UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. ANTHEM, INC., Defendant.	Case No. 1:20-cv-02593-ALC **DEFENDANT ANTHEM, INC.'S ANSWER TO THE AMENDED COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Anthem, Inc. ("Anthem") hereby files its Answer and Affirmative Defenses ("Answer") to Plaintiff's Amended Complaint (Dkt. 26) along with its Counterclaims. Each numbered response in this Answer is made subject to the following limitations. First, unless specifically admitted, Anthem denies each and every allegation in the Amended Complaint. Second, to the extent Plaintiff has included headings, a table of contents, or other impertinent material that is inappropriate under Federal Rules of Civil Procedure 8, 10, or 12(f), no response is necessary and such material should be stricken. To the extent any headings, table of contents, or impertinent material is deemed to require a response, Anthem denies each and every allegation. Any headings from the Amended Complaint that are reproduced herein are reproduced for convenience of reading only.

PRELIMINARY STATEMENT

1. Paragraph 1 contains Plaintiff's characterization of this action, to which no response is required. To the extent a response is required, Anthem admits that Plaintiff purports

to assert claims pursuant to the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.* Anthem denies each and every remaining allegation in paragraph 1.

2. Anthem admits that the Medicare Advantage organizations ("MAOs") that operated the Part C contracts listed in Exhibit 1 during the relevant time period ("Anthem MAOs") administer private Medicare Advantage ("MA" or "Part C") plans under which they assume the financial risk of providing Medicare benefits to members enrolled in their Part C plans and in turn receive monthly payments from the Centers for Medicare & Medicaid Services ("CMS"). To the extent this paragraph references ¶¶ 21–39 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 2.

3. Anthem admits that it understood during the relevant time period that CMS calculated Medicare Advantage payments to Anthem and/or Anthem MAOs using the CMS Hierarchical Condition Category ("CMS-HCC") risk adjustment model, and that Anthem typically submitted to CMS diagnosis codes from the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM diagnosis codes") or the International Classification of Diseases, Tenth Revision, Clinical Modification ("ICD-10-CM diagnosis codes") reported to Anthem and/or Anthem MAOs by providers. To the extent this paragraph references ¶¶ 27–44 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 3.

4. Anthem admits that Anthem MAOs have attested under 42 C.F.R. § 422.504(*l*) that their Medicare Advantage risk adjustment data submissions were "accurate, complete, and truthful" according to the signatory's "best knowledge, information and belief." To the extent

this paragraph references ¶¶ 45–50, 57–61, 70–90, 137–140 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 4.

5. Anthem admits that it implemented a corporate retrospective chart review program using one or more vendors, pursuant to which it obtained medical records from providers concerning services they provided to members enrolled in Anthem MAOs' Part C plans, and the vendor or vendors then reviewed those medical records. To the extent this paragraph references ¶¶ 120–133 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 5.

5 n.1. Anthem admits that beginning with medical records with 2016 dates of service reviewed during its corporate retrospective chart review program's 2017 project year, after its vendor or vendors sent chart review diagnosis coding results to Anthem, Anthem isolated provider-submitted ICD-10-CM or ICD-9-CM diagnosis codes that were not also found in chart review diagnosis coding results for the same member, provider, and date of service. Anthem denies each and every remaining allegation in paragraph 5 footnote 1.

6. Anthem admits that it collected medical records from healthcare providers for its corporate retrospective chart review program and that paragraph 6 quotes a portion of Exhibit 10. To the extent paragraph 6 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. To the extent this paragraph references ¶¶ 111–119 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 6.

7. Anthem admits that under the CMS-HCC risk adjustment model, the submission of ICD-10-CM or ICD-9-CM diagnosis codes by MAOs to CMS, including diagnosis code data corrections, may impact CMS's risk-score calculations and therefore may impact the risk-adjusted portion of CMS's payment to MAOs. To the extent this paragraph references ¶¶ 120–133 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 7.

8. Anthem admits that paragraph 8 quotes portions of a March 9, 2016, email from Anthem's then-Staff Vice President of Anthem's Medicare Programs Revenue & Reconciliation business unit. To the extent paragraph 8 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. To the extent this paragraph references ¶¶ 141–152 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 8.

9. Paragraph 9 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3729(a)(1)(A), (B), and (G), to which Anthem respectfully refers the Court for its complete and accurate content. To the extent this paragraph references ¶¶ 158–178 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 9.

THE PARTIES

10. Anthem admits each and every allegation in paragraph 10.

11. Anthem admits each and every allegation in paragraph 11.

11 n.2. Anthem admits each and every allegation in paragraph 11 footnote 2.

JURISDICTION AND VENUE

12. Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331, 1345, to which Anthem respectfully refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 12.

13. Paragraph 13 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), to which Anthem refers the Court for their complete and accurate contents. Anthem admits for purposes of venue that it transacts business in the Southern District of New York. Anthem denies each and every remaining allegation in paragraph 13.

14. Paragraph 14 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3732(a), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 14.

THE FALSE CLAIMS ACT

15. Anthem admits the False Claims Act was originally enacted in 1863. Anthem denies each and every remaining allegation in paragraph 15.

16. Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3729(a)(1)(A), (B), and (G), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 16.

17. Paragraph 17 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3729(b)(1), to which Anthem

respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 17.

18. Paragraph 18 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3729(a)(1)(B) and (b)(4), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 18.

19. Paragraph 19 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3729(a)(1)(G), (b)(3), S. Rep. 111-10, at 14 (2009), 124 Stat. 119, 753–56 (2010), and 42 U.S.C. § 1320a–7k(d)(2), to which Anthem respectfully refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 19.

20. Paragraph 20 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 31 U.S.C. § 3729(a)(1), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 20.

20 n.3. Paragraph 20 footnote 3 states legal conclusions to which no response is required. To the extent a response is required, paragraph 20 footnote 3 references 28 U.S.C. § 2461 note (Federal Civil Penalties Inflation Adjustment), 64 Fed. Reg. 47099, 47103 (Aug. 30, 1999), and 82 Fed. Reg. 9131, 9131–36 (Feb. 3, 2017), to which Anthem respectfully refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 20 footnote 3.

THE MEDICARE ADVANTAGE PROGRAM AND ITS RISK ADJUSTMENT PAYMENT SYSTEM

A. Medicare Advantage and the Role of Part C MAOs

21. Paragraph 21 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that Medicare is a federally operated health insurance program administered by CMS benefiting individuals 65 and older and certain disabled individuals. Paragraph 21 references 42 U.S.C. § 1395c, *et seq.*, to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 21.

22. Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that Medicare Parts A and B are commonly known as "traditional Medicare"; that Medicare Part A covers inpatient and institutional care; that Medicare Part B covers physician, hospital, outpatient, and ancillary services and durable medical equipment; and upon information and belief that under traditional Medicare, CMS typically reimburses healthcare providers directly using a fee-for-service model under which healthcare providers submit claims to CMS for medical services actually rendered and CMS pays the providers directly for each service based on rates established by the government. Anthem denies each and every remaining allegation in paragraph 22.

23. Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that this case involves Medicare Part C, through which members receive their benefits (including Part A and Part B) through private Part C plans administered by insurance companies, such as Anthem MAOs. Paragraph 23 references 42 U.S.C. §§ 1395w-21 to -28 and 42 C.F.R. §§ 422.2, 422.503(b)(2), to which Anthem respectfully

refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 23.

24. Paragraph 24 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that under Medicare Part C, members receive Medicare benefits administered by private insurance plans, and that when a healthcare provider furnishes medical services to an MA member enrolled in a Part C plan, the provider typically submits claims and encounter data to the MAO that operates that Part C plan. Anthem denies each and every remaining allegation in paragraph 24.

25. Paragraph 25 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 U.S.C. § 1395w-26(b) and 42 C.F.R. Part 422, to which Anthem respectfully refers the Court for their complete and accurate contents. To the extent this paragraph references ¶¶ 57–60 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 25.

26. Anthem admits that Anthem MAOs executed annual written contractual agreements with CMS for all of the Part C plans listed in Exhibit 1 from 2013 to 2018. To the extent paragraph 26 characterizes such agreements, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 26.

26 n.4. Anthem admits that Exhibit 2 is a contract between CMS and Empire HealthChoice HMO (H3370) for contract year 2014 and Exhibit 3 is a contract between CMS and Empire HealthChoice HMO (H3370) for contract year 2015. To the extent paragraph 26 footnote 4 characterizes these documents, Anthem denies the allegation because the referenced

documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 26 footnote 4.

B. Medicare Part C's Risk Adjustment Payment System and the Role of ICD and HCC Codes in CMS's Calculation of Risk Adjustment Payments

27. Paragraph 27 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits upon information and belief that CMS does not compensate MAOs on a fee-for-service basis for specific medical services. Anthem denies each and every remaining allegation in paragraph 27.

28. Paragraph 28 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits upon information and belief that the payments CMS makes to MAOs under Medicare Part C do not depend on the amount of services provided to a specific member. Paragraph 28 references 42 U.S.C. § 1395w-23(a)(1)(B) and 42 C.F.R. §§ 422.254, 425.304, to which Anthem respectfully refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 28.

29. Paragraph 29 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that since 2000, Congress has directed the agency now known as CMS to "adjust" payments to Part C Plans "for such risk factors as age, disability status, gender, institutional status, and such other factors [CMS] determines to be appropriate, including . . . health status . . . so as to ensure actuarial equivalence[,]" and that this process is called "risk adjustment." 42 U.S.C. § 1395w-23(a)(1)(C). Paragraph 29 references 42 U.S.C. § 1395w-23(a)(1)(C), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 29.

29 n.5. Paragraph 29 footnote 5 states legal conclusions to which no response is required. To the extent a response is required, paragraph 29 footnote 5 references 42 C.F.R.

§ 422.310(g)(2), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 29 footnote 5.

30. Paragraph 30 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that risk adjustment pursuant to the CMS-HCC risk adjustment model results in a "risk score," sometimes referred to as the "risk adjustment factor" or "RAF," which is a multiplier that is applied to the bid amount for an applicable MA member and is a component of the payment amount for applicable MA members. Paragraph 30 references 42 C.F.R. § 422.308(e), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 30.

30 n.6. Paragraph 30 footnote 6 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that MAOs submit to CMS a bid for each specific Part C plan and upon information and belief that CMS compares the bids to a benchmark set by CMS. Paragraph 30 footnote 6 references 42 C.F.R. Part 422, subparts F and G, to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 30 footnote 6.

31. Paragraph 31 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that CMS uses demographic factors and health status to calculate a risk score for each MA member pursuant to the CMS-HCC risk adjustment model for MA members enrolled in Part C plans, which is a multiplier that is applied to the bid amount for the relevant MA member and is a component of the payment amount for each MA member; that CMS employs an HCC model; and that each HCC coefficient within the CMS-HCC risk adjustment model aims to correlate with the marginal predicted cost of medical

expenditures for that set of medical disease groupings based on CMS's data from administering the traditional Medicare fee-for-service program. Paragraph 31 references 42 C.F.R. § 422.2, to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 31.

32. Anthem admits that HCCs are disease groupings consisting of disease codes (currently ICD-10-CM codes and previously ICD-9-CM codes); that between 2004 and 2013, there were 70 HCCs in the CMS-HCC risk adjustment model; and that starting in 2014, the number of HCCs in the CMS-HCC risk adjustment model increased to 79. Paragraph 32 references 42 C.F.R. § 422.2, to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 32.

33. Anthem admits that each HCC coefficient within the CMS-HCC risk adjustment model aims to correlate with the marginal predicted cost of medical expenditures for that set of medical disease groupings based on CMS's data from administering the traditional Medicare fee-for-service program and that, using the Version 22 model, some examples of HCCs are HIV/AIDS (HCC 1), metastatic cancer and leukemia (HCC 8), and ischemic stroke (HCC 100). Anthem denies each and every remaining allegation in paragraph 33.

33 n.7. Anthem admits each and every allegation in paragraph 33 footnote 7.

34. Anthem admits that under the CMS-HCC risk adjustment model, HCCs are the basis of the disease component of the MA member risk score, and that under the CMS-HCC risk adjustment model, the disease component of a single MA member's risk score could reflect zero, one, or multiple HCCs for any given MA contract year. Anthem denies each and every remaining allegation in paragraph 34.

35. Anthem lacks sufficient knowledge to admit or deny the allegations and, on that basis, denies each and every allegation in paragraph 35.

36. Anthem admits that CMS uses ICD-10-CM or ICD-9-CM diagnosis codes that are coded from MA member encounters with providers during dates of service in one year (the "DOS year" or "date of service year") to determine payments for each applicable MA member in a future year (the "payment year") pursuant to the CMS-HCC risk adjustment model. Anthem denies each and every remaining allegation in paragraph 36.

37. Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, paragraph 37 references 45 C.F.R. § 162.1002(c) and 42 C.F.R. § 422.310(d)(1), to which Anthem respectfully refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 37.

38. Anthem admits that the ICD coding and classification system uses alphanumeric codes to represent diagnoses, and that the applicable standards for ICD coding have been set forth in two systems: ICD-9-CM and ICD-10-CM. Anthem denies each and every remaining allegation in paragraph 38.

39. Anthem admits that CMS uses ICD-10-CM or ICD-9-CM diagnosis codes that are coded from MA member encounters with providers during the DOS year to determine payments for each applicable MA member in the payment year pursuant to the CMS-HCC risk adjustment model. Anthem denies each and every remaining allegation in paragraph 39.

C. CMS's Risk Adjustment Payment Process and Its RAPS and EDPS Risk Adjustment Data Reporting Systems

40. Anthem lacks sufficient knowledge to admit or deny the allegations and, on that basis, denies each and every allegation in paragraph 40.

41. Anthem admits that it and/or Anthem MAOs receive diagnosis codes from providers and submit ICD-10-CM or ICD-9-CM diagnosis codes to CMS using risk adjustment data reporting systems provided by CMS. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 41.

42. Anthem admits that CMS has utilized two electronic systems for collecting risk adjustment data—the Risk Adjustment Processing System ("RAPS") and the Encounter Data Processing System ("EDPS"). The final sentence in Paragraph 42 states a legal conclusion to which no response is required. To the extent a response is required, Anthem denies the allegation in the final sentence and each and every remaining allegation in paragraph 42.

43. Anthem admits that data submitted through the RAPS system has several components, including AAA, BBB, and CCC records; that a CCC record in part contains the Medicare identification number for a particular member as well as up to ten diagnosis clusters for that member; that each cluster, in turn, contains the date of service from date, date of service thru date, provider type, and ICD-10-CM or ICD-9-CM diagnosis code; and that a cluster may contain a "Delete Indicator" of "D." The final sentence in Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Anthem denies the allegation in the final sentence and each and every remaining allegation in paragraph 43.

43 n.8. Anthem admits that a "Delete Indicator" of "D" indicates to CMS that an ICD-10-CM or ICD-9-CM diagnosis code within a diagnosis cluster for an MA member should be removed from CMS's electronic systems for purposes of the CMS-HCC risk adjustment model. Anthem denies each and every remaining allegation in paragraph 43 footnote 8.

43 n.9. Anthem admits that in the EDPS system, MAOs submit X12 837 5010 formatted data with a number of components, which are in part referred to as "loops"; that ICD-10-CM or ICD-9-CM diagnosis codes are among the data submitted by MAOs to CMS using EDPS; and that the EDPS system has mechanisms that MAOs can use to indicate to CMS that an ICD-10-CM or ICD-9-CM diagnosis code within a diagnosis cluster for an MA member should be removed from CMS's electronic systems for purposes of the CMS-HCC risk adjustment model. Anthem denies each and every remaining allegation in paragraph 43 footnote 9.

44. Paragraph 44 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 C.F.R. § 422.310(g), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 44.

D. CMS Required MAOs to Follow the "Medical Record Documentation" Standard for Part C Risk Adjustment Diagnosis Data Submissions

45. Paragraph 45 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 45 references 42 C.F.R. § 422.310, to which Anthem respectfully refers the Court for its complete and accurate content; that CMS has issued sub-regulatory guidance, including the Medicare Managed Care Manual ("MMC Manual"); and that paragraph 45 references the MMC Manual Chapter 7 (Aug. 2004). To the extent paragraph 45 characterizes the MMC Manual, Anthem denies the allegation because the referenced document speaks for itself. To the extent this paragraph references ¶ 64 of the Amended Complaint, *see* Anthem's response to that paragraph, which is incorporated herein. Anthem denies each and every remaining allegation in paragraph 45.

46. Anthem admits that paragraph 46 quotes portions of the ICD-10-CM Official Guidelines for Coding and Reporting FY 2014. To the extent paragraph 46 characterizes the ICD-10-CM Official Guidelines for Coding and Reporting FY 2014, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 46.

47. Anthem admits that paragraph 47 quotes terms in the ICD-10-CM Official Guidelines for Coding and Reporting FY 2014. To the extent paragraph 47 characterizes the ICD-10-CM Official Guidelines for Coding and Reporting FY 2014, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 47.

48. Anthem admits that CMS has issued sub-regulatory guidance, including the MMC Manual, and that paragraph 48 quotes terms in the MMC Manual (Aug. 2004 and June 2013). To the extent paragraph 48 characterizes the MMC Manual, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 48.

49. Paragraph 49 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits upon information and belief that CMS has offered trainings to MAOs; that CMS has issued sub-regulatory guidance, including the documents listed in paragraph 49; and that paragraph 49 appears to quote certain terms in the 2003 Regional Risk Adjustment Training for MAOs Participant Guide (paragraph 49 is missing a closed quotation mark). To the extent paragraph 49 characterizes the 2003 Participant Guide and other documents referenced in paragraph 49, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 49.

49 n.10. Anthem admits that the website referenced in paragraph 49 footnote 10 includes certain Medicare Advantage-related information. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 49 footnote 10.

50. Paragraph 50 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits upon information and belief that CMS has offered trainings to MAOs; that CMS has issued sub-regulatory guidance, including the document referenced in paragraph 50; and that paragraph 50 quotes portions of the 2005 Risk Adjustment Data Basic Training for MAOs. To the extent paragraph 50 characterizes the 2005 Risk Adjustment Data Basic Training for MAOs, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 50.

E. CMS Required MAOs to Delete Diagnosis Codes That Were Not Supported by Medical Record Documentation

51. Anthem lacks sufficient knowledge to admit or deny the allegations in the first sentence of paragraph 51 and, on that basis, denies each and every allegation in the first sentence of paragraph 51. The remainder of paragraph 51 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 C.F.R. §§ 422.504(*l*) and 422.503(b)(4)(vi), to which Anthem respectfully refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 51.

52. Anthem lacks sufficient knowledge to admit or deny the allegations in the first sentence and beginning of the third sentence of paragraph 52 and, on that basis, denies each and every allegation in the first sentence and beginning of the third sentence of paragraph 52. Anthem admits that the RAPS and EDPS systems have mechanisms that MAOs can use to indicate to CMS that an ICD-10-CM or ICD-9-CM diagnosis code within a diagnosis cluster for

an MA member should be removed from CMS's electronic systems for purposes of the CMS-HCC risk adjustment model. To the extent this paragraph references ¶¶ 58–90 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. The remainder of paragraph 52 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 52.

53. The first sentence of paragraph 53 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies the allegations in the first sentence in paragraph 53. Anthem admits that CMS has issued sub-regulatory guidance, including the MMC Manual, and that paragraph 53 quotes terms in the MMC Manual (June 2013). To the extent paragraph 53 characterizes the MMC Manual, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 53.

54. Paragraph 54 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits upon information and belief that CMS has offered trainings to MAOs; that CMS has issued sub-regulatory guidance, including the documents cited in paragraph 54; and that paragraph 54 quotes terms in the 2003 Regional Risk Adjustment Training for MAOs Participant Guide and 2005 Risk Adjustment Data Basic Training for MAOs Participant Guide. To the extent paragraph 54 characterizes the documents referenced in paragraph 54, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 54.

54 n.11. Anthem admits that the website referenced in paragraph 54 footnote 11 includes certain Medicare Advantage-related information. Anthem lacks sufficient knowledge to

admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 54 footnote 11.

55. Anthem admits upon information and belief that under the CMS-HCC risk adjustment model, CMS may make additional payments to MAOs based on additional ICD-10-CM or ICD-9-CM diagnosis codes submitted to CMS during the timeframe before the applicable reconciliation. To the extent this paragraph references ¶ 44 of the Amended Complaint, *see* Anthem's response to that paragraph, which is incorporated herein. Anthem denies each and every remaining allegation in paragraph 55.

56. Paragraph 56 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 C.F.R. § 422.310(g)(2)(ii), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem admits that in the Medicare Part C context, the timeframe before the applicable reconciliation is known as the "open-period," and the timeframe after the applicable final reconciliation is known as the "closed-period." Anthem denies each any every remaining allegation in paragraph 56.

TO ACCURATELY CALCULATE PART C RISK ADJUSTMENT PAYMENTS, CMS IMPOSED REGULATORY AND CONTRACTUAL OBLIGATIONS ON PART C MAOS – INCLUDING ANTHEM – TO ENSURE THE ACCURACY OF THEIR DIAGNOSIS CODES AND TO DELETE INACCURATE CODES

57. Paragraph 57 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that CMS promulgated certain regulations and authored annual agreements for Medicare Part C. Anthem denies each and every remaining allegation in paragraph 57.

A. CMS Regulations Required MAOs Like Anthem to Implement Compliance Procedures to Ensure the Accuracy of Their Risk Adjustment Diagnosis Data Submissions

58. Paragraph 58 states legal conclusions to which no response is required. To the extent a response is required, this paragraph appears to reference 42 C.F.R. § 422.503 (although citing to 42 U.S.C.) and 65 Fed. Reg. 40170, 40264 (June 29, 2000), to which Anthem respectfully refers the Court for their complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 58.

59. Paragraph 59 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 C.F.R. § 422.503(b)(4)(vi), to which Anthem respectfully refers the Court for its complete and accurate contents. Anthem denies each and every remaining allegation in paragraph 59.

60. Paragraph 60 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 C.F.R. § 422.503(b)(4)(vi)(E)–(F), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 60.

61. Paragraph 61 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 C.F.R. § 422.503(b)(4)(vi)(G), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 61.

B. Anthem and Other MAOs Assumed the Obligation to Ensure the Accuracy of Their Risk Adjustment Data Submissions and to Delete Inaccurate Data by Executing Part C Annual Agreements with CMS

62. Paragraph 62 states legal conclusions to which no response is required. To the extent a response is required, and to the extent that paragraph 62 alleges information about what other MAOs agreed to, Anthem lacks sufficient knowledge to admit or deny the allegations and,

on that basis, denies each and every allegation about what other MAOs agreed to in paragraph 62. To the extent paragraph 62 characterizes Part C agreements, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 62.

63. Paragraph 63 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 63 quotes portions of Part C agreements with CMS that are in Exhibits 2 and 3, and to the extent paragraph 63 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 63.

64. Paragraph 64 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 64 quotes a portion of a Part C agreement with CMS that is in Exhibit 2, and to the extent paragraph 64 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 64.

64 n.12. Anthem admits that paragraph 64 footnote 12 quotes a portion of a Part C agreement with CMS that is in Exhibit 2. To the extent paragraph 64 footnote 12 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 64 footnote 12.

65. Paragraph 65 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 65.

66. Paragraph 66 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 66 quotes a portion of a "Medicare Advantage Outreach and Education Bulletin" dated August 2010 that is in Exhibit 4, and to the

extent paragraph 66 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 66.

66 n.13. Anthem admits that Exhibit 4 is a copy of a "Medicare Advantage Outreach and Education Bulletin" dated August 2010. To the extent paragraph 66 footnote 13 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 66 footnote 13.

67. Paragraph 67 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 67 quotes portions of Exhibit 5. To the extent paragraph 67 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 67.

68. Paragraph 68 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 68 quotes portions of Exhibit 5. To the extent paragraph 68 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 68.

69. Anthem admits that paragraph 69 quotes portions of Exhibit 5. To the extent paragraph 69 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 69.

70. Paragraph 70 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 70 refers to a portion of a Part C

agreement with CMS that is in Exhibit 3 and quotes terms in the MMC Manual (June 2013), and to the extent paragraph 70 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. To the extent this paragraph references ¶¶ 51–60 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 70.

71. Anthem admits that it understood that the RAPS and EDPS systems have mechanisms that MAOs can use to indicate to CMS that an ICD-10-CM or ICD-9-CM diagnosis code within a diagnosis cluster for an MA member should be removed from CMS's electronic systems. Anthem denies each and every remaining allegation in paragraph 71.

72. Anthem admits that it understood that the RAPS and EDPS systems have mechanisms that MAOs can use to indicate to CMS that an ICD-10-CM or ICD-9-CM diagnosis code within a diagnosis cluster for an MA member should be removed from CMS's electronic systems for purposes of the CMS-HCC risk adjustment model, and that paragraph 72 quotes portions of a document titled "Internal Audit Department's Review of Risk Score - Medicare Programs." To the extent paragraph 72 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 72.

73. Anthem admits that paragraph 73 quotes a portion of the deposition transcript of Anthem's then-Chief Compliance Officer. To the extent paragraph 73 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 73.

74. Anthem admits that medical record documentation does not always substantiate ICD-10-CM or ICD-9-CM diagnosis codes received from providers. Anthem denies each and every remaining allegation in paragraph 74.

75. Anthem admits that medical record documentation does not always substantiate ICD-10-CM or ICD-9-CM diagnosis codes received from providers and that paragraph 75 quotes portions of a November 2012 email. To the extent paragraph 75 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 75.

76. Anthem admits that paragraph 76 appears to quote certain terms in an Anthem document. To the extent paragraph 76 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 76.

77. Anthem admits that in some circumstances it and/or Anthem MAOs entered into contractual arrangements with providers under which payments were based in part on Anthem's and/or Anthem MAOs' Medicare Part C premiums from CMS. To the extent paragraph 77 characterizes the deposition transcript of the then-President of Anthem's Medicare business, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 77.

78. Anthem admits that paragraph 78 appears to quote certain terms in an Anthem document. To the extent paragraph 78 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 78.

C. Pursuant to Their EDI Agreements with CMS, MAOs Like Anthem Agreed to Comply with the Obligation to "Research and Correct" Risk Adjustment Data Discrepancies

79. Anthem admits that MAOs execute Electronic Data Interchange ("EDI") Enrollment Forms with CMS to submit risk adjustment data to CMS. Anthem denies each and every remaining allegation in paragraph 79.

80. Paragraph 80 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 80 quotes a portion of an EDI Enrollment Form stamped May 2004 that is in Exhibit 6. To the extent paragraph 80 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 80.

81. Paragraph 81 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that Anthem MAOs executed EDI Enrollment Forms and that paragraph 81 quotes a portion of an EDI Enrollment Form dated October 11, 2013, that is in Exhibit 7, and quotes a portion of an EDI Enrollment Form dated December 2, 2015, that is in Exhibit 8. To the extent paragraph 81 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 81.

82. Anthem admits that paragraph 82 quotes a portion of the deposition transcript of Anthem's then-Chief Compliance Officer. To the extent paragraph 82 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 82.

D. MAOs Like Anthem Submitted Annual Attestations to CMS to Certify That Their Risk Adjustment Diagnosis Data Submissions Were "Accurate" to Their "Best Knowledge, Information, and Belief"

83. Paragraph 83 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits Part C regulations require MAOs to submit annual attestations to CMS for each Part C plan. This paragraph references 42 C.F.R. § 422.504(*l*), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 83.

84. Paragraph 84 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 84 refers to a portion of a Part C agreement with CMS that is in Exhibit 3. To the extent paragraph 84 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 84.

85. Paragraph 85 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every remaining allegation in paragraph 85.

86. Anthem admits that paragraph 86 quotes portions of a "Desk Level Policy" concerning "Risk Adjustment Attestation for Data Submission." To the extent paragraph 86 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 86.

87. Anthem admits that during the relevant period, senior Anthem executives—including the then-President of Anthem's Medicare business—signed annual attestations under 42 C.F.R. § 422.504(*l*) to CMS for Part C plans, and that those attestations were submitted after the final submission deadline for reporting risk adjustment data for the applicable payment year. Anthem denies each and every remaining allegation in paragraph 87.

88. Anthem admits that paragraph 88 quotes portions of an Attestation of Risk Adjustment Data dated June 26, 2015, that is in Exhibit 9. To the extent paragraph 88 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 88.

89. Paragraph 89 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 89 quotes terms in the MMC Manual (Feb. 2004). To the extent paragraph 89 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. This paragraph appears to quote 65 Fed. Reg. 40170, 40268 (June 29, 2000) (although citing to 65 Fed. Reg. at 50268), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 89.

90. Paragraph 90 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that paragraph 90 quotes a portion of a "Provider Announcement" document dated July 2010 that is in Exhibit 11. To the extent paragraph 90 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 90.

THE GOVERNMENT'S EXTENSIVE EFFORTS TO ENSURE THE INTEGRITY AND ACCURACY OF MEDICARE PART C RISK ADJUSTMENT PAYMENTS

A. CMS Sample Audits of Risk Adjustment Data Submissions

91. Anthem admits upon information and belief each and every allegation in paragraph 91.

92. Paragraph 92 states legal conclusions to which no response is required. Anthem admits that CMS has issued sub-regulatory guidance, including the MMC Manual, and that paragraph 92 quotes terms in the MMC Manual (Oct. 2001 and Aug. 2004). To the extent

paragraph 92 characterizes the MMC Manual, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 92.

93. Paragraph 93 states legal conclusions to which no response is required. To the extent a response is required, this paragraph references 42 C.F.R. § 422.310(e), to which Anthem respectfully refers the Court for its complete and accurate content. Anthem denies each and every remaining allegation in paragraph 93.

94. Anthem lacks sufficient knowledge to admit or deny the allegations and, on that basis, denies each and every allegation in paragraph 94.

95. Anthem lacks sufficient knowledge to admit or deny the allegations and, on that basis, denies each and every allegation in paragraph 95. To the extent paragraph 95 characterizes a CMS "Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet," Anthem denies the allegation because the referenced document speaks for itself.

95 n.14. Anthem admits that the website referenced in paragraph 95 footnote 14 includes certain Medicare Advantage-related information. To the extent paragraph 95 footnote 14 characterizes a CMS "Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet," Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 95 footnote 14.

96. Anthem admits that CMS conducted Risk Adjustment Data Validation ("RADV") audits of four Anthem Part C contracts for payment year 2007, and that paragraph 96 references a CMS "Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet." To the extent paragraph 96 characterizes a CMS "Medicare Advantage Risk Adjustment Data

Validation Audits Fact Sheet," Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 96.

96 n.15. Anthem admits upon information and belief that CMS selected a sample of MA members within each contract selected by CMS for RADV audit. To the extent this paragraph references ¶ 94 of the Amended Complaint, *see* Anthem's response to that paragraph, which is incorporated herein. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 96 footnote 15.

97. Anthem admits that members enrolled in a subset of Anthem MAOs' Part C plans were included in CMS's payment year 2012 national RADV audit and that Anthem had internal communications about CMS's payment year 2012 national RADV audit. To the extent paragraph 97 characterizes "an internal Anthem report," Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 97.

B. <u>As Anthem Knew, the Government Has Actively Enforced the Requirement for Accurate Risk Adjustment Diagnosis Data Submissions</u>

98. Anthem lacks sufficient knowledge to admit or deny the allegations and, on that basis, denies each and every allegation in paragraph 98.

99. Anthem admits upon information and belief that in August 2012 the government announced a $3.82 million settlement from SCAN Health Plan. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 99.

100. Anthem admits that in August 2009 a *qui tam* complaint was filed against, *inter alia*, Freedom Health, Inc. ("Freedom"), *see United States ex rel. Sewell v. Freedom Health, Inc.,*

et al., Case No. 8:09-cv-1625 (M.D. Fla.); that in May 2017 Freedom agreed to pay $31,695,593 and enter into a "Corporate Integrity Agreement" to resolve these allegations; and that paragraph 100 quotes a portion of Appendix C of that "Corporate Integrity Agreement." To the extent paragraph 100 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 100.

101. Anthem admits upon information and belief that in October 2018 the government announced a $270 million settlement from DaVita Medical Holdings LLC. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 101.

102. Anthem admits upon information and belief that in August 2019 the government announced a settlement from Beaver Medical Group, L.P. Anthem lacks sufficient knowledge to admit or deny the remaining allegations and, on that basis, denies each and every remaining allegation in paragraph 102.

103. Anthem refers to its response to paragraph 104, which is incorporated herein. Anthem denies each and every remaining allegation in paragraph 103.

104. Anthem admits that paragraph 104 quotes a portion of a September 2012 email from an Anthem employee and a portion of a whistleblower attorney's quote in an article in that email. To the extent paragraph 104 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 104.

105. Anthem admits that paragraph 105 quotes portions of a third-party slide presentation dated February 2015 that Anthem employees emailed in February 2015. To the

extent paragraph 105 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 105.

ANTHEM USED ITS CHART REVIEW PROGRAM SOLELY TO OBTAIN HIGHER PAYMENTS FROM CMS AFTER HAVING MISREPRESENTED THAT PROGRAM AS AN "OVERSIGHT ACTIVITY" THAT WOULD IMPROVE THE ACCURACY OF ANTHEM'S RISK ADJUSTMENT DATA SUBMISSIONS

A. Anthem's Procedures for Submitting to CMS the Diagnosis Codes That It Collected from Providers' Claims

106. Anthem admits that ICD-10-CM or ICD-9-CM diagnosis codes contained in claims submitted by healthcare providers were a source of ICD-10-CM or ICD-9-CM diagnosis codes that Anthem submitted to CMS. Anthem denies each and every remaining allegation in paragraph 106.

107. Anthem admits that during the relevant period, Anthem and/or Anthem MAOs received provider-reported ICD-10-CM or ICD-9-CM diagnosis codes. Anthem admits that paragraph 107 quotes a portion of the deposition transcript of Anthem's then-manager of reporting and data analysis in Anthem's Medicare Programs Revenue & Reconciliation business unit, and that paragraph 107 quotes a portion of a document titled "RAPS Data Processing." To the extent paragraph 107 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 107.

108. Anthem admits that its employees would run computer algorithms on diagnosis code data to look for duplicates and would format the risk adjustment data for electronic submission to CMS consistent with CMS technical specifications, and that if an ICD-10-CM or ICD-9-CM diagnosis code was deemed to have the same member, date of service from date, date of service thru date, provider type, and ICD-10-CM or ICD-9-CM diagnosis code as an accepted

RAPS return, it was removed from electronic submission to CMS to avoid duplicative submissions. To the extent paragraph 108 characterizes the deposition transcript of a former Anthem director, data management team, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 108.

109. Anthem admits it submitted electronic data files, which could contain provider-reported ICD-10-CM or ICD-9-CM diagnosis codes, to CMS using electronic data systems RAPS and EDPS. Anthem denies each and every remaining allegation in paragraph 109.

110. Anthem admits that medical record documentation does not always substantiate ICD-10-CM or ICD-9-CM diagnosis codes received from providers and that paragraph 110 quotes a portion of a November 2012 email. To the extent paragraph 110 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. To the extent this paragraph references ¶¶ 74–78 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 110.

B. To Encourage Providers to Supply Records for Chart Review, Anthem Asserted That Its Chart Review Program Would Be an "Oversight Activity" Designed to Verify the Accuracy of Previously-Submitted Diagnosis Codes Based on Provider Claims

111. Anthem admits that it retained a vendor called MediConnect in 2010 whose responsibilities included collecting and reviewing provider medical records. Anthem denies each and every remaining allegation in paragraph 111.

112. Anthem admits that paragraph 112 quotes a portion of Exhibit 10 and purports to reference Exhibit 11. To the extent paragraph 112 characterizes these documents, Anthem

denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 112.

113. Anthem admits that paragraph 113 quotes a portion of Exhibit 10. To the extent paragraph 113 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 113.

114. Anthem admits that paragraph 114 quotes a portion of Exhibit 10. To the extent paragraph 114 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 114.

115. Anthem admits paragraph 115 quotes a portion of Exhibit 10. To the extent paragraph 115 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 115.

116. Anthem admits paragraph 116 quotes a portion of Exhibit 11. To the extent paragraph 116 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 116.

117. Anthem admits paragraph 117 quotes a portion of Exhibit 11. To the extent paragraph 117 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 117.

118. Anthem denies each and every allegation in paragraph 118.

119. Anthem denies each and every allegation in paragraph 119.

C. In Practice, Anthem Treated Chart Review Solely as a "Revenue Enhancement Program" and Chose Not to Use Chart Review Results to Verify the Accuracy of Previously-Submitted Diagnosis Codes Based on Provider Claims

120. Anthem admits that paragraph 120 quotes portions of Exhibits 10 and 11. To the extent paragraph 120 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 120.

121. Anthem admits that paragraph 121 quotes a portion of a 2014 document titled "Amended and Restated Statement of Work #1 for Medicare Advantage Medical Record Retrieval & Coding." To the extent paragraph 121 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 121.

122. Anthem admits that it understood that MediConnect coders who were abstracting ICD-10-CM or ICD-9-CM diagnosis codes from medical records for Anthem MA members as part of the Anthem corporate retrospective chart review program were not, in advance of those coders' examinations of the members' medical records, provided with the ICD-10-CM or ICD-9-CM diagnosis codes submitted by Anthem to CMS that had been accepted by CMS for those members for the same year of service as the medical record being reviewed. To the extent paragraph 122 characterizes a 2014 document titled "Amended and Restated Statement of Work #1 for Medicare Advantage Medical Record Retrieval & Coding," Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 122.

123. Anthem admits that paragraph 123 quotes a portion of a 2014 document titled "Amended and Restated Statement of Work #1 for Medicare Advantage Medical Record Retrieval & Coding." To the extent paragraph 123 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 123.

124. Anthem admits that paragraph 124 quotes a portion of a 2014 document titled "Amended and Restated Statement of Work #1 for Medicare Advantage Medical Record Retrieval & Coding." To the extent paragraph 124 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 124.

125. Anthem admits that paragraph 125 quotes a portion of a 2014 document titled "Amended and Restated Statement of Work #1 for Medicare Advantage Medical Record Retrieval & Coding." To the extent paragraph 125 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 125.

126. Anthem admits that paragraph 126 quotes a portion of a 2014 document titled "Amended and Restated Statement of Work #1 for Medicare Advantage Medical Record Retrieval & Coding." To the extent paragraph 126 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 126.

127. Anthem admits that paragraph 127 quotes a portion of a 2014 document titled "Amended and Restated Statement of Work #1 for Medicare Advantage Medical Record Retrieval & Coding." To the extent paragraph 127 characterizes this document, Anthem denies

the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 127.

128. Anthem denies each and every allegation in paragraph 128.

129. Anthem admits that before submitting RAPS files to CMS it used SAS software to compare RAPS submission files to accepted RAPS return files and conformed RAPS submission files to CMS technical specifications. To the extent paragraph 129 characterizes the deposition transcript of a former Anthem director, data management team, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 129.

130. Anthem admits that during at least some of the relevant period, Anthem did not use a process to isolate which provider-submitted ICD-10-CM or ICD-9-CM diagnosis codes (if any) were not abstracted by MediConnect coders from medical records. To the extent paragraph 130 characterizes the deposition transcript of a former Anthem director, data management team, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 130.

131. Anthem denies each and every allegation in paragraph 131.

132. Anthem admits that paragraph 132 quotes portions of Exhibit 5. To the extent paragraph 132 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. To the extent this paragraph references ¶ 154 of the Amended Complaint, *see* Anthem's response to that paragraph and its subparagraphs, which is incorporated herein. Anthem denies each and every remaining allegation in paragraph 132.

133. Anthem admits that under the CMS-HCC risk adjustment model, the submission of ICD-10-CM or ICD-9-CM diagnosis codes by MAOs to CMS, including diagnosis code data

corrections, may impact CMS's risk-score calculations and therefore may impact the risk-adjusted portion of CMS's payment to MAOs. Anthem denies each and every remaining allegation in paragraph 133.

ANTHEM KNOWINGLY DISREGARDED ITS OBLIGATION TO DELETE INACCURATE DIAGNOSIS CODES BECAUSE IT PRIORITIZED PROFITABILITY OVER COMPLIANCE

134. Paragraph 134 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 134. To the extent this paragraph references ¶¶ 136–140 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein.

135. Anthem admits that paragraph 135 quotes portions of a March 9, 2016 email from Anthem's then-Staff Vice President of Anthem's Medicare Programs Revenue & Reconciliation business unit. To the extent paragraph characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. To the extent this paragraph references ¶¶ 141–152 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 135.

A. Anthem's Understanding of Its Obligation to Identify and Delete Inaccurate Codes

136. Anthem admits that under the CMS-HCC risk adjustment model, the submission of ICD-10-CM or ICD-9-CM diagnosis codes by MAOs to CMS, including diagnosis code data corrections, may impact CMS's risk-score calculations and therefore may impact the risk-adjusted portion of CMS's payment to MAOs, and admits that paragraph 136 quotes portions of Exhibit 5. To the extent paragraph 136 characterizes this document, Anthem denies the

allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 136.

137. Anthem admits that paragraph 137 quotes portions of Exhibit 11. To the extent paragraph 137 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. To the extent this paragraph references ¶¶ 111–119 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 137.

138. Anthem admits that medical record documentation does not always substantiate ICD-10-CM or ICD-9-CM diagnosis codes received from providers and that paragraph 138 quotes portions of a November 2012 email and portions of a document titled "Medicare Revenue & Reconciliation Compliance Plan." To the extent paragraph 138 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. To the extent this paragraph references ¶ 75 of the Amended Complaint, *see* Anthem's response to that paragraph, which is incorporated herein. Anthem denies each and every remaining allegation in paragraph 138.

139. Anthem admits that paragraph 139 quotes (1) a portion of an EDI Enrollment Form stamped May 2004 that is in Exhibit 6, (2) a portion of an EDI Enrollment Form dated October 11, 2013, that is in Exhibit 7, (3) a portion of an EDI Enrollment Form dated December 2, 2015, that is in Exhibit 8, and (4) a portion of the deposition transcript of Anthem's then-Chief Compliance Officer. To the extent paragraph 139 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 139.

140. Paragraph 140 states legal conclusions to which no response is required. To the extent a response is required, Anthem admits that CMS has conducted RADV audits of Anthem MAOs, among other MAOs, and that paragraph 140 quotes a portion of the deposition transcript of Anthem's then-Chief Compliance Officer. To the extent paragraph 140 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 140.

B. Anthem's Internal Records and Communications Show That It Treated the Chart Review Program as a "Cash Cow," Instead of as an "Oversight Activity"

141. Anthem admits that paragraph 141 quotes a portion of Exhibit 10. To the extent paragraph 141 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 141.

142. Anthem admits that paragraph 142 quotes portions of a document titled "Internal Audit Department's Review of Risk Score – Medicare Programs." To the extent paragraph 142 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 142.

143. Anthem denies each and every allegation in paragraph 143.

144. Anthem admits that paragraph 144 quotes portions of a November 2015 email. To the extent paragraph 144 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 144.

145. Anthem admits that paragraph 145 refers to Exhibit 12. To the extent paragraph 145 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 145.

146. Anthem admits that paragraph 146 quotes portions of a March 2016 email. To the extent paragraph 146 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 146.

147. Anthem denies each and every remaining allegation in paragraph 147.

148. Anthem admits that paragraph 148 quotes a portion of an October 2017 email. To the extent paragraph 148 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 148.

149. Anthem admits that paragraph 149 references a September 2017 email. To the extent paragraph 149 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 149.

150. Anthem admits that paragraph 150 references a portion of a document titled "Medicare Revenue & Reconciliation Compliance Plan," and that paragraph 150 quotes a portion of the deposition transcript of Anthem's then-Staff Vice President of Anthem's Medicare Programs Revenue & Reconciliation business unit. To the extent paragraph 150 characterizes these documents, Anthem denies the allegation because the referenced documents speak for themselves. Anthem denies each and every remaining allegation in paragraph 150.

151. Anthem admits that paragraph 151 references a portion of the deposition transcript of Anthem's then-Staff Vice President of Anthem's Medicare Programs Revenue & Reconciliation business unit. To the extent paragraph 151 characterizes this document, Anthem

denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 151.

152. Anthem admits that paragraph 152 references the deposition transcript of the then-President of Anthem's Medicare business. To the extent paragraph 152 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 152.

ANTHEM'S KNOWING DECISION TO DISREGARD ITS REGULATORY AND CONTRACTUAL OBLIGATIONS RESULTED IN THE SUBMISSIONS OF THOUSANDS OF FALSE CLAIMS AND AVOIDANCE OF ITS OBLIGATION TO REPAY THE GOVERNMENT

153. Anthem denies each and every allegation in paragraph 153.

154. Paragraph 154 states legal conclusions to which no response is required. To the extent any response is necessary, this paragraph contains allegations related to deidentified patients, and Plaintiff has not provided complete patient information to Anthem. Anthem therefore lacks sufficient knowledge to admit or deny the allegations and, on that basis, denies each and every allegation in paragraph 154, including its subparagraphs (a)–(g). To the extent this paragraph references ¶¶ 141–152 of the Amended Complaint, *see* Anthem's responses to those paragraphs, which are incorporated herein. Anthem denies each and every remaining allegation in paragraph 154.

155. Anthem admits that it submitted Part C attestations for its Part C plans in payment years 2013, 2014, 2015, and 2016 and admits that paragraph 155 quotes portions of Exhibit 9. To the extent paragraph 155 characterizes this document, Anthem denies the allegation because the referenced document speaks for itself. Anthem denies each and every remaining allegation in paragraph 155.

156. Anthem denies each and every allegation in paragraph 156.

157. Paragraph 157 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 157. To the extent this paragraph references ¶ 86 of the Amended Complaint, *see* Anthem's response to that paragraph, which is incorporated herein.

FIRST CLAIM
PRESENTATION OF FALSE OR FRAUDULENT CLAIMS
31 U.S.C. § 3729(a)(1)(A)

158. Answering paragraph 158, Anthem reasserts its answers to the above paragraphs as if fully set forth herein.

159. Paragraph 159 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 159.

160. Paragraph 160 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 160.

161. Paragraph 161 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 161.

162. Anthem lacks sufficient knowledge to either admit or deny the allegations and, on that basis, denies each and every allegation in paragraph 162.

SECOND CLAIM
MAKING AND USING FALSE STATEMENTS IN VIOLATION OF THE FCA
31 U.S.C. § 3729(a)(1)(B)

163. Answering paragraph 163, Anthem reasserts its answers to the above paragraphs as if fully set forth herein.

164. Paragraph 164 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 164.

165. Paragraph 165 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 165.

166. Paragraph 166 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 166.

167. Anthem lacks sufficient knowledge to either affirm or deny the allegations and, on that basis, denies each and every allegation in paragraph 167.

THIRD CLAIM
REVERSE FALSE CLAIMS — KNOWINGLY AND IMPROPERLY AVOIDING AN OBLIGATION TO REPAY THE GOVERNMENT
31 U.S.C. § 3729(a)(1)(G)

168. Answering paragraph 168, Anthem reasserts its answers to the above paragraphs as if fully set forth herein.

169. Paragraph 169 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 169.

170. Paragraph 170 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 170.

171. Paragraph 171 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 171.

172. Paragraph 172 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 172.

FOURTH CLAIM
UNJUST ENRICHMENT

173. Answering paragraph 173, Anthem reasserts its answers to the above paragraphs as if fully set forth herein.

174. Paragraph 174 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 174.

175. Paragraph 175 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 175.

FIFTH CLAIM
PAYMENT BY MISTAKE

176. Answering paragraph 176, Anthem reasserts its answers to the above paragraphs as if fully set forth herein.

177. Paragraph 177 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 177.

178. Paragraph 178 states legal conclusions to which no response is required. To the extent a response is required, Anthem denies each and every allegation in paragraph 178.

PRAYER FOR RELIEF

Plaintiff's prayer for relief requires no response. To the extent a response is required, Anthem denies Plaintiff's prayer for relief, including subparagraphs (a)–(d).

AFFIRMATIVE DEFENSES

179. Plaintiff's claims are barred, in whole or in part, by the statute of limitations.

180. To the extent any damages are awarded against Anthem, they must be reduced pursuant to 31 U.S.C. § 3729(a)(2).

181. Plaintiff's causes of action and allegations in the Amended Complaint are vague, ambiguous and uncertain.

182. Damages and claims for which Plaintiff seeks relief in the Amended Complaint, if any, were caused by the acts, errors or omissions of third parties for whose conduct Anthem is not responsible.

183. Plaintiff's claims are barred, in whole or in part, by the existence of an express contract.

184. The penalties and damages that Plaintiff seeks would be an unconstitutionally excessive fine under the Eighth Amendment and Fourteenth Amendment to the United States Constitution because any award would be grossly disproportional to the gravity of Anthem's offense, if any.

185. The United States ratified, or otherwise consented to, the transactions and occurrences that are the subject of this action.

186. Plaintiff's claims are barred, in whole or in part, by the doctrines of course of performance, course of dealing, and usage of trade, which govern the meaning of any contractual agreement under which Anthem received payment by the United States.

187. Anthem is not liable to the extent that the United States failed to take adequate measures to mitigate damages.

188. Plaintiff's claims are barred, in whole or in part, by the doctrine of estoppel.

189. Plaintiff's claims are barred, in whole or in part, because any recovery would result in unjust enrichment.

190. Plaintiff's claims are barred because Anthem made no express or implied false certification.

191. Anthem reserves the right to add additional defenses as discovery progresses.

COUNTERCLAIMS

Anthem, Inc. ("Defendant") hereby alleges as follows as counterclaims (the "Counterclaims") against Plaintiff the United States of America:

1. Anthem incorporates by reference the responses and affirmative defenses contained in Anthem's Answer to Plaintiff's Amended Complaint as described above as if fully set forth herein.

JURISDICTION AND VENUE

2. These Counterclaims present a federal question arising out of the same contracts at issue in Plaintiff's Amended Complaint and therefore implicate this Court's subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1367, and Federal Rule of Civil Procedure 13. Anthem notes that because these Counterclaims seek monetary relief stemming from contractual relations between Anthem and Plaintiff, they appear to be subject to the jurisdiction of the Court of Federal Claims under 28 U.S.C. § 1491(a). In advance of filing these Counterclaims, counsel for Anthem and the United States met and conferred about whether the United States would stipulate that these Counterclaims are not compulsory within the meaning of Rule 13(a) because the United States would not agree to waive sovereign immunity over such claims for relief. Counsel for the United States advised counsel for Anthem that it would take a proposed stipulation under advisement. Because Plaintiff has thus far declined to stipulate that these Counterclaims are not compulsory counterclaims that must be brought in this action under Rule 13(a), Anthem asserts these Counterclaims here out of an abundance of caution.

PARTIES

3. Plaintiff and Counter-Defendant is the United States of America. The U.S. Department of Health and Human Services ("HHS"), through its component agency the Centers for Medicare & Medicaid Services ("CMS"), administers the Medicare Part C program.

4. Defendant and Counter-Plaintiff Anthem, Inc., formerly known as WellPoint, is an Indiana corporation whose affiliates (the "Anthem MAOs") executed the Medicare Part C contracts listed in Exhibit 1 of Plaintiff's Amended Complaint (reattached here as Counterclaim Exhibit A) during the time period at issue in Plaintiff's Amended Complaint.

FACTUAL ALLEGATIONS

Medicare Advantage

5. Medicare is a federal health insurance program administered by CMS. Beneficiaries may receive hospital and medical benefits through "traditional" Medicare, also known as Medicare Parts A and B, or through "Medicare Advantage," also known as Medicare Part C. CMS contracts with Medicare Advantage Organizations ("MAOs"), such as the Anthem MAOs, to offer Medicare Advantage plans to Medicare Advantage members.

6. In traditional Medicare, CMS reimburses physicians and other healthcare providers on a fee-for-service basis, compensating them retrospectively for services already rendered to beneficiaries. In the Medicare Advantage program, CMS pays monthly premiums to MAOs for *prospectively* accepting the risk of providing Medicare benefits to their members. The MAOs are liable for the actual cost of medical services rendered to their members, subject to the specific provisions and limitations of the individual Medicare Advantage contracts.

7. The monthly payment from CMS to MAOs takes into account the MAO members' health-risk profiles during the previous year to estimate the healthcare costs those members are likely to incur in the coming year. CMS, in other words, pays MAOs more for Medicare Advantage members who are more likely to incur additional healthcare costs based in part on each of the members' prior-year health profiles. This process of adjusting payments to account for variations in the anticipated cost of insuring members is known as "risk adjustment."

8. CMS calculates payments to MAOs, such as the Anthem MAOs, using the CMS Hierarchical Condition Category ("HCC") risk-adjustment model. Each HCC is a group of different "diagnosis codes," which are alphanumerical codes that correspond to illnesses or medical conditions diagnosed by healthcare providers. CMS determines the expected costs of

care for the health conditions encompassed in each HCC by calculating "risk coefficients" designed to measure the marginal expected costs of providing medical care for traditional Medicare beneficiaries diagnosed with those same conditions. CMS derives its risk coefficients using diagnosis codes it receives from healthcare providers who treat traditional Medicare beneficiaries; CMS examines how much it spends to provide benefits to those traditional Medicare beneficiaries and uses traditional Medicare diagnosis code data to predict how much it would cost an MAO to provide Medicare benefits to a member with a similar diagnosis. CMS pays for healthcare services rendered to beneficiaries in the traditional Medicare program based on the representations made by healthcare providers on the claim forms submitted by those providers. The agency does not audit the vast majority of that traditional Medicare diagnosis code data to determine if the codes are substantiated by the medical record documentation for those beneficiaries.

9. During the period at issue in this case, CMS had knowledge that a significant percentage of diagnosis codes submitted by healthcare providers in traditional Medicare is not substantiated by medical record documentation. CMS nevertheless used those unsubstantiated diagnosis codes in calculating its risk coefficients for medical conditions in the Medicare Advantage program; in other words, diagnosis codes that were not substantiated by medical record documentation were baked into the CMS-HCC risk adjustment payment model for the Medicare Advantage program.

10. This feature causes the Medicare Advantage risk-adjustment model to understate the amounts that CMS expends to treat different medical conditions in the traditional Medicare program. Because some traditional Medicare providers report unsubstantiated diagnosis codes to CMS and CMS does not remove those unsubstantiated diagnosis codes when measuring the costs

associated with the underlying beneficiaries' health care services, CMS's calculations spread costs to more beneficiaries than the beneficiaries' medical records can substantiate. The obvious result of these calculations is a lowered average rate of expenditures per beneficiary—i.e., by including unsubstantiated diagnosis codes when estimating costs associated with a given condition, CMS spreads the costs across more beneficiaries and lowers the average expected cost of health care services associated with that condition. When CMS applies the resulting lower risk coefficients to MAO payments in the Medicare Advantage risk-adjustment model, CMS systematically underpays MAOs if it then adjusts payments to the MAOs to account only for members whose diagnosis codes are substantiated by medical record documentation. Because CMS's risk coefficients reflect the cost of providing care for a population that includes *both* traditional Medicare diagnosis codes supported by medical records *and* traditional Medicare diagnosis codes *not* supported by medical records, CMS underpays MAOs when it applies those coefficients to adjust Medicare Advantage payments only for a population of members whose diagnosis codes are substantiated by medical record documentation because such payments are necessarily less than the estimated cost of treating an equivalent population in traditional Medicare. *See, e.g.*, 42 U.S.C. § 1395w-23(a)(1)(C)(i) (directing CMS to "adjust" payments to ensure "actuarial equivalence").

Chart Reviews

11. Just like CMS in the traditional Medicare program, MAOs cannot feasibly audit the millions of diagnosis codes that they receive from healthcare providers treating their members each year, which the MAOs then submit to CMS. CMS knows this reality, and has not required MAOs to affirmatively audit all diagnosis codes they submit to the agency. During the period at issue in Plaintiff's Amended Complaint, CMS did not require MAOs to undertake

specific compliance measures or to affirmatively verify that provider-submitted diagnosis codes were always substantiated by medical records.

12. CMS regulations do require that MAOs make good-faith efforts to report to the agency all medical conditions for each member and certify that the risk adjustment data they submit to CMS is "accurate, complete, and truthful" according to the signatory's "best knowledge, information and belief." To satisfy this requirement, it is common industry practice for MAOs to review their members' medical records to determine if they may substantiate additional diagnosis codes that healthcare providers did not report. CMS has expressly authorized MAOs to submit additional diagnosis codes that they identify through these retrospective chart reviews.

13. No CMS regulation or sub-regulatory guidance has ever required MAOs to use these chart reviews to separately compare the findings of their chart reviews to the provider-submitted diagnosis codes they previously submitted to CMS and to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart review findings.

14. In fact, CMS affirmatively *declined* to impose any such requirement. In January 2014, CMS proposed a rule that would have prohibited MAOs from conducting retrospective chart reviews to find previously unreported diagnosis codes unless those retrospective chart reviews were also designed to confirm that all codes that the MAO had previously submitted to CMS had adequate substantiation in medical record documentation. After receiving negative comments from industry participants, who called it "fundamentally at odds with the [Medicare Advantage] payment model," *see, e.g.*, Humana Inc., Comment Letter on Proposed Chart Review Rule at 44 (March 7, 2014), https://beta.regulations.gov/comment/CMS-2014-0007-

1652, CMS *withdrew* that rule, declining to impose the requirement that Plaintiff now seeks to retroactively impose through litigation.

Part C Contract and Bid Process

15. MAOs enter into annual contracts with CMS through which MAOs agree to cover their members' Medicare benefits for the coming year in exchange for premium payment from CMS.

16. As referenced in the Anthem MAOs' contracts with CMS, MAOs develop an annual benefit and price bid proposal that they submit to CMS. An MAO's bid must reflect its estimate of the payment that the MAO will require to provide the benefits covered by traditional Medicare to a beneficiary with an average risk profile for the specific population in the bid's service area. This estimate must include all estimated revenue required, including administrative costs. To make these estimates, an MAO must calculate anticipated revenues and expenses, taking into account CMS's risk coefficients and CMS's risk score model, as set forth in a rate announcement issued by CMS. A "risk score," also known as a "risk adjustment factor" or "RAF," is a multiplier that is applied to the bid amount for an applicable Medicare Advantage member, and the risk score model is a component of the bid proposal that estimates the risk score at the population level associated with the bid.

17. CMS is required to determine whether the bid reasonably and equitably reflects the estimated revenue requirements for providing the benefits under the Medicare Advantage plan. If the bid does not, CMS cannot accept it. The bid undergoes a review and audit, and if CMS determines that the bid is reasonable and equitable and accepts it, then CMS agrees to pay the MAO under the contract for each member consistent with the MAO's bid.

18. During the relevant time period, the Anthem MAOs formulated their Medicare Advantage bids with the reasonable understanding that CMS did not require them to compare the findings of their chart reviews to the provider-submitted diagnosis codes previously submitted to CMS or to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews. Indeed, the agency's conduct, including its withdrawal of its 2014 proposed rule, indicated that no requirement existed for MAOs to compare the findings of chart reviews to the provider-submitted diagnosis codes they previously submitted to CMS or to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews.

19. CMS accepted the Anthem MAOs' bids knowing that it had not communicated a requirement for MAOs to conduct retrospective chart reviews. CMS also accepted the Anthem MAOs' bids knowing that it had not communicated a requirement for MAOs to compare the findings of their chart reviews to the provider-submitted diagnosis codes previously submitted to CMS or to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews.

20. CMS and the Anthem MAOs entered into multiple contracts during the time period at issue in Plaintiff's Amended Complaint. For example, on August 29, 2013, Anthem MAO Empire HealthChoice HMO, Inc. (H3370) entered into a contract with CMS for contract year 2014, as evidenced by Exhibit 2 attached to Plaintiff's Amended Complaint (reattached here as Counterclaim Exhibit B). This contract references the bid submissions made by Empire HealthChoice HMO. *See, e.g.*, Counterclaim Ex. A at Art. III(A)(1) (referencing EmpireBlue's "final benefit and bid price proposal as approved by CMS"). This contract does not state that Empire HealthChoice HMO was obligated to compare the findings of its chart reviews to the

provider-submitted diagnosis codes previously submitted to CMS or to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews.

21. Empire HealthChoice HMO (H3370) also entered into a contract with CMS for contract year 2015, as evidenced by Exhibit 3 attached to Plaintiff's Amended Complaint (reattached here as Counterclaim Exhibit C). This contract references the bid submissions made by Empire HealthChoice HMO. *See, e.g.*, Counterclaim Ex. C at Art. III(A)(1) (referencing EmpireBlue's "final benefit and bid price proposal as approved by CMS"). This contract does not state that Empire HealthChoice HMO was obligated to compare the findings of its chart reviews to the provider-submitted diagnosis codes previously submitted to CMS or to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews.

CAUSES OF ACTION

Count I: Breach of Contract

22. Anthem repeats and restates the allegations in Paragraphs 1 to 21 as if fully set forth in this paragraph.

23. During the relevant time period for Plaintiff's Amended Complaint, CMS and the Anthem MAOs were parties to Part C contracts relating to each Anthem MAO's participation in the Medicare Advantage program. For example, Empire HealthChoice HMO, Inc. (H3370), contracted with CMS as part of the Medicare Advantage program for both contract year 2014 (Counterclaim Ex. B) and contract year 2015 (Counterclaim Ex. C).

24. Anthem MAOs performed all requirements and obligations under those Part C contracts.

25. As referenced in Anthem MAOs' contracts with CMS, the Anthem MAOs submitted bid proposals to CMS. *See, e.g.*, Counterclaim Ex. B at Art. III(A)(1); Counterclaim

Ex. C at Art. III(A)(1). CMS approved and accepted those bid proposals, and agreed to pay Anthem MAOs based on those approved bids.

26. The Anthem MAOs' bids were premised on the parties' mutual understanding that Anthem was not obligated to compare the findings of its chart reviews to the provider-submitted diagnosis codes previously submitted to CMS or to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews.

27. Plaintiff's lawsuit improperly seeks to deprive Anthem of compensation legally owed to Anthem under the Part C contracts between the parties in which the Anthem MAOs agreed to cover the Medicare benefits of their members. Plaintiff's allegations in the Amended Complaint that Anthem was required to compare the findings of its chart reviews to the provider-submitted diagnosis codes previously submitted to CMS and to submit diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews contradict the parties' assumptions underlying the Anthem MAOs' bids, the terms of the parties' contracts, and both parties' course of performance under those contracts.

28. Depriving the Anthem MAOs of risk adjusted payments under those Part C contracts with CMS would breach those agreements. Plaintiff is, in effect, seeking to rescind payments owed to the Anthem MAOs for coverage and services provided by Anthem under the terms of the contracts. Such liability would proximately cause the Anthem MAOs to suffer actual monetary loss, entitling Anthem to recover compensatory damages in an amount to be determined at trial.

Count II: Breach of the Covenant of Good Faith and Fair Dealing

29. Anthem repeats and restates the allegations in Paragraphs 1 to 28 as if fully set forth in this paragraph.

30. During the relevant time period for Plaintiff's Amended Complaint, CMS and the Anthem MAOs were parties to Part C contracts relating to the Anthem MAOs' participation in Medicare Advantage. For example, Empire HealthChoice HMO, Inc. (H3370), contracted with CMS as part of the Medicare Advantage program for both contract year 2014 (Counterclaim Ex. B) and contract year 2015 (Counterclaim Ex. C). These contracts, like all contracts, impose a duty of good faith and fair dealing upon the parties in performance and enforcement of the contracts.

31. Anthem MAOs performed all requirements and obligations under those Part C contracts.

32. Plaintiff's attempt to hold the Anthem MAOs liable for not comparing the findings of its chart reviews to the provider-submitted diagnosis codes previously submitted to CMS or submitting diagnosis code data corrections for any diagnosis codes not reflected in the chart reviews violates Plaintiff's duty of good faith and fair dealing. Plaintiff's lawsuit in effect demands that the Anthem MAOs perform operational tasks not required by the Part C contracts. Plaintiff knew that, when it executed the Part C contracts with the Anthem MAOs, the contracts stated no such obligation, Anthem did not understand those contracts to impose such an obligation, and that Plaintiff's own conduct and representations confirmed that no such obligation existed.

33. Plaintiff further breached the covenant of good faith and fair dealing by continuing to accept benefits from the Anthem MAOs under the parties' Part C contracts while pursuing litigation to recover its payments under those same contracts. Having secured the benefits of Anthem's performance, Plaintiff is now attempting to recover the payments it made in exchange for those benefits.

34. Such liability would proximately cause the Anthem MAOs to suffer actual monetary loss, entitling Anthem to recover compensatory damages in an amount to be determined at trial.

PRAYER FOR RELIEF

35. Anthem requests that the Amended Complaint be dismissed with prejudice and that the relief sought by Plaintiff in the Amended Complaint be denied. Anthem further requests that its counterclaims be granted and that the Court grant the relief sought in each of the counterclaims, as well as costs and disbursements of this litigation, including attorneys' fees and such other and further relief in favor of Anthem as this Court deems just and proper.

Dated: November 16, 2022

Respectfully submitted,

By: /s/ K. Lee Blalack, II

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Counterclaim Exhibit A

Exhibit 1

Plan Number	Plan Name	Anthem Subsidiaries
H0147	HealthKeepers (Medicare-Medicaid Plan)	Healthkeepers, Inc.
H0564	Anthem MediBlue Plus (HMO) d/b/a Blue Cross Senior Secure Plan I	Blue Cross Of California.
H1394	Anthem MediBlue Dual Advantage	HMO Colorado, Inc..
H1517	Anthem Medicare Preferred Core	Anthem Insurance Companies, Inc..
H1607	Anthem MediBlue Access Plus (PPO)	Anthem Insurance Companies, Inc..
H1849	Anthem MediBlue Plus d/b/a Anthem Senior Advantage Value	Anthem Health Plans Of Kentucky, Inc..
H1894	Amerivantage Classic (HMO)	Amerigroup Washington, Inc..
H2836	Anthem MediBlue Preferred Standard	Anthem Health Plans, Inc..
H3342	Empire MediBlue Access (PPO) d/b/a Empire MediBlue Freedom II	Empire Healthchoice Assurance, Inc..
H3370	Empire MediBlue Plus (HMO)	Empire Healthchoice Hmo, Inc..
H3447	Anthem MediBlue Plus (HMO) d/b/a Anthem MediBlue Local	Healthkeepers, Inc..
H3536	Anthem MediBlue Plus (HMO d/b/a Anthem MediBlue Select	Matthew Thornton Health Plan, Inc..
H3655	Anthem MediBlue Essential (HMO) d/b/a Anthem Senior Advantage Plus	Community Insurance Company.
H4036	Anthem MediBlue Access (PPO) d/b/a Anthem Medicare Preferred Core	Anthem Insurance Companies, Inc..
H4211	Amerivantage Classic	Amerigroup Georgia Managed Care Company, Inc.
H4909	Anthem MediBlue Access (PPO) d/b/a Anthem Medicare Preferred Core	Anthem Health Plans Of Virginia, Inc..
H5422	Anthem MediBlue Plus (HMO) d/b/a BCBSHP Dual Advantage	Blue Cross Blue Shield Of Georgia.
H5529	Anthem Medicare Preferred Standard	Community Insurance Company.
H5530	Anthem MediBlue Access d/b/a Anthem Medicare Preferred Standard	Anthem Health Plans Of Kentucky, Inc..
H5854	Anthem MediBlue Select (HMO) d/b/a Anthem MediBlue Select	Anthem Health Plans, Inc..
H6229	Anthem Blue Cross Cal MediConnect	Blue Cross Of California Partnership Plan Inc..
H6786	Anthem MediBlue Access (PPO)	Anthem Health Plans Of Maine, Inc..
H7728	Anthem Medicare Preferred Premier	Anthem Health Plans Of New Hampshire, Inc..
H8417	Empire BlueCross BlueShield HealthPlus FIDA Plan (Medicare-Medicaid Plan)	Amerigroup New York, Llc.

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Exhibit 1

Plan Number	Plan Name	Anthem Subsidiaries
H8432	Empire MediBlue Plus (HMO); Anthem Dual Advantage	Anthem Health Plans Of Maine, Inc.
H8552	Anthem MediBlue Access (PPO); Anthem Medicare Preferred Standard	Anthem Blue Cross Life And Health Insurance Co..
H9525	Anthem MediBlue Plus (HMO)	Compcare Health Services Insurance Corporation.
H9525	Anthem MediBlue Select	Compcare Health Services Insurance Corporation.
H9886	Anthem MediBlue Plus (HMO)	Hmo Missouri, Inc..
H9947	BCBSGa MediBlue Access (PPO)	Blue Cross Blue Shield Of Georgia.
H9954	Anthem MediBlue Dual Advantage	Anthem Insurance Companies, Inc. (Hmo).
Hl517	Anthem Medicare Preferred Core	Anthem Insurance Companies, Inc..
Hl607	Anthem Medicare Preferred Standard	Anthem Insurance Companies, Inc..
Hl849	Anthem Senior Advantage Value (HMO)	Anthem Health Plans Of Kentucky, Inc..
R5941	Anthem MediBlue Access (Regional PPO)	Anthem Insurance Companies, Inc..

Counterclaim Exhibit B

**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 (H3370)

Between

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

and

EMPIRE HEALTHCHOICE HMO, INC.
(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.)

**Article I
Term of Contract**

The term of this contract shall be from the date of signature by CMS' authorized representative through December 31, 2014, 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 2013 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 2013 contract, the parties' execution of this contract does not extinguish or interrupt any pending obligations or actions that may have arisen under the 2013 or prior year contracts.

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.

2. 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.

2. 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:

(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

1. The MA Organization agrees to comply with all applicable provider requirements in 42 CFR Part 422 Subpart E, including provider certification requirements, anti-discrimination 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. Chronic Care Improvement Program

(a) Each MA organization must have a chronic care improvement program and must establish criteria for participation in the program. The CCIP must have a method for identifying enrollees with multiple or sufficiently severe chronic conditions who meet the criteria for participation in the program and a mechanism for monitoring enrollees' participation in the program.

(b) Plans have flexibility to choose the design of their program; however, in addition to meeting the requirements specified above, the CCIP selected must be relevant to the plan's MA population. MA organizations are required to submit annual reports on their CCIP program to CMS.

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.

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 §422.112, 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

1. 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).

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 must also*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. **[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)]**

Article V
MA Organization Relationship with Related Entities, Contractors, and Subcontractors

A. Notwithstanding any relationship(s) that the MA Organization may have with related entities, contractors, or subcontractors, 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 related entities, contractors, or subcontractors to agree that—

1. HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to this contract; and

2. 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 providers, related entities, contractors, or subcontractors (first tier and downstream 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 provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph D of this Article.

3. A provision requiring that any services or other activity performed by a first tier, downstream, or 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 first tier, downstream, or related entity:

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.

5. 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) The facilities of the MA Organization; and

(iii) 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).

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 will not enter into a contract with 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. **[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)]**

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 42CFR Part 422.

(iv) 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.

(v) 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.

(vi) substantially fails to comply with the requirements in 42 CFR Part 422 Subpart M relating to grievances and appeals.

(vii) fails to provide CMS with valid risk adjustment data as required under 42 CFR §§422.310 and 423.329(b)(3).

(viii) fails to implement an acceptable quality improvement program as required under 42 CFR Part 422 Subpart D.

(ix) substantially fails to comply with the prompt payment requirements in 42 CFR §422.520.

(x) substantially fails to comply with the service access requirements in 42 CFR §422.112.

(xi) fails to comply with the requirements of 42 CFR §422.208 regarding physician incentive plans.

(xii) substantially fails to comply with the marketing requirements in 42 CFR Part 422 Subpart V.

(b) Notice. If CMS decides to terminate a contract for reasons other than the grounds specified in subparagraph 1 (a) of this paragraph, it will give notice of the termination as follows:

(i) CMS will notify the MA Organization in writing 90 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 days before the effective date of the termination.

(iii) The MA Organization will notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.

(c) Expedited termination of contract by CMS.

(i) For terminations based on violations prescribed in subparagraph 1(a)(iv) or (v) of this paragraph, 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.

(d) 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.

(e) 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 will not enter into an agreement with 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. **[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

2. 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)]**

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).

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).

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 (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), 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 (INDICATE MONTH AND YEAR) 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 (INDICATE MONTH AND YEAR) 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.

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 (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), 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 (INDICATE DATES) all (INDICATE TYPE - DIAGNOSIS/ENCOUNTER) 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.

ATTACHMENT C - Medicare Advantage Plan Attestation of Benefit Plan and Price

In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR THE MA ORGANIZATION

LEEBA LESSIN

_____

Contracting Official Name

8/29/2013 1:42:51 PM

_____

Date

EMPIRE HEALTHCHOICE HMO, INC.

_____

Organization

1 Liberty Plaza
165 Broadway
New York, NY 10006

_____

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

_____

Danielle R. Moon, J.D., M.P.A
Director
Medicare Drug and Health
Plan Contract Administration Group,
Center for Medicare

9/26/2013 11:18:12 AM

_____

Date

H3370

Counterclaim Exhibit C

**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 (H3370)

Between

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

and

EMPIRE HEALTHCHOICE HMO, INC.
(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.)

**Article I
Term of Contract**

The term of this contract shall be from the date of signature by CMS' authorized representative through December 31, 2015, 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 2014 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 2014 contract, the parties' execution of this contract does not extinguish or interrupt any pending obligations or actions that may have arisen under the 2014 or prior year contracts.

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.

2. 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.

2. 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:

(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

1. The MA Organization agrees to comply with all applicable provider requirements in 42 CFR Part 422 Subpart E, including provider certification requirements, anti-discrimination 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. Chronic Care Improvement Program

(a) Each MA organization must have a chronic care improvement program and must establish criteria for participation in the program. The CCIP must have a method for identifying enrollees with multiple or sufficiently severe chronic conditions who meet the criteria for participation in the program and a mechanism for monitoring enrollees' participation in the program.

(b) Plans have flexibility to choose the design of their program; however, in addition to meeting the requirements specified above, the CCIP selected must be relevant to the plan's MA population. MA organizations are required to submit annual reports on their CCIP program to CMS.

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.

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 §422.112, 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

1. 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).

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 must also*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. **[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 related entities, contractors, or subcontractors, 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 related entities, contractors, or subcontractors 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, to 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 providers, related entities, contractors, or subcontractors (first tier and downstream 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 provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph D of this Article.

3. A provision requiring that any services or other activity performed by a first tier, downstream, or 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 first tier, downstream, or related entity:

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.

5. 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) The facilities of the MA Organization; and

(iii) 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).

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 will not enter into a contract with 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. **[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)]**

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 42CFR Part 422.

(iv) 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.

(v) 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.

(vi) substantially fails to comply with the requirements in 42 CFR Part 422 Subpart M relating to grievances and appeals.

(vii) fails to provide CMS with valid risk adjustment data as required under 42 CFR §§422.310 and 423.329(b)(3).

(viii) fails to implement an acceptable quality improvement program as required under 42 CFR Part 422 Subpart D.

(ix) substantially fails to comply with the prompt payment requirements in 42 CFR §422.520.

(x) substantially fails to comply with the service access requirements in 42 CFR §422.112.

(xi) fails to comply with the requirements of 42 CFR §422.208 regarding physician incentive plans.

(xii) substantially fails to comply with the marketing requirements in 42 CFR Part 422 Subpart V.

(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.

(d) 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.

(e) 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 will not enter into an agreement with 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. **[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

2. 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)]**

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).

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).

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 (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), 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 (INDICATE MONTH AND YEAR) 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 (INDICATE MONTH AND YEAR) 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.

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 (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), 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 (INDICATE DATES) all (INDICATE TYPE - DIAGNOSIS/ENCOUNTER) 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.

ATTACHMENT C - Medicare Advantage Plan Attestation of Benefit Plan and Price

In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR THE MA ORGANIZATION

MARC RUSSO

_____

Contracting Official Name

8/27/2014 3:17:12 PM

_____

Date

EMPIRE HEALTHCHOICE HMO, INC.

_____

Organization

1 Liberty Plaza
165 Broadway
New York, NY 10006

_____

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

_____

Kathryn A. Coleman
Acting Director
Medicare Drug and Health
Plan Contract Administration Group,
Center for Medicare

9/11/2014 1:10:21 PM

_____

Date

H3370