Medicare coverage, whether or not the plan uses a pre-authorization review program, 42 C.F.R. § 422.112(a)(6)(ii); 42 C.F.R. § 422.566(a); 42 U.S.C. § 1395w-22(g).

ANSWER: Defendant admits that MA plans must certify their compliance with CMS guidelines in order to participate in the MA system. The remaining allegations in Paragraph 48 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

49. Insurers must certify that the proposed MA plan will be operated in compliance with the Medicare statute, Medicare regulations, and all Medicare non-regulatory guidance, procedures, and policies regarding coverage and treatment of beneficiaries. 42 U.S.C. § 1395w- 27; 42 C.F.R. § 422.101; 42 C.F.R. § 422.504(a). Compliance with these "requirements and conditions" is expressly "material to performance of the contract" between CMS and the MA plans. 42 C.F.R. § 422.504(a); 42 U.S.C. § 1395w-27.

ANSWER: Defendant admits that MA plans must certify their compliance with CMS guidelines in order to participate in the MA system. The remaining allegations in Paragraph 49 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations. Defendant particularly denies the compliance characterized in Paragraph 49 is "material" as that term is used in the False Claims Act and interpretive law.

50. Insurers offering MA plans must further explicitly certify compliance with the "False Claims Act." 42 C.F.R. § 422.504(h)(1).

ANSWER: The allegations in Paragraph 50 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

51. These certifications are made in each MA plan contract and annual "bid package," which also specify the services the insurer pledges the MA plan will provide. At a minimum this must include all Medicare services. 42 U.S.C. § 1395w-27. 2016 MA Contract Template ("MA Contract," *attached as* Exhibit 1); CY 2016 Benefit Attestation ("Benefit Attestation," Attachment C to the MA Contract and *attached as* Exhibit 2). CMS then pays the monthly capitation payments based on the annual MA plan bids.

ANSWER: Defendant admits that MA plans submit a bid to CMS in order to participate in the MA program. The remaining allegations in Paragraph 51 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

52. In the MA contracts with CMS, for example, each insurer certifies:

a. **That its MA plans will operate "in compliance with the requirements of this contract and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.)."**

b. That the insurer will provide "enrollees in each of its MA plans the basic benefits as required under 42 C.F.R. § 422.101."

c. For "Beneficiary Protections," that each plan complies "with all requirements in 42 C.F.R. O Part 422, Subpart M governing [individualized] coverage determinations."

d. That all MA plan services will be provided "in a manner consistent with professionally recognized standards of health care." Exhibit 1, MA Contract at RESP0002-03.

ANSWER: Defendant admits the allegations in Paragraph 52 provide quotes from a purported MA contract with CMS, and that document speaks for itself. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

53. Similarly, each year each insurer submitted an MA bid for each proposed MA plan, and a "Plan Benefit Package" that detailed the terms on which its MA Plan would operate. 42 C.F.R. § 422.254(a); Exhibit 1, MA Contract, RESP0002. This bid submission includes an "[a]ttestation that the bid(s) are in compliance with the applicable laws, rules, CY2018 bid instructions, and current CMS guidance."[6]That submission also included a "Medicare Advantage Plan Attestation of Benefit Plan and Price," in which the insurer's CEO, CFO, or a direct-report designee re-certified, every year, that:

> "I further attest that these benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations and program guidance that CMS has issued to date and will issue . . . [including] the Medicare Prescription Drug Benefit Manual, the Medicare Managed Care Manual, and the CMS memoranda issued through the Health Plan Management System." Exhibit 2, Benefit Attestation at RESP0031.

ANSWER: Defendant admits that MA plans submit a bid to CMS in order to participate in the MA program. Defendant further admits the allegations in Paragraph 53 provide quotes from a purported MA contract with CMS and www.cms.gov, and those documents speak for themselves. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

54. Insurers also certify that MA plans are in compliance with these core Medicare requirements in each monthly request for payment. Each month, as a prerequisite to receiving the capitation payments, the insurer must certify and submit to CMS the number of beneficiaries enrolled in the MA plan and to whom it provided all benefits promised in its annual bid package. *See* Attestation of Enrollment Information (Exhibit 1, MA Contract at RESP0008-09, 0026, "Attachment A") and Attestation of Risk Adjustment Data (Exhibit 1, MA Contract at RESP0008-09, 0027, "Attachment B").

ANSWER: Defendant admits the allegations in Paragraph 54 provide quotes from a purported MA contract with CMS, and that document speaks for itself. To the extent a response is required,

[6]CY2018 Medicare Advantage "Bid Price Tool" instructions, *available at* www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Pricing-Tools-and-Instructions-Items/BPT2018.html (download "CY2018 Bid Tools and Instructions") (defining the applicable law as the Medicare statute and applicable "rules" as the Medicare regulations "42 CFR Parts 400, 403, 411, 417, 422, and 423").

Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

55. The capitation payments are the government payments that Defendants "claim" from CMS each month. Exhibit 1, MA Contract RESP0026-27, Attachments A and B ("the MA Organization hereby requests payment.") The monthly request for payment expressly states the number of beneficiaries for whom the MA plan provided coverage for all of the services listed in that MA plan's annual bid package (as identified by the MA plan identification number), and thus represents that the MA plan provided all required and promised services.

ANSWER: Defendant admits that MA plans receive monthly capitation payments from the government, but specifically denies Relator's characterization that these are "claims." The remaining allegations in Paragraph 55 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

56. The MA payment claim form includes: (a) the plan identification number (corresponding to the package of services promised in the plan's annual bid submission); (b) the enrollment count of individuals for whom the plan provided required services for the month; and (c) a certification by the insurer that:

> **each enrollee for whom the organization is requesting payment is validly enrolled in an MA plan offered by the organization and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.**

42 C.F.R. § 422.504(l)(1). *See* Exhibit 1, MA Contract at RESP0026, Attachment A. In determining payment, CMS thus relies upon the representations made by the insurer in the MA plan bid package, including that the coverage is fully compliant with Medicare coverage requirements. These certifications with the "requests for payment under the [MA] contract," are explicitly designated as "a condition for receiving a monthly [MA] payment." 42 C.F.R. § 422.504(l). The monthly payment from CMS is thus based on the representation by the insurer that it provided all services

promised in its MA contract, and in compliance with all Medicare coverage rules.

ANSWER: Defendant admits the allegations in Paragraph 56 provide quotes from a purported MA contract with CMS, and that document speaks for itself. Defendant denies that CMS relies upon, or makes payments based upon, representations made in the MA plan bid package. The remaining allegations in Paragraph 56 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

57. AIM likewise is bound to comply with the mandatory Medicare Advantage requirements. AIM contracted with the insurers to review and make coverage determinations for their MA plans. Accordingly, as an MA subcontractor (a "first tier," "downstream" or "related entity" under the Medicare regulations), AIM was also required to perform "in accordance with ... with the MA [plan's] contractual obligations" to CMS and to "comply with all applicable Medicare laws, regulations, and CMS instructions." 42 C.F.R. § 422.504(i)(3) – (i)(4).

ANSWER: Defendant admits that it is subject to CMS regulations, and that Defendant contracted with MA plans to provide UM. The remaining allegations in Paragraph 55 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

5. The insurer certifications are required to obtain payment under the Medicare statute.

58. If an insurer did not truthfully certify, and abide by, the Basic Benefit Requirement of Medicare coverage then they were in violation of the requirements under which CMS enters into an MA contract or pays an insurer. 42 U.S.C. § 1395w-22(a)(1)(A); 42 U.S.C. § 1395w-27. See also 42 C.F.R. Part 422, Subpart K §§ 422.500-527.

ANSWER: The allegations in Paragraph 58 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

59. If CMS had known that a MA plan's contract and bid falsely assured that it would provide at least the care provided by original Medicare, when the insurer planned to provide lesser and defective insurance than CMS contracted for, CMS would not have contracted with the insurer for that MA plan.

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 59, and therefore denies them.

60. And if CMS had known that an insurer lied to CMS about MA plan coverage, and provided, in any given month, lesser and defective insurance than CMS contracted for, CMS would not have paid that insurer for the MA plan.

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 60, and therefore denies them.

V. FACTUAL ALLEGATIONS OF FRAUD

A. AIM promised to deny medical care and increase the profits of the MA plans.

61. The insurers hired AIM to cut costs and increase profits by denying care to Medicare beneficiaries covered by their MA plans. AIM's sales pitch and business model was simple. AIM promised, upon pain of financial penalty, to deliver savings on the cost of MA plan medical coverage. Every month, AIM reported to each of its insurer clients the number of procedures denied and the amount of dollars saved for its MA plans.

ANSWER: Defendant admits that it contracted with MA plans to provide pre-authorization UM services. Defendant denies the remaining allegations in Paragraph 61.

62. In AIM's marketing to prospective clients, and in many of its contracts with insurers for their MA plans, AIM promised to deny requests at specific rates to hit cost savings goals. AIM knew that the targeted denial rates and cost

savings could not be achieved without wrongly denying coverage in violation of Medicare requirements.

ANSWER: Denied.

63. AIM routinely ensured the insurers that the MA plan cost savings they realized would be at least a multiple of the cost of AIM's services. AIM also agreed to hold harmless certain insurers for any shortfall in the guaranteed MA plan cost savings.

ANSWER: Defendant admits that it contracted with MA plans to provide UM services with the goal of reducing the amount of procedures that were not medically necessary. Defendant denies the remaining allegations in Paragraph 63.

64. To win MA plan business, AIM promised concrete cost savings tied to denial rates as high as 5%-9%. AIM, however, knew that if it complied with Medicare requirements, the denial rate would be much lower. AIM knew, for example, that the Medicare compliant denial rate for diagnostic imaging services would have been only 0.5% to 1.5%.

ANSWER: Denied.

65. AIM's general business model was to deny coverage requests, regardless of merit or medical need, to meet denial rate targets. This is especially true for the lucrative MA plan clients, whom AIM charged as much as three times the rate it charged non-MA, commercial plans for its services.

ANSWER: Denied.

66. As far as Dr. Nedza is aware, AIM never failed to meet a contractual denial target for any MA plan of any insurer.

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 66 as it relates to Relator's knowledge. Defendant denies the remaining allegations in Paragraph 66, and specifically denies there was a "contractual denial target."

B. Overview of AIM's rigged review process.

67. AIM's rigged review process worked basically as follows: (1) A treating doctor or other medical provider sent AIM a request for pre-authorization for insurance coverage (insurance approval before the medical service is provided); (2) AIM decided whether the insurer should approve or deny the pre-authorization request for the MA plan; AIM denied many requests on the basis of fraudulently designed procedural technicalities—with no medical review or justification—and in other cases determined coverage based on its own coverage criteria, which were designed to increase denials not to follow Medicare coverage rules; (3) AIM communicated its determination to the insurer, medical provider, and/or the MA beneficiary; (4) The insurer then adopted AIM's decision and approved or denied the request accordingly.

ANSWER: Denied.

68. Among other medical procedures, AIM reviewed MA plan coverage requests for: Computerized Tomography ("CT"), Echocardiography, Magnetic Resonance Angiograms ("MRA"), Magnetic Resonance Imaging ("MRI"), and Positron Emission Tomography ("PET") scans, and sleep studies.

ANSWER: Admitted.

69. When a request for approval passed through AIM's rigged review process it did so in three steps, none of which followed the mandated Medicare requirements or provided full MA coverage.

ANSWER: Denied.

70. First, a medical provider submitted a request with basic information to AIM either via telephone to one of AIM's three call centers or online through AIM's Provider Portal. At this step, AIM reviewed requests using a crude computer algorithm that did not utilize Medicare coverage rules and was incapable of making individualized determinations of medical appropriateness. AIM engineered the algorithm to optimize denials, but its unsophisticated nature made it difficult to calibrate. When AIM failed to hit predetermined denial rate targets, AIM simply switched off the algorithm and initially denied all requests.

ANSWER: Defendant admits that it received information from medical providers to inform Defendant's UM process and make a pre-authorization determination. Defendant denies the remaining allegations in Paragraph 70.

71. Second, when a request was denied at step one, the medical provider had to speak with an AIM nurse reviewer. But AIM constructed procedural barriers to prevent this communication, thereby increasing denials without regard to medical necessity. Nurse reviewers were instructed to make a single attempt to contact the medical provider. If a provider failed to respond within a day, the request was automatically denied. If the medical provider tried to submit patient records to justify a request, AIM's fax machines were secretly and arbitrarily set to shut off after receiving ten pages, reducing the chance that the relevant information would reach the reviewer.

ANSWER: Defendant admits that initial denials could prompt further review by one of Defendant's nurse reviewers in consultation with beneficiaries' medical providers. Defendant denies the remaining allegations in Paragraph 71.

72. If a provider managed to speak to a nurse reviewer and provide more information, the reviewer evaluated the request using the step one algorithm as well as what AIM referred to as its "MD/RN tool." The "tool" was a set of AIM's internal coverage rules and any plan- specific policies on AIM's intranet, and did not include Medicare coverage rules. AIM's nurse reviewers thus again evaluated requests without relying on the Medicare coverage rules.

ANSWER: Defendant admits that at one point it used a tool referred to as the "MD/RN tool" that incorporated coverage rules. Defendant denies the remaining allegations in Paragraph 72.

73. Third, when a request for pre-authorization was not approved by the nurse reviewer, the medical provider had to speak with one of AIM's physician reviewers, navigating the same procedural roadblocks to do so. The physician reviewer again considered the request relying on the AIM's internal guidelines in the MD/RN tool rather than the Medicare coverage rules. At this step, if the request was not approved, AIM formally denied pre-authorization.

ANSWER: Defendant admits that any request initially denied was required to be reviewed by one of Defendant's physician reviewers, which would include an opportunity for the beneficiaries' medical providers to speak with one of the Defendant's physician reviewers. Defendant denies the remaining allegations in Paragraph 73.

74. When AIM denied pre-authorization for a medical procedure, the MA plan likewise denied pre-authorization. Without pre-authorization, the Medicare

beneficiary was denied Medicare coverage for the medical procedure deemed necessary by the beneficiary's treating physician and denied without regard to the applicable Medicare rules.

ANSWER: Defendant is without sufficient knowledge to form a belief about the truth of whether MA plans adopted Defendant's recommendations. Defendant denies the remaining allegations in Paragraph 74.

C. Mechanics of fraud: how the Defendants' scheme intentionally and wrongly denied requests for medical care.

75. Throughout the pre-authorization review process, AIM used numerous fraudulent and unlawful practices and tactics to drive down approvals and drive up profits. AIM denied numerous requests for review on baseless and indefensible procedural excuses—entirely unrelated to medical necessity. Separately, when a request was actually considered on the medical merits, AIM applied restrictive coverage rules that contravene Medicare requirements.

ANSWER: Denied.

2. Without any medical basis, AIM periodically categorically refused to approve requests solely to increase denials and hit profit targets.

76. When AIM's rigged pre-authorization review process failed to produce enough denials, AIM had a procedure to categorically declined to approve requests with no review of medical merit in order to increase denial rates.

ANSWER: Denied.

77. As alleged above, normally the first step in AIM's rigged review process was to use its algorithms to evaluate a request with the basic information a provider submitted online or via the call center. Requests that did not meet AIM's restrictive criteria and satisfy AIM's crude algorithms were not approved and were subjected to additional review; the provider had to speak with a nurse reviewer about the specific patient and medical needs.

ANSWER: Denied.

78. To ensure it met the contractual guarantees of pre-determined denial rates and cost savings, AIM monitored the denial rates by type of procedure and by client MA insurance plan on a weekly basis. Weekly reports included the

"WOT Transfer and Impact Rate" and "Impact and Transfer Trend" reports, run for each client, each week. If the internal reports indicated that AIM was not denying a sufficient number of requests to a hit contractual target for a particular plan, AIM executives ordered that AIM categorically decline to approve all requests for a specific diagnostic procedure for that specific MA plan (e.g., all CT scans for a specific plan). The instruction to categorically withhold approval of requests came directly from AIM's top leadership, including Chief Operating Officer Randy Hutchinson, Sr. Vice President Dr. Julie Thiel, and/or Chief Strategy Officer Michael Backus. Upon directions from AIM's executive officers, the AIM computer algorithm was turned off, and AIM refused to approve entire categories of requests for pre-authorization in the first step of its rigged review process. Rather than AIM's typical first step approval rate of 70-80%, every request was denied, and put in the long queue for AIM nurse review, regardless of medical appropriateness. AIM referred to this process as "implement 100% transfers" or "turn off approvals."

ANSWER: Defendant admits that it tracked denial rates resulting from its UM process. Defendant denies the remaining allegations in Paragraph 78.

79. **AIM's sole basis for turning "off" the algorithm was to increase denial rates in order to meet contractual denial targets. Although some requests were ultimately approved upon further review, the blanket "turn off" significantly increased denials by imposing additional steps and delay without any medical basis whatsoever. This manipulation of the rigged review was done without regard to medical necessity, patient safety, or Medicare requirements and solely to meet AIM's contractually promised denial rates.**

ANSWER: Denied.

80. **Moreover, from at least 2012 until at least early 2015 (when Dr. Nedza left AIM), AIM worked to develop more complex algorithms that would allow for a more sophisticated implementation of denials. AIM sought to replace the crude process of turning the algorithms off completely with a refined algorithm "thermostat" that would be set to meet specific contractual targets for denial of requests for each test, for each client, with no consideration of medical appropriateness, patient safety, or Medicare coverage rules. It was an effort to create a more automatic implementation of this fraud.**

ANSWER: Defendant admits that it developed and implemented changes to its UM process and associated algorithms from 2012 through 2015. Defendant denies the remaining allegations in Paragraph 80.

81. By the time Dr. Nedza left AIM in early 2015, AIM had yet to implement the new algorithms with "thermostat" controls, but it continued to pay outside contractors to work on it.

ANSWER: Denied.

82. Even without "thermostat" controls, AIM's algorithms were designed to manipulate the review process to increase denials and profits. AIM's algorithms were crude and limited applications. They could only handle questions with "yes" or "no" responses, calculate simple scores, and process three questions for any particular request (an initial question and two follow up questions about the condition of the patient). This was inadequate to properly implement even the AIM Guidelines, let alone the Medicare rules for coverage, or to determine medical appropriateness on an individualized basis.

ANSWER: Denied.

83. Moreover, AIM's algorithms were written and updated by staff with no medical background or experience, and AIM intentionally failed to subject the computer algorithms to any testing to evaluate any degree of compliance with the Medicare coverage rules.

ANSWER: Denied.

84. Despite knowing the limitations of its computer algorithms and that they were not based on Medicare coverage rules, AIM continued to use them to deny requests and subject medically justified and Medicare-covered requests to further delay and review where they could be weeded out and denied through additional methods.

ANSWER: Denied.

85. Thus, whether the AIM algorithms were turned on to improperly screen requests for denial, or turned off so that no requests were initially approved, the first stage of AIM's review was rigged to wrongfully prevent Medicare beneficiaries from obtaining medical care and cause MA plans to provide defective insurance, and violated numerous Medicare requirements by erecting "inappropriate barriers to needed care." CMS, Medicare Managed Care Manual, §4.110.1.1 (2016).

ANSWER: Denied.

3. Without any medical basis, AIM used secret, arbitrary deadlines to deny requests for "case aging" rather than upon any medical merit or need.

86. AIM also fraudulently increased denials with a processing rule that arbitrarily denied requests whenever a medical provider failed to respond to an inquiry from AIM within one business day. AIM intentionally did not disclose this processing rule to providers or beneficiaries of MA plans in order to maximize its negative impact on the requests. AIM referred to this secret policy as "case aging." If the medical provider failed to return a call from AIM within one business day, AIM simply had the pre-authorization request denied by one of its staff physicians without review.

ANSWER: Defendant admits that requests for pre-authorization would eventually be denied if a medical provider did not provide sufficient information to approve the request within the required case turn-around time. Defendant denies the remaining allegations in Paragraph 86.

87. AIM's leadership, specifically including CEO Brandon Cady, endorsed the secret "case aging" rule as an inexpensive and effective way to increase denials. Denying requests based on this undisclosed and unjustified basis provided a significant cost savings for AIM and increased profits at the expense of patient care. Denials based on the arbitrary and secret "case- aging" policy violated the key Medicare requirement that insurers operating MA plans make individualized determinations based on medical necessity and appropriateness. 42 C.F.R. §422.112(a)(6)(ii); 42 C.F.R. § 422.566(d); CMS, Medicare Managed Care Manual, § 4.10.16 and § 13.40.1.1. Such denials also contradicted Medicare's requirement that insurers make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the medical provider of the MA plan beneficiary to make coverage determinations. CMS, Updated Guidance on Outreach for Information to Support Coverage Decisions (February 22, 2017). This so-called "case aging" policy would have been in violation of these Medicare rules even if it had been disclosed to the medical providers. The fact that it was kept secret makes clear that it was designed to manufacture false denials of requests for proper Medicare covered procedures.

ANSWER: Denied, and Defendant specifically denies Relator's characterization of the law.

88. AIM went even further in its efforts to maximize the fraudulent impact of its secret "case aging" rule. In addition to keeping the denial policy secret, AIM also prohibited its nurse and physician reviewers from making more than one contact to a medical provider to get additional information related to a pre-authorization request. Like "case aging," the "one contact limit" rule was kept

secret from the medical providers. The secret "one contact limit" policy flatly contradicted Medicare's requirement that insurers make "reasonable and diligent efforts to obtain all necessary medical records and other pertinent information within the required time limits." CMS, Medicare Managed Care Manual § 13.70.7.1; CMS, Best Practices and Common Findings Memo #2 from 2012 Program Audits, (July 30, 2013) (criticizing insurers that operate MA plans where they "failed to conduct appropriate outreach to obtain needed medical documentation" and requiring "at a minimum 2 attempts to contact a provider's office during the provider's business hours on 2 different days and at different times of the day" for appropriate outreach); CMS, Updated Guidance on Outreach for Information to Support Coverage Decisions (February 22, 2017).

ANSWER: Denied, and Defendant specifically denies Relator's characterization of the law.

89. AIM was well aware that this one-call policy violated Medicare requirements. On November 14, 2014, Jennifer Dullum, AIM's Vice President of Compliance, wrote that AIM staff "currently make one call out for Medicare Advantage (MA) cases." Ms. Dullum identified four prior instances by specific date going back to 2012, where CMS indicated that such policies and practices violate Medicare requirements, and that MA plans must try to contact beneficiaries multiple times. Nonetheless, AIM continued the knowingly illegal policy in order to fraudulently boost denials of requests for pre-authorization from medical providers.

ANSWER: Defendant denies the allegations contained in the first sentence of Paragraph 89. The allegations in the second and third sentences of Paragraph 89 purport to quote or characterize the contents of a document, the contents of which speak for themselves. Defendant denies the remaining allegations contained in Paragraph 89.

90. Fraudulent "case aging" denials were enhanced by AIM rules that medical providers be kept in the dark about AIM's procedures and that prohibited its own staff from more than a single contact with medical providers. These procedures and rules violated the patients' rights to fair and full review, denied requests for indefensible reasons unrelated to medical merit, and contravened Medicare's physician review rules. These policies were, however, very effective in achieving their fraudulent goal of increasing the care denied in MA plans and causing them to provide materially less insurance coverage than required by law and purchased by CMS.

ANSWER: Denied.

4. Without any medical basis, AIM systematically, arbitrarily, and secretly curtailed the submission and review of patient medical information.

91. AIM implemented another secret processing rule that maximized denials by limiting the information that its own reviewers were provided about requests. Medical providers often submitted medical documentation in support of requests to AIM by facsimile. Review of this documentation was often necessary to evaluate the propriety of the request. Beginning in about 2012 or 2013, AIM set an arbitrary and undisclosed limit of ten pages that it would receive from medical providers via facsimile. After ten pages, the fax machines at AIM simply stopped printing the incoming medical records, so the complete record was not received. As a result, critical medical information was often not included in AIM's review. Further, because the ten- page limit was kept secret from the medical providers, like AIM's other rigged review policies, the medical providers could not even choose to send in the ten most relevant pages from their patients' medical records.

ANSWER: Denied.

92. AIM's refusal to consider medical documentation beyond the first ten pages of a patient's medical record allowed AIM to deny pre-authorization requests for lack of information that had in fact been sent by the requesting providers, and violated AIM's duty to make individualized coverage determinations based on an individual patient's medical history. CMS, Medicare Managed Care Manual, § 4.10.16. It also violated the Medicare requirement that insurers use a fair process to make MA plan coverage decisions based on medical need. 42 C.F.R. § 422.566(a); 42 U.S.C. § 1395w-22(g). And it was a flagrant violation of the requirement that a decision be based on "all relevant documentation that is submitted with the claim." 42 C.F.R. § 410.32.

ANSWER: The allegations in Paragraph 92 include legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, denied.

93. AIM's secret processing rule that arbitrarily limited the review of medical documentation furthered AIM's scheme to improperly deny coverage to MA beneficiaries that should have been provided under Medicare requirements and fraudulently allowed the insurers to provide less MA plan coverage than the government purchased.

ANSWER: Denied.

5. Even when it considered the medical merits of a request, AIM denied coverage based on restrictive internal rules, while ignoring Medicare coverage rules.

94. Even in instances when AIM actually considered a Medicare request on the medical merits, AIM intentionally and systematically avoided compliance with requirements regarding the scope of Medicare coverage. MA insurance is required to cover "all services that are covered" by original Medicare, 42 C.F.R. § 422.101(a); 42 C.F.R. § 422.504(a); 42 U.S.C. § 1395w–22(a)(1)(A), including diagnostic imaging services, 42 U.S.C. § 1395x(s)(2)(C). AIM's rigged review process violated that fundamental obligation.

ANSWER: Denied, and Defendant specifically denies Relator's characterization of the law.

95. MA plans are legally required to pay for medical services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. 42 U.S.C. § 1395y(a)(1)(A)-(B). Determinations of reasonable and necessary services required application of the coverage rules in CMS National Coverage Determinations ("NCDs") and Local Coverage Determinations ("LCDs"). The NCDs and LCDs "specify under what clinical circumstances an item or service is considered to be reasonable and necessary." CMS, Medicare Program Integrity Manual § 13.1.3.

ANSWER: The allegations in Paragraph 95 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

96. AIM intentionally and systematically did not apply the Medicare coverage rules, the NCDs and LCDs, to make coverage decisions. Dr. Nedza, AIM's Chief Medical Officer, repeatedly warned top AIM executives that the Medicare rules were mandatory and binding. Putting profits over patients, AIM insisted regardless that requests for MA plans be reviewed based on its own "AIM Guidelines," which were much stricter than Medicare coverage rules, and which facilitated AIM's fraudulent denial of requests that should have been approved.

ANSWER: Denied.

97. AIM's "MD/RN tool," which AIM's nurse and physician reviewers used to evaluate coverage requests, was a set of coverage rules, policies, and documents on AIM's intranet comprised of different tabs for each insurance plan. Each tab included the AIM Guidelines and any substantive additional terms ("medical policies") of insurance plan. The MD/RN tool did not include the content of Medicare coverage rules, LCDs or NCDs. While AIM took the time to implement insurance-plan-specific rules to deny requests, AIM consistently implemented measures to prevent consideration of Medicare coverage rules.

ANSWER: Defendant admits that at one point it had used a tool referred to as the "MD/RN tool" that incorporated coverage rules. Defendant denies the remaining allegations in Paragraph 97.

98. The MD/RN tool did include a link to the CMS website, which theoretically might have allowed an AIM nurse or physician reviewer to examine NCDs and LCDs if they were willing and able to take the time to do so. However, in practice, AIM required each reviewer to process such a high volume of requests that even if a reviewer wanted to find, review and apply the relevant Medicare coverage rules, there was no time to do so. This was an intentional part of AIM's fraudulent scheme. As Julie Thiel told Dr. Nedza and other AIM executives on multiple occasions in 2013 and 2014, AIM intentionally refused to hire enough reviewers to spend that much time on any single request.

ANSWER: Defendant admits that at one point it had used a tool referred to as the "MD/RN tool" that incorporated coverage rules, and further admits the tool had a link to CMS's website. Defendant denies the remaining allegations in Paragraph 98.

99. In fact, AIM knew its reviewers did not use Medicare rules because it regularly monitored how often a nurse or physician reviewer clicked on the links to the CMS website on the MD/RN tool ("click rate"), and the rate was very low.

ANSWER: Denied.

100. The restrictive AIM Guidelines were created not to comply with Medicare requirements, but rather to save insurance plans money. The following are a few examples of how AIM Guidelines for imaging benefits materially deviated from Medicare coverage rules:

a. **Requiring physical therapy prior to approving an imaging request where Medicare coverage rules would cover the imaging and not require physical therapy;**

b. **Denying requests for imaging of adjacent sites where Medicare coverage rules would cover both scans; and,**

c. **Denying requests for bilateral imaging where Medicare coverage rules would cover both scans.**

ANSWER: Denied.

101. AIM's official policy was that the AIM Guidelines trumped any contrary Medicare coverage rules or requirements. AIM's policy stated that AIM would deny claims when the AIM Guidelines supported denial, even when the denial was "not consistent with" a Medicare coverage rule "in a NCD or LCD."

ANSWER: Denied.

102. As AIM explained on April 4, 2013 to Dr. Richard Frank, the National Staff Vice President and Medical Director for Medicare Advantage of Defendant Anthem, AIM's policy was explicitly to deny a request for services that was a "Covered Benefit" under Medicare if the request was not consistent with the "AIM Guidelines."

ANSWER: Denied.

103. AIM thus used application of its own Guidelines, as well as other coverage request review schemes, to wrongly and fraudulently deny Medicare beneficiaries the right to an individualized review based on medical need and the Medicare coverage rules. CMS, Medicare Managed Care Manual, § 4.10.16; 42 C.F.R. § 422.112(a)(6)(ii); 42 C.F.R. § 422.566(a); 42 U.S.C. § 1395w-22(g).

ANSWER: Denied.

104. The insurers, by contracting with AIM and relying on AIM's coverage determinations, fraudulently and systematically failed and refused to provide the full coverage guaranteed by Medicare, even though CMS had paid for full Medicare insurance coverage, and paid each MA plan to provide that coverage in reliance on the certification that MA plan coverage was the same or better than that provided by original Medicare. The insurers, moreover, were well aware of the fact that AIM was not applying Medicare coverage rules. "AIM

client contracts [with the MA plans] clearly delineate use of AIM Guidelines as the source for the medical necessity determination," instead of Medicare coverage rules. AIM Guidelines and Clinical Script Process (December 17, 2009). AIM and the insurers thus contracted for the intentional violation of the essential Medicare coverage rules and requirements.

ANSWER: Defendant denies that the MA plans, by contracting with AIM and relying on AIM's coverage determinations, fraudulently and systematically failed and refused to provide the full coverage guaranteed by Medicare, even though CMS had paid for full Medicare insurance coverage, and paid each MA plan to provide that coverage in reliance on the certification that MA plan coverage was the same or better than that provided by original Medicare. Defendant lacks information sufficient to form a belief about the truth of the remaining allegations in Paragraph 104, and therefore denies them. The remaining allegations in Paragraph 104 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

6. To conceal the fraudulent denials on procedural technicalities and restrictive substantive rules, AIM falsified mandatory notices to Medicare beneficiaries.

105. While AIM's fraudulent review and denial system was revealed to its insurer clients, AIM took efforts to conceal its fraud from Medicare beneficiaries and their medical providers. When AIM issued a formal Medicare Notice of Denial of Medical Coverage to the Medicare Advantage beneficiary and provider, AIM was required by law to provide a "detailed explanation" and "description of the applicable Medicare coverage rule." CMS, Form Instructions for the Notice of Denial of Medicare Coverage (or Payment) CMS-100003- NDMCP; CMS, Medicare Managed Care Manual, § 13.90.6 (requiring the use of CMS-10003- NDMCP); 42 U.S.C. §1395ff(a)(4). See also 42 U.S.C. § 1395w-22(g)(1)(B).

ANSWER: Defendant denies it engaged in fraud or fraudulent concealment to anyone. The remaining allegations in Paragraph 105 are legal conclusions and Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the

allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

106. To cover up its baseless rejection of Medicare requests and prevent improper denials from being challenged, AIM did not provide the actual reason for denial to the patient in its denial letters. Instead, AIM lied to the patients and quoted language from an AIM Guideline, which it fraudulently misrepresented to be language from the Medicare coverage rules.

ANSWER: Denied.

7. To amplify the fraudulent denials on procedural technicalities and restrictive substantive rules, AIM established practices to increase denials, trained, encouraged and directed staff to deny requests, and developed a "culture of no," re-enforced by financial incentives.

107. At each step of the scheme, AIM established rules and procedures to increase the denial of requests and to drive up profits, and also trained AIM staff to maximize the effectiveness of the fraudulent scheme.

ANSWER: Denied.

108. AIM's rules barred AIM staff from working with medical providers in efforts to approve meritorious requests. In the first step of the review process, AIM's call center staff were not medically-trained professionals and had no training on (or even access to) either the AIM Guidelines or the Medicare coverage rules. These call center staff were forbidden from offering suggestions or assistance to medical providers or re-running the algorithms based on additional information. In short, they were forbidden from doing anything that would increase the likelihood of getting a meritorious request approved by AIM's rigged system.

ANSWER: Denied.

109. Similarly, at the second level, AIM directed nurse reviewers to not ask medical providers follow-up questions that could lead to approval of requests. Thus, even if an AIM nurse reviewer knew—or believed—the request might be medically appropriate, if the provider did not give just the right information about the patient to fit the request into one of AIM's narrow approval criteria, AIM played a game of "gotcha" and denied the request.

ANSWER: Denied.

110. AIM also trained its call center staff, nurses, and physicians on how to systematically deny requests. AIM had an education team of three individuals, one for each call center, who reported to Senior Vice President Julie Thiel and were responsible for training the nursing review staff. Likewise, AIM had a group of three physicians to give ongoing training to physician reviewers at each call center.

ANSWER: Defendant admits it had a training program to train staff about pre-authorization requests. Defendant denies the remaining allegations in Paragraph 110.

111. These teams used trainings in how to deny requests, including lectures and case studies, to ensure nurse and physician reviewers knew what excuses and fact patterns to use to deny requests for pre-authorization, and to do so even when AIM's Guidelines were written to suggest that reviewers had discretion to approve the request.

ANSWER: Denied.

112. Though AIM did not provide any ongoing training on Medicare coverage rules, AIM did regularly train its reviewers on changes to the AIM Guidelines and updated ways to deny requests. AIM staff were given scenarios and hypotheticals of patients and told how to respond and deny requests. The training was coupled with testing to ensure quality control and uniformity of denials between reviewers.

ANSWER: Defendant admits it regularly trained its reviewers on updates to AIM Guidelines. Defendant denies the remaining allegations in Paragraph 112.

113. AIM trained its reviewers to be even more restrictive than its own already restrictive AIM Guidelines. Although some of the AIM Guidelines suggest that requests for pre- authorization for certain scans should be scrutinized, AIM instructed its reviewers to instead simply deny those requests. For example, while the AIM Guidelines indicated that "simultaneous ordering of multiple examinations may subject these examinations to more intensive levels of review," AIM reviewers simply denied requests for simultaneous orders.

ANSWER: Denied.

114. Similarly, AIM instructed its reviewers to use the AIM Guidelines to deny requests for simultaneous orders of tests on many adjacent body parts (such as upper and middle back scans), even when both scans were medically necessary and would be covered under Medicare rules. Several AIM physician

reviewers objected to this directive and complained to Dr. Nedza that it forced the patient to visit the doctor twice, on separate days, with separate co- pays, and without medical justification. This both increased patient expense and unnecessarily delayed necessary diagnostic procedures.

ANSWER: Denied.

115. AIM further reinforced its rules and expected denial rates through rigorous tracking of data and financial bonuses to its staff, which were tied to outcome metrics. The cost to AIM in nurse and physician expenses of each review was tracked in the "AIM Cost Per Case" report. Likewise, AIM tracked detailed metrics about every individual person on its review staff. AIM calculated requests processed per day, average review time, and denials for every individual.

ANSWER: Defendant admits that it tracked denial rates resulting from its UM process. Defendant denies the remaining allegations in Paragraph 115.

116. Individual performance metrics were used as a basis for AIM staff performance evaluations and bonuses. The more effective a staff member was in denying claims, the more they were paid.

ANSWER: Denied.

D. Defendants caused the insurers to provide materially deficient MA coverage.

117. AIM used a myriad of tactics to rig the review process, including faulty algorithms, blatantly ignoring and avoiding Medicare rules, corrupt training of staff, secretly turning off fax machines that prevented the consideration of essential medical records, strictly limiting contact with medical providers, and secretly denying requests for no medical basis at all after one business day. Individually, these fraudulent practices violate the basic substantive and procedural requirements that exist to protect seniors and others participating in the Medicare program from deficient medical care and the government from over paying.

ANSWER: Denied.

118. Under original Medicare, beneficiaries are generally not subjected to formal pre- authorization requirements. Medicare Advantage plans, on the other hand, sometimes engage in pre-authorization review. The insurers who used AIM's rigged process for MA plans, however, rather than engaging in a legitimate pre-authorization evaluation, profited from the enhanced denial

rates produced by AIM's fraudulently designed system to deny requests that should have been covered under Medicare rules.

ANSWER: Defendant admits that traditional Medicare generally does not apply pre-authorization requirements. Defendant further admits that Medicare Advantage plans typically apply some form of lawful pre-authorization review. Defendant denies that it had a "rigged review process." Defendant denies the remaining allegations in Paragraph 118.

119. Collectively, Defendants' tactics caused insurers to provide defective and deficient MA plan coverage, and substantially less insurance than required by the Medicare statute, Medicare rules, and MA contracts. CMS pays insurers offering MA plans only if they cover *all* Medicare services. That is what the government promises seniors and others in promoting Medicare Advantage, and that in turn is the fundamental promise the insurers make to the government.

ANSWER: Denied.

120. The deficiency of the MA plans that used AIM's rigged review process was dramatic. As noted above, proper reliance on Medicare's coverage rules for the relevant preauthorization requests results in denial rates between about 0.5% and 1.5%. In contrast, according to AIM's own internal estimates, reliance on the rigged review process and more restrictive AIM Guidelines resulted in denial rates as high as 5 to 9%.

ANSWER: Denied.

121. After AIM refused Dr. Nedza's attempts to stop these fraudulent practices over three years, she left rather than continue to provide her services to a company that violated the law and showed no concern for the health of Medicare beneficiaries. She left without taking patient files to cite the names and dates of patients wrongfully denied medical care, but the names and dates of tens of thousands of Medicare beneficiaries cheated out of more than $100 million in medical care by AIM will be readily apparent from a review of AIM's records. AIM logged every request and every beneficiary, and diligently counted and calculated the denials caused by the rigged AIM review process for each plan, for each type of scan, each and every month.

ANSWER: Defendant admits that Relator left AIM in January 2015. Defendant admits it tracked denial rates resulting from its UM process. Defendant admits that it logged every request

and every beneficiary, and, in order to comply with regulatory and accreditation requirements, diligently counted and calculated the denials caused by the AIM review process for each plan, for each type of scan, each and every month. Defendant denies that it had a "rigged review process." Defendant lacks information sufficient to form a belief about the truth of the remaining allegations in Paragraph 121, and therefore denies them.

122. As a result of the denials generated by the rigged AIM review process, the MA plans provided by the insurers were fatally flawed and defective—both in process and in substance—and statements and claims made by the insurers in contracting with CMS and collecting monthly payments for their MA plans were false and fraudulent.

ANSWER: Denied.

E. Defendants' systemic violations of Medicare coverage requirements knowingly and intentionally caused insurers to defraud the government.

1. AIM studied and quantified the impact of continuing to violate Medicare requirements, but decided it was too expensive to follow the law.

123. AIM not only intentionally violated the Medicare coverage requirements by creating and using a fraudulently rigged review process, it also carefully tracked the degree of success of this fraud scheme.

ANSWER: Denied.

124. During Dr. Nedza's tenure, AIM carefully quantified how much it was cheating Medicare. In 2013, AIM senior medical staff members Dr. Thomas Power and Deborah Lamm reviewed 164 MA patient files that AIM had denied and determined that 160 should have been approved under Medicare policy. This means AIM properly denied only 4 of the 164 cases, or 2.5% of the denials. The findings of this study were widely discussed among top AIM management, including Dr. Nedza, Brandon Cady (CEO), Julie Thiel (Senior VP of Clinical Programs), Randy Hutchinson (COO), and Christopher Kurtenbach (VP of Operations).

ANSWER: Denied.

125. In an experiment with Medicare compliance from January to April 2014, detailed further below, AIM confirmed that if it followed Medicare requirements its denial rate would drop to near 0%. AIM could not, of course, sell a review process that led to a near 0% denials for MA plans since high denial rates were what AIM was selling to its customers.

ANSWER: Denied.

126. AIM's own marketing materials further reveal that AIM knew how far out of compliance its rigged review process was with Medicare requirements. In preparing 2013 promotional materials to sell AIM services to the Health Care Services Corporation (a very large Blue Cross Blue Shield affiliate), AIM's draft materials stated that review of requests under Medicare requirements would result in a denial rate of just 0.5%, a rate far below what AIM promised to deliver under its rigged review process. AIM's rigged review process had denial rates of 5% - 9% of requests. These promotional materials were developed by AIM's business team, with review and approval from AIM's leadership including Anne Pukstys (VP Client Management), Christiane Shah (VP Solutions Management), and Randy Hutchinson (COO). These marketing materials promised the client insurer a dramatic cost savings, but also admitted the "compliance risk" of using AIM's review system on Medicare Advantage requests because some denials "will likely be overturned by CMS."

ANSWER: The allegations in Paragraph 126 purport to quote or characterize the contents of documents, the contents of which speak for themselves. Defendant denies the remaining allegations contained in Paragraph 126.

2. AIM executives openly and continually discussed the decision to violate Medicare requirements.

127. The choice to defraud Medicare in search of profits was openly discussed by AIM executives. From 2012 to 2015, the period of Dr. Nedza's employment, AIM's internal communications and documentation reflect a conscious disregard and avoidance of Medicare coverage requirements. AIM's top executives openly discussed how AIM violated Medicare requirements and denied care that was properly covered by Medicare. The serious legal risks of the continuing failure to implement a Medicare-compliant system were understood and accepted at the highest levels of corporate leadership of AIM. At numerous executive committee meetings and on other occasions, Dr. Nedza personally participated in discussions of how AIM was actively violating Medicare's core and basic requirements for coverage with top AIM leaders including Brandon Cady (CEO), Joel Cesario (CFO), James Chow (former

COO), Randy Hutchinson (COO), Michael Backus (CSO), and Julie Thiel (SVP) throughout 2012, 2013, and 2014.

ANSWER: Defendant admits that it continually evaluated its compliance with CMS regulations, and that Defendant's leadership was part of some of these discussions. Defendant further admits AIM employed Relator between 2012 and 2015. Defendant denies the remaining allegations in Paragraph 127.

128. **AIM executives likewise continually discussed violation of Medicare coverage rules and other requirements nearly weekly at Physician Leadership Committee meetings and regular Quality Committee meetings in 2012, 2013, and 2014. AIM executives also discussed the fraud on Medicare in countless emails during this time as AIM refused to follow Medicare requirements and put in place a Medicare-compliant review process.**

ANSWER: Defendant admits it regularly conducted Physician Leadership Committee meetings, and that compliance with CMS regulations was a topic of discussion for the Committee. Defendant denies the remaining allegations in Paragraph 128.

129. **On several occasions during her tenure at AIM, Dr. Julie Thiel, AIM's Senior Vice President of Clinical Programs, urged AIM to stop inappropriately denying requests for MA pre-authorization, including in an October 15, 2013 email to other AIM executives, including COO Randy Hutchinson and VP Christiane Shah. On that occasion, she proposed that AIM simply approve all Medicare requests to stop "incorrectly denying" Medicare requests.**

ANSWER: Denied.

130. **Similarly, as part of her continuous efforts to reform the AIM process, Dr. Nedza repeatedly spoke and emailed with AIM's top leadership, including Dr. Thiel, James Chow, Randy Hutchinson, and Brandon Cady, about AIM's violation of Medicare requirements and AIM's failure to make the changes necessary to provide full MA coverage to MA beneficiaries.**

ANSWER: Defendant admits that it evaluated its compliance with CMS regulations, and that Defendant's leadership was involved in some of these discussions. Defendant denies the remaining allegations in Paragraph 130.

131. Following a decision in late 2014 for Anthem MA plans to increasingly use the AIM rigged review process, AIM's Vice President of Compliance, Jennifer Dullum, remarked that AIM's rigged review process risked landing the insurance plan clients in jail.

ANSWER: Defendant admits it was aware that noncompliance with CMS regulations could, under appropriate circumstances, result in the imposition of a spectrum of government sanctions provided under law. Defendant denies the remaining allegations in Paragraph 131.

132. At least through the end of 2014, AIM's top executives openly discussed the fact that AIM was violating Medicare requirements and not providing the insurance CMS purchased, and they nonetheless chose to continue. The problem, as AIM COO Randy Hutchinson put it in an email, was that following Medicare coverage rules and core requirements "will impact the value" of AIM to the MA plans, and AIM's very business model. AIM consciously and intentionally decided it was more profitable to keep the Medicare business by defrauding the government.

ANSWER: Defendant admits that it evaluated its compliance with CMS regulations, and that Defendant's leadership was part of some of these discussions. Defendant denies the remaining allegations in Paragraph 132.

3. By 2014, AIM was so concerned about the risk of continued fraud that it began to experiment with increased Medicare compliance.

133. In 2012 and 2013, out of concern that AIM's systemic Medicare fraud would be detected and result in legal consequences, AIM executive leadership considered routing all MA requests to trained nurse reviewers who would actually follow and implement Medicare coverage rules and requirements. However, Brandon Cady rejected that idea because it was too expensive. AIM refused to provide the staff and time needed to separately and accurately assess MA requests, and refused to give up the profits generated by use of the rigged review process.

ANSWER: Denied.

134. But the concerns at AIM about the ongoing and intentional defrauding of Medicare continued, and as a result, for a short period from January to April 2014, AIM tried switching MA requests from the fraudulently rigged review process to a review process that only denied MA requests based on specific

Medicare-compliant criteria. AIM made this temporary change for the MA plans of certain insurer clients, including BCBS of North Carolina, BCBS of Michigan, and Health First Health Plans in Florida. The resultant denial rates dropped to close to 0%. The business side of AIM, led by COO Randy Hutchinson, with the agreement of CEO Brandon Cady, and VP Christiane Shah, pushed back against the trial review process. As a result, AIM returned to using the rigged review process to deny MA pre-authorization requests, with the resultant return to excessive denial rates and increased profits.

ANSWER: Denied.

135. **After the rejected January to April 2014 Medicare compliance experiment, AIM developed another modified review process for Medicare requests. Under the leadership of Dr. Julie Thiel, AIM created a purportedly "hybrid" review process that would improve AIM compliance with Medicare coverage rules, but would still fall short of actual, full compliance with Medicare requirements.**

ANSWER: Defendant admits that it developed a "hybrid" UM model that it has used with some of its MA plan customers. Defendant denies the remaining allegations in Paragraph 135.

136. **AIM implemented the "hybrid" review process for several MA plans from approximately September to December 2014. Again, AIM's denial rates plummeted to about 1%. AIM's denials and savings for its clients were so low that, as Anne Puksty [sic], VP of Client Management outlined in an email on November 6, 2014, AIM planned to apologize to a MA plan for the hybrid program and to pin the failure on "a mistake."**

ANSWER: The allegations in Paragraph 136 purport to quote or characterize the contents of a document, the contents of which speaks for itself. Defendant denies the remaining allegations contained in Paragraph 136.

137. **AIM then abandoned "hybrid" review process and began to develop yet another review model—the fourth in 2014 alone—for Medicare claims. The latest iteration was called the "hierarchical model." This model involved routing all MA requests to dedicated MA reviewers, applying Medicare NCDs (but not LCDs), and using Medicare coverage rules as the basis for some denials. AIM made plans to finally rollout this "hierarchical" review process to some MA plans starting on January 1, 2015. The "hierarchical" review process, if implemented, would have resulted in following some, but not all, Medicare coverage rules.**

ANSWER: Defendant admits that it developed a "hierarchical" UM model that it used with some of its MA plan customers. Defendant denies the remaining allegations in Paragraph 137.

138. Regardless, at the same time, AIM also continued to offer its traditional rigged review process for insurers to use with their MA plans. AIM executives, including Christiane Shah, VP of Client Management, believed that some insurers would still choose the higher profits for their MA plans from the rigged review process over following the law. She was correct.

ANSWER: Denied.

139. For example, on October 6, 2014, Defendant Regence of Idaho told AIM executives, including Christiane Shah, that it preferred to stay with the existing rigged review process rather than the "more compliant" hybrid model. Likewise, on October 10, 2014, Anne Puksty [sic], AIM VP of Client Management, argued that for MA plans "compliance risk will be taken under advisement and will be weighed against the business / financial risk" of giving up the savings AIM had been generating and that MA plans had "already booked for 2015."

ANSWER: The allegations in Paragraph 139 purport to quote or characterize the contents of documents, the contents of which speak for themselves. Defendant denies the remaining allegations contained in Paragraph 139.

140. As Ms. Shah explained in an email to other AIM executives on another occasion, in selling the rigged review process to Independence Blue Cross, AIM sales strategy was to convince the MA plan "business decision makers" to "override the compliance concerns" and to "take the compliance risk in return for CoC [Cost of Care] value" generated by hiring AIM.

ANSWER: The allegations in Paragraph 140 purport to quote or characterize the contents of a document, the contents of which speaks for itself. Defendant denies the remaining allegations contained in Paragraph 140.

141. AIM's rigged review process was so fraudulent and generated so many wrongful denials of care to MA beneficiaries that eventually in December 2014, BCBS of Michigan even threatened to self-report to CMS its own violation of Medicare requirements caused by accepting AIM fraudulent

determinations. Ultimately, AIM marketing executives, including Anne Putsky [sic], "walked them off the cliff" and convinced BCBS Michigan not to do so.

ANSWER: Denied.

142. Even with the changes in 2014, AIM executives, including COO Randy Hutchinson and VP Christiane Shah, discussed revising AIM's contracts with MA plans, such as Defendants BCBS of Michigan and BCBS of North Carolina, to absolve AIM of responsibility for the MA plans' fraud on Medicare.

ANSWER: Denied.

143. Ultimately, while Dr. Nedza still worked for AIM, and in spite of her continuous efforts, AIM never implemented a review process that came close to complying with the twin essential Medicare requirements of providing full MA coverage to Medicare beneficiaries based on Medicare coverage rules. AIM consistently, consciously and intentionally chose to defraud the government in service of the drive to make greater profits.

ANSWER: Denied.

4. Anthem Inc. condoned AIM's rigged review process, but for a time refused to use the fraudulent system, until Anthem too relented in search of profits.

144. Anthem Inc., AIM's parent company, was at all times fully aware of, endorsed, and profited from AIM's fraud.

ANSWER: Defendant admits that Anthem is Defendant's parent, and on information and belief, admits that Anthem was aware AIM provided UM services. Defendant denies the remaining allegations in Paragraph 144.

145. AIM and Anthem executives regularly discussed AIM's rigged review process, the fact that the process violated Medicare coverage rules and requirements, and, in light of the fraud, whether the MA plans of Anthem's insurance company subsidiaries would use the rigged AIM review process.

ANSWER: Defendant admits that Defendant and Anthem discussed Defendant's UM process. Defendant denies the remaining allegations in Paragraph 145.

146. Dr. Nedza personally participated in numerous conversations where AIM and Anthem executives discussed the fact that AIM's rigged review process violated Medicare requirements. On April 4, 2013, for example, she reported to Dr. Richard Frank, Anthem's National Staff Vice President and Medical Director for Medicare Advantage, that AIM's policy and procedure was to follow the internal AIM Guidelines to deny care, even when a procedure is specifically and expressly a "Covered Benefit" according to Medicare. Similarly, in mid-2014, Dr. Nedza spoke with Dr. Steve Friedhoff, Anthem's Senior Vice President of the Clinical Strategy and Programs, while at a meeting in San Francisco. He acknowledged that Anthem was aware that the rigged AIM review process violated Medicare requirements.

ANSWER: Defendant admits that Defendant and Anthem discussed Defendant's UM process and that Relator, at times, participated in those discussions. Defendant further admits that Relator had discussions with Dr. Richard Frank regarding the UM system. Defendant denies the remaining allegations in Paragraph 146.

147. Some Anthem executives, such as Vice President Dr. Alan Rosenberg tried to have Anthem take control of approving and revising the AIM Guidelines because of his concern that AIM was violating Medicare coverage requirements. However, AIM and its executives pushed back. Ultimately, Anthem CEO Angela Braly resolved the dispute by siding with AIM and permitting AIM to maintain control over the AIM Guidelines and continue its very lucrative but unlawful review process for MA plans.

ANSWER: Defendant admits that it was in control of its UM process and design, and that Defendant received feedback from Anthem. Defendant denies the remaining allegations of Paragraph 147.

148. These discussions were ongoing as part of Anthem's regular oversight of its subsidiary, AIM. They also occurred in the context of the years-long discussions about whether Anthem would use the rigged AIM review process for the numerous large MA plans operated by its insurer subsidiaries.

ANSWER: Defendant admits that Defendant and Anthem discussed Defendant's UM process. Defendant denies the remaining allegations in Paragraph 148.

149. From at least 2008 to 2011, Anthem, Inc. directed its subsidiary insurers to use the fraudulently rigged review process offered by its other subsidiary, AIM, for their MA plans.

ANSWER: Denied.

150. Then, in 2011 or 2012, Anthem decided that the AIM's practices were so dangerously unlawful that they should not be used by their subsidiary insurers. Anthem forbid them from further use of the rigged AIM review process for MA plans, even though doing so meant giving up tens of millions of dollars in profits each year.

ANSWER: Denied.

151. Anthem, nonetheless, allowed AIM to continue to sell the fraudulently rigged review process to non-Anthem-owned insurers for their MA plans, knowing that it violated Medicare requirements and cheated the government. Anthem did so to continue to reap the profits from AIM's revenue.

ANSWER: Defendant admits that AIM provided UM services to both Anthem and non-Anthem MA plans. Defendant denies the remaining allegations in Paragraph 151.

152. Thereafter, AIM executives lobbied Anthem to return to allowing Anthem subsidiary insurers to use the rigged AIM review process in order to increase AIM revenues.

ANSWER: Defendant admits that it advocated the use of its UM system to Anthem for use with Anthem's subsidiaries' MA plans.

153. Finally, in late 2014, Dr. Richard Frank, Anthem's National Staff Vice President and Medical Director for Medicare Advantage and Dr. Steve Friedhoff, Senior Vice President of Clinical Program and Strategy for Anthem, convinced Anthem corporate management to boost the bottom line of its subsidiary insurers by allowing them to use the AIM rigged review process for MA plans. The decision to return to the rigged AIM review was approved by Anthem's top leadership, including Dr. Mary McCluskey (Anthem's Chief Medical Officer for Government Products).

ANSWER: Defendant lacks information sufficient to form a belief about the truth of the allegations in Paragraph 153, and therefore denies them.

154. Anthem simply decided the potential profits warranted the risk of being caught defrauding Medicare. AIM executives discussed the legal risk of Anthem's decision. CEO Brandon Cady told Dr. Nedza at the time in 2014 that he wanted to be sure that Anthem's CEO "Mary McCluskey's name is on an email" approving the decision "so when we get caught [by CMS] it's on her." Mr. Cady wanted Anthem and Dr. McCluskey to face the criminal ramifications and responsibility if Anthem's MA plans were barred from the MA program.

ANSWER: Defendant admits that it discussed its UM system's legal compliance with Anthem. Defendant denies the remaining allegations in Paragraph 154.

155. Despite years of concerns, Anthem never ordered, instructed, or caused its subsidiary AIM to comply with the law and stop defrauding Medicare. Instead Anthem encouraged the fraudulent practices, all the while enjoying the fruits of AIM's fraudulent misconduct - AIM's profits and profits AIM generated for Anthem's subsidiary insurers.

ANSWER: Denied.

F. AIM's scheme enriched Defendants at the expense of Medicare beneficiaries.

156. AIM's rigged review process caused insurers to deny Medicare beneficiaries coverage for services that should have been approved. Without pre-authorization, the MA plans would not cover the imaging procedures. Without insurance coverage, Medicare beneficiaries were forced to either pay exorbitant out of pocket prices, or, more realistically for most, simply forgo the procedure.

ANSWER: Defendant denies that it had a "rigged review process." Defendant otherwise lacks information sufficient to form a belief about the truth of the allegations in Paragraph 156, and therefore denies them.

157. This wrongful denial of Medicare coverage was particularly insidious for the imaging tests, because such tests are necessary to detect and monitor serious illnesses and develop timely and appropriate treatment plans for everything from broken bones to potentially fatal diseases such as cancer and heart disease. AIM effectively denied not only a simple CT scan or PET scan, for example, but all of the necessary and critical medical care that would be indicated by those studies.

ANSWER: Defendant denies that it ever recommended denying medically necessary treatment. The remaining allegations in Paragraph 157 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

158. Insurers in their MA plans have a clear and strict legal obligation to make proper and Medicare compliant coverage determinations to ensure that Medicare beneficiaries receive all the healthcare to which they are guaranteed under the Medicare statute and to which they were promised by CMS promoting the MA program.

ANSWER: The allegations in Paragraph 158 are Relator's characterizations to which no response is required. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

159. AIM and Anthem knowingly wrongfully caused the private insurers to deny MA coverage, cheating Medicare beneficiaries out of care and falsely claiming and cheating the government out of capitation payments. The Medicare beneficiaries received less care than the government purchased on their behalf, and less care than the MA plans certified they cover.

ANSWER: Denied.

160. This was clear-cut and premeditated fraud, enabled by the false representations, statements, and claims AIM and Anthem caused the insurers to make to the government. Defendants fraudulently inflated the insurance companies' MA plan profits by tens of millions of dollars each year. The profits from cheating the Medicare program and Medicare beneficiaries were split between AIM, which got a fee for each MA plan member each month, and the insurers, which were paid by the government at the rate of fully Medicare compliant MA plans but were in fact providing plans which delivered far less.

ANSWER: Defendant admits it received payments from MA plans for providing the MA plans UM services. Defendant denies the remaining allegations in Paragraph 160.

161. This fraud was a win-win-win system—for AIM, for the insurers, and for Anthem—so long as AIM denied enough patient care regardless of medical need to hit the annual denial rate targets in its contracts. It was a lose-lose system for the Medicare beneficiaries and the government, both of whom were defrauded by the improper denials of coverage for medical care.

ANSWER: Denied.

G. AIM and Anthem caused the submission of false claims and false statements to the federal government to enable this fraud.

162. AIM and Anthem caused the insurers to defraud the federal government in violation 31 U.S.C. § 3729(a)(1)(A) and (B). This fraud violates the False Claims Act in at least three ways.

ANSWER: Denied.

163. *First,* AIM and Anthem caused the insurers to deliver to the government fatally defective and deficient Medicare Advantage insurance coverage. The government did, and lawfully only could, contract for insurance that covers all services covered by original Medicare. This Basic Benefit Rule of Medicare is the foundation of the Medicare Advantage program and is literally the definition what the government is purchasing. Likewise, the second pillar of Medicare Advantage is that each request for coverage be processed based on individual information and medical need so that seniors and other Medicare beneficiaries do not fall victim to corporate profiteering. Through AIM and Anthem, the insurers provided defective insurance without either key attribute: the MA plans provided materially less coverage than the government purchased and the Medicare statute requires, and did so by basing coverage determinations on fraudulent gimmicks, secret rules, unjustified excuses, and profit calculations, not medical need. Just like delivering defective devices or deficient products on a defense contract, Defendants caused the insurers to deliver defective and deficient health insurance to CMS. They did so knowingly and intentionally, flouting basic and admitted Medicare requirements to unlawfully inflate profits at the expense of the government and Medicare beneficiaries.

ANSWER: Defendant denies it caused MA plans to deliver fatally defective and deficient MA insurance coverage. The remaining allegations in Paragraph 163 are either Relator's

characterizations to which no response is required, or allegations that Defendant lacks information sufficient to form a belief about its truth. To the extent a response is required, Defendant denies the allegations to the extent they are inconsistent with, or are Relator's interpretation of, CMS and Medicare Advantage regulations.

ANSWER:

164. *Second*, every insurer submitted materially false statements to obtain an MA contract (or annual contract renewal). Under the Medicare statute, every insurer must certify, annually, that its MA plan complies with the Basic Benefit Requirement and other Medicare coverage rules. 42 U.S.C. § 1395w-27; 42 U.S.C. § 1395w-22(a)(1)(A). Without this false certification, CMS would not under the Medicare statute contract with an insurer for an MA plan and the insurer would not and lawfully could not have received a single government payment. Id.

ANSWER: Defendant denies the allegations contained in paragraph 164 to the extent that they contend that the insurers' statements were materially false or fraudulent because they relied on AIM to perform UM services. Defendant further denies Relator's characterization of the law. Defendant lacks information sufficient to form a belief about the truth of the remaining allegations in Paragraph 164, and therefore denies them.

165. The insurers did not simply promise in the MA contract and bids to provide certain services, and then breach by later failing to provide the promised services. The promises and statements were intentionally false from the start, fraudulently made to obtain government contracts. At the time of the false statements, made annually, the insurers were already failing and refusing to provide full Medicare coverage in compliance with Medicare's requirements, by outsourcing denials to AIM's rigged review process. The insurers were already using—and planned to continue—AIM's rigged review process, and never planned to provide all the Medicare coverage for which the government was contracting. AIM and Anthem thus caused the insurers to submit false certifications and statements to CMS to obtain an MA contract (or bid package approval). False statements to obtain a government contract is fraud in the inducement, classic fraud, and violates the False Claims Act.

ANSWER: Defendant denies the allegations contained in paragraph 165 to the extent that they contend that the insurers' bids were false or fraudulent because they relied on AIM to perform UM services. Defendant denies that it had a "rigged review process." Defendant lacks information sufficient to form a belief about the truth of the remaining allegations in Paragraph 165, and therefore denies them.

166. ***Third,*** **every monthly payment request from an insurer to CMS was false or fraudulent and induced by the false statement certifying that the MA plan had provided all Medicare services in compliance with its annual contract or "bid." Every month, each insurer submitted a request for a capitation payment to CMS for each MA plan. Every request stated the number of Medicare beneficiaries for which the insurer had provided all of the services required by and listed in a specific MA contract bid, identified by number.** ***See*** **Exhibit 1 at Attachment A and B. That statement was false because the MA plans, by denying coverage through AIM, actually provided materially less coverage than required by Medicare. Defendants thus caused the insurers to submit false claims and make false statements in support of claims for payment each and every month an insurer used AIM's rigged review process to deny necessary care to Medicare beneficiaries.**

ANSWER: Defendant denies the allegations contained in paragraph 166 to the extent that they contend that the insurers' monthly payment requests were false or fraudulent because they relied on AIM to perform UM services. Defendant denies that it had a "rigged review process." Defendant lacks information sufficient to form a belief about the truth of the remaining allegations in Paragraph 166, and therefore denies them.

167. By failing to provide coverage required under the MA program, Defendants caused the insurers to repeatedly present false or fraudulent claims for payment or approval to the federal government in violation 31 U.S.C. § 3729(a)(1)(A) and repeatedly and knowingly made or used or caused false statements or records to be made or used material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

ANSWER: Denied.

COUNT I

(Violations of 31 U.S.C. § 3729(a)(1)(A))

168. Relator-Plaintiff repeats and re-alleges paragraphs 1-167.

ANSWER: Defendant repeats and re-alleges its answers to Paragraphs 1-167.

169. This Count is brought by Dr. Nedza in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729(a)(1)(A).

ANSWER: Defendant admits that Relator brought claims for alleged violations of 31 U.S.C. § 3729(a)(1)(A). Defendant denies the remaining allegations in Paragraph 169.

170. By virtue of the acts described above, among others, Defendants repeatedly and knowingly caused to be presented, false or fraudulent claim for payment or approval to the Center for Medicare and Medicaid Services.

ANSWER: Denied.

171. By virtue of the acts described above, among others, Defendants have violated the False Claims Act by repeatedly and knowingly causing false or fraudulent claims to be presented to the Government for payment or approval.

ANSWER: Denied.

172. Plaintiff United States, unaware of the falsity of the claims and/or statements or records, and in reliance on their accuracy, paid for claims that would otherwise not have been allowed.

ANSWER: Denied.

COUNT II

(Violations of 31 U.S.C. § 3729(a)(1)(B))

173. Relator-Plaintiff repeats and re-alleges paragraphs 1-167.

ANSWER: Defendant repeats and re-alleges its answers to Paragraphs 1-167.

174. This Count is brought by Dr. Nedza in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729(a)(1)(B).

ANSWER: Defendant admits that Relator brought claims for alleged violations of 31 U.S.C. § 3729(a)(1)(B). Defendant denies the remaining allegations in Paragraph 174.

175. By virtue of the acts described above, among others, Defendants repeatedly and knowingly made or used or caused false statements or records to be made or used that were material to a false or fraudulent claim.

ANSWER: Denied.

176. Plaintiff United States, unaware of the falsity of the claims and/or statements or records, and in reliance on their accuracy, paid for claims that would otherwise not have been allowed.

ANSWER: Denied.

AFFIRMATIVE DEFENSES

Without admitting any of the allegations in the Complaint, Defendant asserts and alleges the following Affirmative Defenses.

First Affirmative Defense

The Complaint and its alleged causes of action fail to state a claim upon which relief may be granted, particularly under Federal Rules of Civil Procedure 8(a) and 9(b).

Second Affirmative Defense

Relator's theories underlying the Complaint and its alleged causes of action are incorrect as a matter of law including but not limited to because the Complaint fails to plead objective falsity.

Third Affirmative Defense

Relator's theories underlying the Complaint and its alleged causes of action are incorrect as a matter of law including but not limited to because the Complaint fails to satisfy the materiality requirements of the False Claims Act.

Fourth Affirmative Defense

Relator's theories underlying the Complaint and its alleged causes of action are incorrect as a matter of law because they are based on non-binding regulatory and sub-regulatory guidance.

Fifth Affirmative Defense

The Complaint and its alleged causes of action do not relate to conduct by Defendant for which Defendant had the requisite scienter or intent for False Claims Act liability, 31 U.S.C. § 3729 *et seq*., and even if it did, Relator's causes of action are barred, in whole or in part, because the government's knowledge of the facts underlying the allegedly false claims negates the scienter requirement of the False Claims Act.

Sixth Affirmative Defense

Defendant did not knowingly present or cause to be presented a false or fraudulent claim for payment or approval.

Seventh Affirmative Defense

Defendant did not knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.

Eighth Affirmative Defense

Defendant at all times complied with applicable legal standards, regulations and rules.

Ninth Affirmative Defense

The claims and allegations in the Complaint and its alleged causes of action are barred to the extent they amount to differences of subjective medical, clinical, and scientific opinions that do not create or establish violations of the False Claims Act or any other statutory or common law provision.

Tenth Affirmative Defense

The claims and allegations in the Complaint and its alleged causes of action are barred, in whole or in part, because the government's knowledge of the facts underlying the allegedly false claims negates the falsity requirement of the False Claims Act, 31 U.S.C. § 3729 *et seq*.

Eleventh Affirmative Defense

The claims and allegations in the Complaint and its alleged causes of action are barred, in whole or in part, because the government's knowledge of the facts underlying the allegedly false claims negates the materiality requirement of the False Claims Act, 31 U.S.C. § 3729 *et seq*.

Twelfth Affirmative Defense

The claims and allegations in the Complaint and its alleged causes of action are barred because any actions taken by Defendant with respect to the subject matters alleged in the Complaint were taken in good faith and/or in reasonable reliance upon regulatory interpretations and judgments by the Government and/or its agents and contractors upon whom Defendant was entitled to rely.

Thirteenth Affirmative Defense

Relator's claims are barred because Defendant neither made nor caused to be made any express or implied false certification.

Fourteenth Affirmative Defense

None of Defendant's alleged statements or actions was the proximate cause or cause in fact of any injury to, or alleged loss by, the United States.

Fifteenth Affirmative Defense

Relator's claims are barred because any injuries sustained were the result of the United States' own conduct or the intervening conduct of third parties.

Sixteenth Affirmative Defense

To the extent Relator seeks damages and/or penalties unrelated to or vastly greater than the alleged actual damages sustained by the United States, such damages or civil penalties are unconstitutional and violate the Excessive Fines Clause of the Eighth Amendment and Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution.

Seventeenth Affirmative Defense

The Relator's claims for damages are barred because she seeks damages that are speculative and remote.

Eighteenth Affirmative Defense

Any allegedly inappropriate conduct alleged in the Complaint was *ultra vires* and thus not attributable to Defendant under the doctrine of *respondeat superior*.

Additional Affirmative Defenses

Defendant reserves the right to assert additional affirmative defenses as the litigation proceeds, and to amend its affirmative defenses to conform to the facts and pleadings developed in the course of this case.

WHEREFORE, Defendant denies that Relator is entitled to any relief whatsoever, and requests that this Court enter judgment in Defendant's favor, dismiss the Relator's claims in their entirety, and provide for such other relief as this Court deems just and proper.

Dated: June 4, 2020

Respectfully submitted,

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