UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

| UNITED STATES, EX REL. DR. SUSAN NEDZA, |) |
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| Plaintiff-Relator, |)) No. 15-cv-6937 |
| v. |) JUDGE JORGE L. ALONSO |
| American Imaging Management, Inc. and Anthem Inc., |))) |
| Defendants. |) JURY TRIAL DEMANDED) |
| |) THIRD AMENDED COMPLAINT) FOR VIOLATIONS) OF THE FEDERAL FALSE) CLAIMS ACT) |

THIRD AMENDED COMPLAINT

Plaintiff-Relator Dr. Susan Nedza, through her attorneys, on behalf of the United States of America (the "Government"), for her Complaint against American Imaging Management, Inc. ("AIM") and its parent company Anthem Inc. ("Anthem," formerly known as WellPoint) (collectively "Defendants"), alleges as follows:

I. <u>INTRODUCTION</u>

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").

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

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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.

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.

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.

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

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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.

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.

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).

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.

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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%.

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.

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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.

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.

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.

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

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mental suffering; while AIM and its parent company Anthem, and AIM's clients, the insurers offering MA plans, all enjoyed excess and illegal profits.

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.

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).

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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.

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.

II. <u>PARTIES</u>

19. The Relator, Dr. Nedza, served as Chief Medical Officer and a member of the executive team at AIM from July 2012 until January 2015.¹ 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 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.

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.

¹ 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.

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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.² 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.

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

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.

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. §1395-1395111.

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.

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

² Evidence-based clinical tools are clinical algorithms that enable doctors to effectively and efficiently manage patient care.

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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.

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 Community Health Plans.

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

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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").

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.

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.

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).

IV. <u>LEGAL FRAMEWORK</u>

A. The Medicare Program

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").

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.

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.

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.

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.

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.

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."³

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.

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

³ Medicare.gov, Things to know about Medicare Advantage Plans, *available at* www.medicare.gov/sign-up-changeplans/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-healthplans/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.

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determinations. These two requirements define an MA plan; they are what the insurers certify to CMS; and what CMS promises to MA beneficiaries.

1. 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).

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.

43. An MA plan must make coverage decisions in compliance with NCDs, LCDs, and all "Medicare manuals and instructions." 42 U.S.C. § 1395y(1); 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.

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

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"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.

2. 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.

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 preauthorization 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).

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.

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3. 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).

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.

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

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.

- 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.
- 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."4 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.

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

⁴ CY2018 Medicare Advantage "Bid Price Tool" instruction*s, 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").

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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").

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.

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(1)(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(1). The monthly payment from CMS is thus based on the representation by the insurer

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that it provided all services promised in its MA contract, and in compliance with all Medicare coverage rules.

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).

4. 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.

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.

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.

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.

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.

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.

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%.

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.

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

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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.

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.

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.

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.

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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.

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.

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.

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.

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.

1. 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.

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.

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

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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."

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.

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.

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.

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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.

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.

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.

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).

2. 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.

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 "caseaging" 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.

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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).

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.

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

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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.

3. 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 tenpage 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.

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.

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.

4. 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.

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.

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,

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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.

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.

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.

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.

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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.

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."

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."

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).

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

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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.

5. 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).

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.

6. 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.

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.

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.

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.

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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.

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.

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.

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 copays, and without medical justification. This both increased patient expense and unnecessarily delayed necessary diagnostic procedures.

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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.

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.

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.

118. Under original Medicare, beneficiaries are generally not subjected to formal preauthorization 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.

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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.

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%.

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.

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

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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.

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.

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).

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.

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

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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."

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.

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

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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.

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.

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.

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.

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.

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.

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.

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.

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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, 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."

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.

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.

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, 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."

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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.

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, "walked them off the cliff" and convinced BCBS Michigan not to do so.

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.

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.

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.

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

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fraud, whether the MA plans of Anthem's insurance company subsidiaries would use the rigged AIM review process.

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.

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.

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.

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.

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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.

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.

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.

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).

154. Anthem simply decided the potential profits warranted the of risk 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.

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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.

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.

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, for example, but all of the necessary and critical medical care that would be indicated by those studies.

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.

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.

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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.

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.

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.

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

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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.

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.

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

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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.

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.

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).

COUNT I

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

168. Relator-Plaintiff repeats and re-alleges 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).

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.

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.

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.

COUNT II

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

173. Relator-Plaintiff repeats and re-alleges 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).

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for entry of judgment awarding the following damages or

relief to the following parties and against Defendants:

To the UNITED STATES GOVERNMENT:

- 1. Three times the amount of actual damages sustained by the United States Government;
- 2. A civil penalty of not less than \$11,463 and not more than \$22,927 for each false claim submitted to the United States Government, or a greater amount if allowed by law;
- 3. Prejudgment interest and all other applicable interest; and,
- 4. All further relief the Court deems just and proper.

To the RELATOR:

- 1. The maximum amount allowed under 31 U.S.C. § 3730(d);
- 2. Reimbursement of all costs and expenses Relator incurs in connection with this action;
- 3. Reasonable attorneys' fees;
- 4. Expert witness fees;
- 5. All other costs of this action; and
- 6. All further relief the Court deems just and proper.

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JURY DEMAND

Relator requests a jury trial on all claims that can be tried to a jury.

Dated: May 24, 2019

By:

<u>/s/ Matthew J. Piers</u> One of the Attorneys for Relator-Plaintiff Dr. Susan Nedza

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CERTIFICATE OF SERVICE

The undersigned, an attorney, certifies that she caused a copy of this THIRD AMENDED

COMPLAINT to be served through CM/ECF system to counsel of record on Friday, May 24,

2019.

Respectfully submitted,

/s/ Matthew J. Piers One of the Attorneys for Relator-Plaintiff Dr. Susan Nedza

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EXHIBIT 1

CONTRACT WITH ELIGIBLE MEDICARE ADVANTAGE (MA) ORGANIZATION PURSUANT TO SECTIONS 1851 THROUGH 1859 OF THE SOCIAL SECURITY ACT FOR THE OPERATION OF A MEDICARE ADVANTAGE COORDINATED CARE PLAN(S)

("MA Contract")

CONTRACT WITH ELIGIBLE MEDICARE ADVANTAGE (MA) ORGANIZATION PURSUANT TO SECTIONS 1851 THROUGH 1859 OF THE SOCIAL SECURITY ACT FOR THE OPERATION OF A MEDICARE ADVANTAGE COORDINATED CARE PLAN(S)

CONTRACT (<<CONTRACT_ID>>)

Between

Centers for Medicare & Medicaid Services (hereinafter referred to as CMS)

and

<<u><CONTRACT_NAME>>></u> (hereinafter referred to as the MA Organization)

CMS and the MA Organization, an entity which has been determined to be an eligible Medicare Advantage Organization by the Administrator of the Centers for Medicare & Medicaid Services under 42 CFR §422.503, agree to the following for the purposes of §§ 1851 through 1859 of the Social Security Act (hereinafter referred to as the Act):

(NOTE: Citations indicated in brackets are placed in the text of this contract to note the regulatory authority for certain contract provisions. All references to Part 422 are to 42 CFR Part 422.)

<<CONTRACT_ID>>

Article I Term of Contract

The term of this contract shall be from the date of signature by CMS' authorized representative through December 31, 2016, after which this contract may be renewed for successive one-year periods in accordance with 42 CFR §422.505(c) and as discussed in Paragraph A of Article VII below. **[422.505]**

This contract governs the respective rights and obligations of the parties as of the effective date set forth above, and supersedes any prior agreements between the MA Organization and CMS as of such date. MA organizations offering Part D benefits also must execute an Addendum to the Medicare Managed Care Contract Pursuant to §§ 1860D-1 through 1860D-43 of the Social Security Act for the Operation of a Voluntary Medicare Prescription Drug Plan (hereafter the "Part D Addendum"). For MA Organizations offering MA-PD plans, the Part D Addendum governs the rights and obligations of the parties relating to the provision of Part D benefits, in accordance with its terms, as of its effective date.

Article II Coordinated Care Plan

- A. The MA Organization agrees to operate one or more coordinated care plans as defined in 42 CFR §422.4(a)(1)(iii)), including at least one MA-PD plan as required under 42 CFR §422.4(c), as described in its final Plan Benefit Package (PBP) bid submission (benefit and price bid) proposal as approved by CMS and as attested to in the Medicare Advantage Attestation of Benefit Plan and Price, and 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. Except as provided in paragraph (C) of this Article, this contract is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract and any regulations or policies implementing or interpreting such statutory provisions.
- C. CMS will not implement, other than at the beginning of a calendar year, requirements under 42 CFR Part 422 that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute. **[422.521]**
- D. If the MA Organization had a contract with CMS for Contract Year 2015 under the contract ID number designated above, this document is considered a renewal of the existing contract. While the terms of this document supersede the terms of the 2015 contract, the parties' execution of this contract does not extinguish or interrupt any pending obligations or actions that may have arisen under the 2015 or prior year contracts.

<<CONTRACT_ID>>

E. This contract is in no way intended to supersede or modify 42 CFR, Part 422. Failure to reference a regulatory requirement in this contract does not affect the applicability of such requirements to the MA organization and CMS.

Article III Functions To Be Performed By Medicare Advantage Organization

A. PROVISION OF BENEFITS

- 1. The MA Organization agrees to provide enrollees in each of its MA plans the basic benefits as required under 42 CFR §422.101 and, to the extent applicable, supplemental benefits under 42 CFR §422.102 and as established in the MA Organization's final benefit and price bid proposal as approved by CMS and listed in the MA Organization Plan Attestation of Benefit Plan and Price, which is attached to this contract. The MA Organization agrees to provide access to such benefits as required under subpart C in a manner consistent with professionally recognized standards of health care and according to the access standards stated in 42 CFR §422.112.
- The MA Organization agrees to provide post-hospital extended care services, should an MA enrollee elect such coverage, through a home skilled nursing facility, as defined at 42 CFR §422.133(b), according to the requirements of § 1852(l) of the Act and 42 CFR §422.133. [422. 133; 422.504(a)(3)]

B. ENROLLMENT REQUIREMENTS

- 1. The MA Organization agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in 42 CFR Part 422, Subpart B.
- The MA Organization shall comply with the provisions of 42 CFR §422.110 concerning prohibitions against discrimination in beneficiary enrollment, other than in enrolling eligible beneficiaries in a CMA-approved special needs plan that exclusively enrolls special needs individuals as consistent with 42 CFR §§422.2, 422.4(a)(1)(iv) and 422.52. [422.504(a)(2)]

C. BENEFICIARY PROTECTIONS

- 1. The MA Organization agrees to comply with all requirements in 42 CFR O Part 422, Subpart M governing coverage determinations, grievances, and appeals. [422.504(a)(7)]
- 2. The MA Organization agrees to comply with the confidentiality and enrollee record accuracy requirements in 42 CFR §422.118.
- 3. Beneficiary Financial Protections. The MA Organization agrees to comply with the following requirements:

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- (a)Each MA Organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the MA Organization. To meet this requirement the MA Organization must--
 - (i) Ensure that all contractual or other written arrangements with providers prohibit the Organization's providers from holding any beneficiary enrollee liable for payment of any fees that are the legal obligation of the MA Organization; and
 - (ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the MA Organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA Organization, to provide services to the organization's beneficiary enrollees.
 [422.504(g)(1)]
- (b) The MA Organization must provide for continuation of enrollee health care benefits-
 - (i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and
 - (ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of the MA Organization's insolvency, through the date of discharge. [422.504(g)(2)]
- (c) In meeting the requirements of this paragraph, other than the provider contract requirements specified in subparagraph 3(a) of this paragraph, the MA Organization may use—
 - (i) Contractual arrangements;
 - (ii) Insurance acceptable to CMS;
 - (iii)Financial reserves acceptable to CMS; or
 - (iv)Any other arrangement acceptable to CMS. [422.504(g)(3)]

D. PROVIDER PROTECTIONS

 The MA Organization agrees to comply with all applicable provider requirements in 42 CFR Part 422 Subpart E, including provider certification requirements, antidiscrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans. [422.504(a)(6)]

- 2. Prompt Payment.
 - (a) The MA Organization must pay 95 percent of "clean claims" within 30 days of receipt if they are claims for covered services that are not furnished under a written agreement between the organization and the provider.
 - (i) The MA Organization must pay interest on clean claims that are not paid within 30 days in accordance with §§ 1816(c)(2) and 1842(c)(2) of the Act.
 - (ii) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request. [422.520(a)]
 - (b) Contracts or other written agreements between the MA Organization and its providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA Organization and the relevant provider. **[422.520(b)]**
 - (c) If CMS determines, after giving notice and opportunity for hearing, that the MA Organization has failed to make payments in accordance with subparagraph (2)(a) of this paragraph, CMS may provide—
 - (i) For direct payment of the sums owed to providers; and
 - (ii) For appropriate reduction in the amounts that would otherwise be paid to the MA Organization, to reflect the amounts of the direct payments and the cost of making those payments. **[422.520(c)]**

E. QUALITY IMPROVEMENT PROGRAM

- 1. The MA Organization agrees to operate, for each plan that it offers, an ongoing quality improvement program as stated in accordance with § 1852(e) of the Social Security Act and 42 CFR §422.152.
- 2. The MA Organization agrees to develop and operate a chronic care improvement program in accordance with the requirements of 42 CFR §422.152(c).
- 3. Performance Measurement and Reporting: The MA Organization shall measure performance under its MA plans using standard measures required by CMS, and report (at the organization level) its performance to CMS. The standard measures required by CMS during the term of this contract will be uniform data collection and reporting instruments, to include the Health Plan and Employer Data Information Set (HEDIS), Consumer Assessment of Health Plan Satisfaction (CAHPS) survey, and Health Outcomes Survey (HOS). These measures will address clinical areas, including effectiveness of care, enrollee perception of care and use of services; and non-clinical

areas including access to and availability of services, appeals and grievances, and organizational characteristics. [422.152(b)(1), (e)]

- 4. Utilization Review:
 - (a) An MA Organization for an MA coordinated care plan must use written protocols for utilization review and policies and procedures must reflect current standards of medical practice in processing requests for initial or continued authorization of services and have in effect mechanisms to detect both underutilization and over utilization of services. [422.152(b)]
 - (b) For MA regional preferred provider organizations (RPPOs) and MA local preferred provider organizations (PPOs) that are offered by an organization that is not licensed or organized under State law as an HMOs, if the MA Organization uses written protocols for utilization review, those policies and procedures must reflect current standards of medical practice in processing requests for initial or continued authorization of services and include mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation. [422.152(e)]
- 5. Information Systems:
 - (a) The MA Organization must:
 - (i) Maintain a health information system that collects, analyzes and integrates the data necessary to implement its quality improvement program;
 - (ii) Ensure that the information entered into the system (particularly that received from providers) is reliable and complete;
 - (iii)Make all collected information available to CMS. [422.152(f)(1)]
- 6. External Review: The MA Organization will comply with any requests by Quality Improvement Organizations to review the MA Organization's medical records in connection with appeals of discharges from hospitals, skilled nursing facilities, and home health agencies.
- 7. The MA Organization agrees to address complaints received by CMS against the MA Organization as required in 42 CFR §422.504(a)(15) by:
 - (a) Addressing and resolving complaints in the CMS complaint tracking system; and
 - (b) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the MA plan's main Web page.

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F. COMPLIANCE PLAN

The MA Organization agrees to implement a compliance plan in accordance with the requirements of 42 CFR §422.503(b)(4)(vi). **[422.503(b)(4)(vi)]**

G. COMPLIANCE DEEMED ON THE BASIS OF ACCREDITATION

CMS may deem the MA Organization to have met the quality improvement requirements of §1852(e) of the Act and 42 CFR §422.152, the confidentiality and accuracy of enrollee records requirements of §1852(h) of the Act and 42 CFR §422.118, the anti-discrimination requirements of §1852(b) of the Act and 42 CFR §422.110, the access to services requirements of §1852(d) of the Act and 42 CFR §422.12, the advance directives requirements of §1852(i) of the Act and 42 CFR §422.128, the provider participation requirements of §1852(j) of the Act and 42 CFR Part 422, Subpart E, and the applicable requirements described in 42 CFR §423.156, if the MA Organization is fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by CMS and the accreditation organization used the standards approved by CMS for the purposes of assessing the MA Organization's compliance with Medicare requirements. The provisions of 42 CFR §422.156 shall govern the MA Organization's use of deemed status to meet MA program requirements.

H. PROGRAM INTEGRITY

- 1. The MA Organization agrees to provide notice based on best knowledge, information, and belief to CMS of any integrity items related to payments from governmental entities, both federal and state, for healthcare or prescription drug services. These items include any investigations, legal actions or matters subject to arbitration brought involving the MA Organization (or MA Organization's firm if applicable) and its subcontractors (excluding contracted network providers), including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. In providing the notice, the sponsor shall keep the government informed of when the integrity item is initiated and when it is closed. Notice should be provided of the details concerning any resolution and monetary payments as well as any settlement agreements or corporate integrity agreements.
- 2. The MA Organization agrees to provide notice based on best knowledge, information, and belief to CMS in the event the MA Organization or any of its subcontractors is criminally convicted or has a civil judgment entered against it for fraudulent activities or is sanctioned under any Federal program involving the provision of health care or prescription drug services.
- I. MARKETING

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- The MA Organization may not distribute any marketing materials, as defined in 42 CFR §422.2260 and in the Marketing Materials Guidelines for Medicare Advantage-Prescription Drug Plans and Prescription Drug Plans (Medicare Marketing Guidelines), unless they have been filed with and not disapproved by CMS in accordance with 42 CFR §422.2264 The file and use process set out at 42 CFR §422.2262 must be used, unless the MA organization notifies CMS that it will not use this process.
- 2. CMS and the MA Organization shall agree upon language setting forth the benefits, exclusions and other language of the Plan. The MA Organization bears full responsibility for the accuracy of its marketing materials. CMS, in its sole discretion, may order the MA Organization to print and distribute the agreed upon marketing materials, in a format approved by CMS. The MA Organization must disclose the information to each enrollee electing a plan as outlined in 42 CFR §422.111.
- 3. The MA Organization agrees that any advertising material, including that labeled promotional material, marketing materials, or supplemental literature, shall be truthful and not misleading. All marketing materials must include the Contract number. All membership identification cards must include the Contract number on the front of the card.
- 4. The MA Organization must comply with the Medicare Marketing Guidelines, as well as all applicable statutes and regulations, including and without limitation § 1851(h) of the Act and 42 CFR §422.111, 42 CFR Part 422 Subpart V and 42 CFR Part 423 Subpart V. Failure to comply may result in sanctions as provided in 42 CFR Part 422 Subpart O.

Article IV CMS Payment to MA Organization

- A. The MA Organization agrees to develop its annual benefit and price bid proposal and submit to CMS all required information on premiums, benefits, and cost sharing, as required under 42 CFR Part 422 Subpart F. [422.504(a)(10)]
- B. METHODOLOGY

CMS agrees to pay the MA Organization under this contract in accordance with the provisions of § 1853 of the Act and 42 CFR Part 422 Subpart G. [422.504(a)(9)]

C. ELECTRONIC HEALTH RECORDS INCENTIVE PROGRAM PAYMENTS

The MA Organization agrees to abide by the requirements in 42 CFR §§495.200 et seq. and §1853(l) and (m) of the Act, including the fact that payment_will be made directly to MA-affiliated hospitals that are certified Medicare hospitals through the Medicare FFS hospital incentive payment program.

D. ATTESTATION OF PAYMENT DATA (Attachments A, B, and C).

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As a condition for receiving a monthly payment under paragraph B of this article, and 42 CFR Part 422 Subpart G, the MA Organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on the forms attached hereto as Attachment A (enrollment attestation) and Attachment B (risk adjustment data) which attest to (*based on best knowledge, information and belief, as of the date specified on the attestation form*) the accuracy, completeness, and truthfulness of the data identified on these attachments. The Medicare Advantage Plan Attestation of Benefit Plan and Price must be signed and attached to the executed version of this contract.

(NOTE: The forms included as attachments to this contract are for reference only. CMS will provide instructions for the completion and submission of the forms in separate documents. MA Organizations should not take any action on the forms until appropriate CMS instructions become available.)

- 1. Attachment A requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest based on best knowledge, information, and belief that each enrollee for whom the MA Organization is requesting payment is validly enrolled, or was validly enrolled during the period for which payment is requested, in an MA plan offered by the MA Organization. The MA Organization shall submit completed enrollment attestation forms to CMS, or its contractor, on a monthly basis.
- 2. Attachment B requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must *attest to (based on best knowledge, information and belief, as of the date specified on the attestation form)* that the risk adjustment data it submits to CMS under 42 CFR §422.310 are accurate, complete, and truthful. The MA Organization shall make annual attestations to this effect for risk adjustment data on Attachment B and according to a schedule to be published by CMS. If such risk adjustment data are generated by a related entity, contractor, or subcontractor of an MA Organization, such entity, contractor, or subcontractor of an *MA* Organization, such entity, contractor, or *subcontractor form)* the accuracy, completeness, and truthfulness of the data. **[422.504(l)]**
- 3. The Medicare Advantage Plan Attestation of Benefit Plan and Price (an example of which is attached hereto as Attachment C) requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest (*based on best knowledge, information and belief, as of the date specified on the attestation form*) that the information and documentation comprising the bid submission proposal is accurate, complete, and truthful and fully conforms to the Bid Form and Plan Benefit Package requirements; and that the benefits described in the CMS-approved proposed bid submission agree with the benefit package the MA Organization will offer during the period covered by the proposed bid

submission. This document is being sent separately to the MA Organization and must be signed and attached to the executed version of this contract, and is incorporated herein by reference. **[422.504(l)]**

4. The MA Organization must certify based on best knowledge, information, and belief, that the information provided for the purposes of reporting and returning of overpayments under 42 CFR §422.326 is accurate, complete, and truthful. The form for this certification will be determined by CMS. **[422.504(l)]**

Article V

MA Organization Relationship with Related Entities, Contractors, and Subcontractors

- A. Notwithstanding any relationship(s) that the MA Organization may have with first tier, downstream, or related entities, the MA Organization maintains full responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS. [422.504(i)(1)]
- B. The MA Organization agrees to require all first tier, downstream, and related entities to agree that--
 - 1. HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related entities related to CMS' contract with the MA organization;
 - 2. HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph B (1) of this Article directly from any first tier, downstream, or related entity;
 - 3. For records subject to review under paragraph B(2) of this Article, except in exceptional circumstances, CMS will provide notification to the MA organization that a direct request for information has been initiated; and
 - 4. HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent information for any particular contract period for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later. [422.504(i)(2)]
- C. The MA Organization agrees that all contracts or written arrangements into which the MA Organization enters with first tier, downstream, and related entities shall contain the following elements:
 - 1. Enrollee protection provisions that provide—

- (a) Consistent with Article III, paragraph C, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the legal obligation of the MA Organization; and
- (b) Consistent with Article III, paragraph C, provision for the continuation of benefits.
- 2. Accountability provisions that indicate that the MA Organization may only delegate activities or functions to a first tier, downstream, or related entity in a manner consistent with requirements set forth at paragraph D of this Article.
- A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract or written agreement will be consistent and comply with the MA Organization's contractual obligations. [422.504(i)(3)]
- D. If any of the MA Organization's activities or responsibilities under this contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or provider:
 - 1. Each and every contract must specify delegated activities and reporting responsibilities.
 - 2. Each and every contract must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA Organization determine that such parties have not performed satisfactorily.
 - 3. Each and every contract must specify that the performance of the parties is monitored by the MA Organization on an ongoing basis.
 - 4. Each and every contract must specify that either—
 - (a) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA Organization; or
 - (b) The credentialing process will be reviewed and approved by the MA Organization and the MA Organization must audit the credentialing process on an ongoing basis.
 - Each and every contract must specify that the first tier, downstream, or related entity comply with all applicable Medicare laws, regulations, and CMS instructions. [422.504(i)(4)]
- E. If the MA Organization delegates selection of the providers, contractors, or subcontractors to another organization, the MA Organization's contract with that organization must state that the CMS-contracting MA Organization retains the right to approve, suspend, or terminate any such arrangement. [422.504(i)(5)]
- F. As of the date of this contract and throughout its term, the MA Organization

- 1. Agrees that any physician incentive plan it operates meets the requirements of 42 CFR §422.208, and
- 2. Has assured that all physicians and physician groups that the MA Organization's physician incentive plan places at substantial financial risk have adequate stop-loss protection in accordance with 42 CFR §422.208(f). **[422.208]**

Article VI Records Requirements

A. MAINTENANCE OF RECORDS

- 1. The MA Organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that—
 - (a) Are sufficient to do the following:
 - (i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the benefit and price bid) of the MA Organization.
 - (ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the MA Organization.
 - (iii)Enable CMS to audit and inspect any books and records of the MA Organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.
 - (iv)Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the benefit and price bid proposal.
 - (v) Establish component rates of the benefit and price bid for determining additional and supplementary benefits.
 - (vi)Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and
 - (b) Include at least records of the following:
 - (i) Ownership and operation of the MA Organization's financial, medical, and other record keeping systems.
 - (ii) Financial statements for the current contract period and ten prior periods.

- (iii)Federal income tax or informational returns for the current contract period and ten prior periods.
- (iv)Asset acquisition, lease, sale, or other action.
- (v) Agreements, contracts (including, but not limited to, with related or unrelated prescription drug benefit managers) and subcontracts.
- (vi)Franchise, marketing, and management agreements.
- (vii) Schedules of charges for the MA Organization's fee-for-service patients.
- (viii) Matters pertaining to costs of operations.
- (ix)Amounts of income received, by source and payment.
- (x) Cash flow statements.
- (xi)Any financial reports filed with other Federal programs or State authorities.[422.504(d)]
- 2. Access to facilities and records. The MA Organization agrees to the following:
 - (a) The Department of Health and Human Services (HHS), the Comptroller General, or their designee may evaluate, through inspection or other means--
 - (i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;
 - (ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;
 - (iii)The facilities of the MA Organization; and
 - (iv)The enrollment and disenrollment records for the current contract period and ten prior periods.
 - (b) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, documents, papers, patient care documentation, and other records of the MA Organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

- (c) The MA Organization agrees to make available, for the purposes specified in paragraph A of this Article, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require, in a manner that meets CMS record maintenance requirements.
- (d) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the final date of the contract period or completion of audit, whichever is later unless-
 - (i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA Organization at least 30 days before the normal disposition date;
 - (ii) There has been a termination, dispute, or fraud or similar fault by the MA Organization, in which case the retention may be extended to 10 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or
 - (iii)HHS, the Comptroller General, or their designee determines that there is a reasonable possibility of fraud, in which case they may inspect, evaluate, and audit the MA Organization at any time. [422.504(e)]

B. REPORTING REQUIREMENTS

- 1. The MA Organization shall have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information as described in the remainder of this paragraph.[422.516(a)]
- 2. The MA Organization agrees to submit to CMS certified financial information that must include the following:
 - (a) Such information as CMS may require demonstrating that the organization has a fiscally sound operation, including:
 - (i) The cost of its operations;
 - (ii) A description, submitted to CMS annually and within 120 days of the end of the fiscal year, of significant business transactions (as defined in 42 CFR §422.500) between the MA Organization and a party in interest showing that the costs of the transactions listed in subparagraph (2)(a)(v) of this paragraph do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

- (iii)If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.
- (iv)A combined financial statement for the MA Organization and a party in interest if either of the following conditions is met:
 - (aa) Thirty five percent or more of the costs of operation of the MA Organization go to a party in interest.
 - (bb) Thirty five percent or more of the revenue of a party in interest is from the MA Organization. [422.516(b)]
- (v) Requirements for combined financial statements.
 - (aa) The combined financial statements required by this subparagraph must display in separate columns the financial information for the MA Organization and each of the parties in interest.
 - (bb) Inter-entity transactions must be eliminated in the consolidated column.
 - (cc) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.
 - (dd) Upon written request from the MA Organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this subparagraph with respect to a particular entity. [422.516(c)]
- (vi)A description of any loans or other special financial arrangements the MA Organization makes with contractors, subcontractors, and related entities.[422.516(e)]
- (b) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA Organization. [422.504(f)]
- (c) Patterns of utilization of the MA Organization's services. [422.516(a)(2)]
- 3. The MA Organization agrees to participate in surveys required by CMS and to submit to CMS all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

- (a) The benefits covered under the MA plan;
- (b) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan.
- (c) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;
- (d) Plan quality and performance indicators for the benefits under the plan including --
 - (i) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;
 - (ii) Information on Medicare enrollee satisfaction;
 - (iii)The patterns of utilization of plan services;
 - (iv)The availability, accessibility, and acceptability of the plan's services;
 - (v) Information on health outcomes and other performance measures required by CMS;
 - (vi)The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and
 - (vii) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;
 - (viii) Information about beneficiary appeals and their disposition;
 - (ix)Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;
 - (x) Any other information deemed necessary by CMS for the administration or evaluation of the Medicare program. [422.504(f)(2)]
- 4. The MA Organization agrees to provide to its enrollees and upon request, to any individual eligible to elect an MA plan, all informational requirements under 42 CFR §422.64 and, upon an enrollee's, request, the financial disclosure information required under 42 CFR §422.516. [422.504(f)(3)]
- 5. Reporting and disclosure under ERISA -

- (a) For any employees' health benefits plan that includes an MA Organization in its offerings, the MA Organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the MA Organization) under the Employee Retirement Income Security Act of 1974 (ERISA).
- (b) The MA Organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA. [422.516(d)]
- 6. Electronic communication. The MA Organization must have the capacity to communicate with CMS electronically. **[422.504(b)]**
- 7. Risk Adjustment data. The MA Organization agrees to comply with the requirements in 42 CFR §422.310 for submitting risk adjustment data to CMS. [422.504(a)(8)]
- 8. The MA Organization acknowledges that CMS releases to the public summary reconciled Part D Payment data after the reconciliation of Part C and Part D Payments for the contract year as provided in 42 CFR §422.504(n) and, for Part D plan sponsors, 42 CFR §423.505(o).
- The MA Organization agrees that it must subject information collected pursuant to 42 CFR §422.516(a) to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS. [422.516(g)]

Article VII Renewal of the MA Contract

A. RENEWAL OF CONTRACT

In accordance with 42 CFR §422.505, following the initial contract period, this contract is renewable annually only if-

- 1. The MA Organization has not provided CMS with a notice of intention not to renew; [422.506(a)]
- 2. CMS and the MA Organization reach agreement on the bid under 42 CFR Part 422, Subpart F; and **[422.505(d)]**
- 3. CMS informs the MA Organization that it authorizes a renewal.

B. NONRENEWAL OF CONTRACT

- 1. Nonrenewal by the Organization.
 - (a) In accordance with 42 CFR §422.506, the MA Organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason, provided it meets the time frames for doing so set forth in this subparagraph.
 - (b) If the MA Organization does not intend to renew its contract, it must notify--
 - (i) CMS, in writing, by the first Monday in June of the year in which the contract would end, pursuant to 42 CFR §422.506
 - (ii) Each Medicare enrollee by mail, at least 90 calendar days before the date on which the nonrenewal is effective. This notice must include a written description of all alternatives available for obtaining Medicare services within the service area including alternative MA plans, MA-PD plans, Medigap options, and original Medicare and prescription drug plans and must receive CMS approval prior to issuance.
 - (c) CMS may accept a nonrenewal notice submitted after the applicable annual non-renewal notice deadline if
 - (i) The MA Organization notifies its Medicare enrollees and the public in accordance with subparagraph 1(b)(ii) of this paragraph; and
 - (ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.
 - (d) If the MA Organization does not renew a contract under this subparagraph, CMS may deny an application for a new contract or a service area expansion from the Organization or with any organization whose covered persons, as defined at 42 CFR §422.506(a)(5), also served as covered persons for the non-renewing MA Organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type, or service area of the previous contract. [422.506(a)]
- 2. CMS decision not to renew.
 - (a) CMS may elect not to authorize renewal of a contract for any of the following reasons:
 - (i) For any of the reasons listed in 42 CFR §422.510(a) which would also permit CMS to terminate the contract.

- (ii) The MA Organization has committed any of the acts in 42 CFR §422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under 42 CFR Part 422 Subpart O.
- (iii)The MA Organization did not submit a benefit and price bid or the benefit and price bid was not acceptable [422.505(d)]
- (b) Notice. CMS shall provide notice of its decision whether to authorize renewal of the contract as follows:
 - (i) To the MA Organization by August 1 of the contract year, except in the event described in subparagraph (2)(a)(iii) of this paragraph, for which notice will be sent by September 1.
 - (ii) To the MA Organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.
- (c) Notice of appeal rights. CMS shall give the MA Organization written notice of its right to reconsideration of the decision not to renew in accordance with 42 CFR §422.644.[422.506(b)]

Article VIII Modification or Termination of the Contract

A. MODIFICATION OR TERMINATION OF CONTRACT BY MUTUAL CONSENT

- 1. This contract may be modified or terminated at any time by written mutual consent.
 - (a) If the contract is modified by written mutual consent, the MA Organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within time frames specified by CMS. [422.508(a)(2)]
 - (b) If the contract is terminated by written mutual consent, except as provided in subparagraph 2 of this paragraph, the MA Organization must provide notice to its Medicare enrollees and the general public as provided in paragraph B, subparagraph 2(b) of this Article. [422.508(a)(1)]
- 2. If this contract is terminated by written mutual consent and replaced the day following such termination by a new MA contract, the MA Organization is not required to provide the notice specified in paragraph B of this Article. **[422.508(b)]**
- 3. As a condition of the consent to a mutual termination, CMS will require as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances

warranting special consideration. This prohibition may apply regardless of the product type, contract type, or service area of the previous contract. **[422.508(c)]**

B. TERMINATION OF THE CONTRACT BY CMS OR THE MA ORGANIZATION

- 1. Termination by CMS.
 - (a) CMS may at any time terminate a contract if CMS determines that the MA Organization meets any of the following:
 - (i) has failed substantially to carry out the terms of its contract with CMS.
 - (ii) is carrying out its contract in a manner that is inconsistent with the efficient and effective implementation of 42 CFR Part 422.

(iii)no longer substantially meets the applicable conditions of 42 CFR Part 422.

- (b) CMS may make a determination under paragraph B(1)(a)(i), (ii), or (iii) of this Article if the MA Organization has had one or more of the following occur:
 - (i) based on creditable evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care program, including submission of false or fraudulent data.
 - (ii) experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists.
 - (iii)substantially failed to comply with the requirements in 42 CFR Part 422 Subpart M relating to grievances and appeals.
 - (iv)failed to provide CMS with valid data as required under 42 CFR §§422.310.
 - (v) failed to implement an acceptable quality assessment and performance improvement program as required under 42 CFR Part 422 Subpart D.
 - (vi)substantially failed to comply with the prompt payment requirements in 42 CFR §422.520.
 - (vii) substantially failed to comply with the service access requirements in 42 CFR §422.112.
 - (viii) failed to comply with the requirements of 42 CFR §422.208 regarding physician incentive plans.

- (ix)substantially failed to comply with the marketing requirements in 42 CFR Part 422 Subpart V.
- (x) Failed to comply with regulatory requirements contained in 42 CFR Parts 422 or 423 or both.
- (xi)Failed to meet CMS performance requirements in carrying out the regulatory requirements contained in 42 CFR Parts 422 or 423 or both.
- (xii) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years.
- (xiii) Has failed to report MLR data in a timely and accurate manner in accordance with 42 CFR §422.2460.
- (c) Notice. If CMS decides to terminate a contract, it will give notice of the termination as follows:
 - (i) CMS will notify the MA Organization in writing at least 45 calendar days before the intended date of the termination.
 - (ii) The MA Organization will notify its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.
 - (iii)The MA Organization will notify the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.
- (d) Expedited termination of contract by CMS.
 - (i) For terminations based on violations prescribed in subparagraph 1(b)(i) or (b)(ii) of this paragraph or if CMS determines that a delay in termination would pose an imminent and serious threat to the health of the individuals enrolled with the MA Organization, CMS will notify the MA Organization in writing that its contract has been terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA Organization covering the period of the month following the contract termination.
 - (ii) CMS will notify the MA Organization's Medicare enrollees in writing of CMS' decision to terminate the MA Organization's contract. This notice will occur no later than 30 days after CMS notifies the plan of its decision to terminate this contract. CMS will simultaneously inform the Medicare enrollees of alternative

options for obtaining Medicare services, including alternative MA Organizations in a similar geographic area and original Medicare.

- (iii)CMS will notify the general public of the termination no later than 30 days after notifying the MA Organization of CMS' decision to terminate this contract. This notice will be published in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.
- (e) Corrective action plan
 - (i) General. Before providing a notice of intent to terminate a contract for reasons other than the grounds specified in subparagraph 1(a)(iv) or (v) of this paragraph, CMS will provide the MA Organization with notice specifying the MA Organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement an approved corrective action plan to correct the deficiencies that are the basis of the proposed termination.
 - (ii) Exceptions. If a contract is terminated under subparagraph 1(a)(iv) or (v) of this paragraph, the MA Organization will not be provided with the opportunity to develop and implement a corrective action plan.
- (f) Appeal rights. If CMS decides to terminate this contract, it will send written notice to the MA Organization informing it of its termination appeal rights in accordance with 42 CFR Part 422 Subpart N. [422.510(d)]
- 2. Termination by the MA Organization
 - (a) Cause for termination. The MA Organization may terminate this contract if CMS fails to substantially carry out the terms of the contract.
 - (b) Notice. The MA Organization must give advance notice as follows:
 - (i) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA Organization is requesting contract termination.
 - (ii) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA and MA-PD plans, PDP plans, Medigap options, and original Medicare and must receive CMS approval.
 - (iii)To the general public at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general

circulation in each community or county located in the MA Organization's geographic area.

- (c) Effective date of termination. The effective date of the termination will be determined by CMS and will be at least 90 days after the date CMS receives the MA Organization's notice of intent to terminate.
- (d) CMS' liability. CMS' liability for payment to the MA Organization ends as of the first day of the month after the last month for which the contract is in effect, but CMS shall make payments for amounts owed prior to termination but not yet paid.
- (e) Effect of termination by the organization. CMS may deny an application for a new contract or service area expansion from the MA Organization or with an organization whose covered persons, as defined in 42 CFR §422.512(e)(2), also served as covered persons for the terminating MA Organization for a period of two years from the date the Organization has terminated this contract, unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type, or service area of the previous contract. [422.512]

Article IX Requirements of Other Laws and Regulations

- A. The MA Organization agrees to comply with--
 - 1. Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 USC §§3729 et seq.), and the anti-kickback statute (§ 1128B(b) of the Act): and
 - HIPAA administrative simplification rules at 45 CFR Parts 160, 162, and 164.
 [422.504(h)]
- B. Pursuant to § 13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), the MA Organization agrees that as it implements, acquires, or upgrades its health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under § 3004 of the Public Health Service Act, as amended by § 13101 of the ARRA.
- C. The MA Organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS, notwithstanding any relationship(s) that the MA Organization may have with related entities, contractors, or subcontractors. **[422.504(i)]**

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D. In the event that any provision of this contract conflicts with the provisions of any statute or regulation applicable to an MA Organization, the provisions of the statute or regulation shall have full force and effect.

Article X Severability

The MA Organization agrees that, upon CMS' request, this contract will be amended to exclude any MA plan or State-licensed entity specified by CMS, and a separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made. **[422.504(k)]**

Article XI Miscellaneous

A. DEFINITIONS

Terms not otherwise defined in this contract shall have the meaning given to such terms in 42 CFR Part 422.

B. ALTERATION TO ORIGINAL CONTRACT TERMS

The MA Organization agrees that it has not altered in any way the terms of this contract presented for signature by CMS. The MA Organization agrees that any alterations to the original text the MA Organization may make to this contract shall not be binding on the parties.

C. APPROVAL TO BEGIN MARKETING AND ENROLLMENT

The MA Organization agrees that it must complete CMS operational requirements prior to receiving CMS approval to begin Part C marketing and enrollment activities. Such activities include, but are not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications (or contracting with an entity qualified to perform such functions on the MA Organization's Sponsor's behalf) and successfully demonstrating capability to submit accurate and timely price comparison data. To establish and successfully test connectivity, the MA Organization must, 1) establish and test physical connectivity to the CMS data center, 2) acquire user identifications and passwords, 3) receive, store, and maintain data necessary to perform enrollments and send and receive transactions to and from CMS, and 4) check and receive transaction status information.

D. MA Organization agrees to maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities) as required in 42 CFR§ 422.504(a)(14).

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- E. MA Organization agrees to maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services as required by 42 CFR §422.504(a)(17).
- F. MA Organization agrees to maintain a Part C summary plan rating score of at least 3 stars as required by 42 CFR §422.504(a)(18).
- G. CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations, or guidance. If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents and outlier relative to the performance of other MA organizations. [422.504(m)]
- H. **Business Continuity**: The MA organization agrees to develop, maintain, and implement a business continuity plan as required by 42 CFR §422.504(o).

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ATTACHMENT A

ATTESTATION OF ENROLLMENT INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (<u>INSERT NAME OF MA ORGANIZATION</u>), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (<u>INSERT PLAN IDENTIFICATION NUMBERS HERE</u>), the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This attestation shall not be considered a waiver of the MA Organization's right to seek payment adjustments from CMS based on information or data which does not become available until after the date the MA Organization submits this attestation.

1. The MA Organization has reported to CMS for the month of (<u>INDICATE MONTH</u> <u>AND YEAR</u>) all new enrollments, disenrollments, and appropriate changes in enrollees' status with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The MA Organization has reviewed the CMS monthly membership report and reply listing for the month of (<u>INDICATE MONTH AND YEAR</u>) for the above-stated MA plans and has reported to CMS any discrepancies between the report and the MA Organization's records. For those portions of the monthly membership report and the reply listing to which the MA Organization raises no objection, the MA Organization, through the certifying CEO/CFO, will be deemed to have attested, based on best knowledge, information, and belief as of the date indicated below, to its accuracy, completeness, and truthfulness.

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ATTACHMENT B

ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (<u>INSERT NAME OF MA ORGANIZATION</u>), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (<u>INSERT PLAN IDENTIFICATION NUMBERS HERE</u>), the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS during the period of (<u>INDICATE DATES</u>) all (<u>INDICATE TYPE - DIAGNOSIS/ENCOUNTER</u>) risk adjustment data available to the MA Organization with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

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<u>ATTACHMENT C – Medicare Advantage Plan Attestation of Benefit Plan and Price</u>

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In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR THE MA ORGANIZATION

<<<u>CONTRACTING_OFFICIAL_NAME</u>>> Contracting Official Name

<<<u>DATE_STAMP>></u> Date

Center for Medicare

<<<u>CONTRACT_NAME>></u> Organization <<ADDRESS>> Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

<<<u>DANIELLE MOON ESIG>></u> Kathryn A. Coleman Director Medicare Drug and Health Plan Contract Administration Group, <<<u>DATE_STAMP>></u> Date

<<CONTRACT_ID>>

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EXHIBIT 2

CY 2016 BENEFIT ATTESTATION

("Benefit Attestation")

CY 2016 Benefit Attestation

Please review the following information. If all of the information is correct, then electronically sign the benefit attestation.

Medicare Advantage Attestation of Benefit Plan

(Company Name)

Hxxxx

Date: 00/00/2015

Prescription Drug Plan Attestation of Benefit Plan (Company Name) Sxxxx Date: 00/00/2015

I attest that I have examined the Plan Benefit Packages (PBPs) identified below and that the benefits identified in the PBPs are those that the above-stated organization will make available to eligible beneficiaries in the approved service area during program year 2016. I further attest that we have reviewed the bid pricing tools (BPTs) with the certifying actuary and have determined them to be consistent with the PBPs being attested to here.

PARAGRAPH FOR A/B ONLY COST

I attest that I have examined the Plan Benefit Packages (PBPs) identified below and that the benefits identified in the PBPs are those that the above-stated organization will make available to eligible beneficiaries in the approved service area during program year 2016.

(NOTE: ONLY DISPLAY THIS PARAGRAPH IF THE CONTRACTOR OFFERS AT LEAST ONE "800 SERIES" PLAN. THIS SAME ATTESTATION BELOW CAN BE USED FOR: ALL EMPLOYER/UNION DIRECT "E" CONTRACTS; ALL "S" AND "H" CONTRACTS THAT HAVE INDIVIDUAL AND "800 SERIES" PLANS; AND ANY "S" OR "H" CONTRACTS THAT ARE OFFERING ONLY "800 SERIES" PLANS IN 2016 (ENTITIES QUALIFIED TO ONLY OFFER "800 SERIES" PLANS IN 2016 ARE STANDALONE PDPS, NON-NETWORK PFFS AND MSA CONTRACTS)

I attest that I have examined the employer/union-only group waiver ("800 series") PBPs identified below and that these PBPs are those that the above-stated organization will make available only to eligible employer/union-sponsored group plan beneficiaries in the approved service area during program year 2016. I further attest we have reviewed any MA bid pricing tools (BPTs) associated with these PBPs (no Part D bids are required for 2016 "800 series" PBPs) with the certifying actuary and have determined them to be consistent with any MA PBPs being attested to here.

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 during the remainder of 2015 and 2016, including but not limited to, the 2016 Call Letter, the 2016 Solicitations for New Contract Applicants, the Medicare Prescription Drug Benefit Manual, the Medicare Managed Care Manual, and the CMS memoranda issued through the Health Plan Management System (HPMS).

<<<u>CONTRACTING_OFFICIAL_NAME</u> >> Contracting Official Name

<<<u>DATE_STAMP>></u> Date

<<<u>CONTRACT_NAME>></u> Organization <<ADDRESS>> Address