

INTERROGATORIES of Elevance Health, Inc.

All of the following questions must be answered. ATTACH A FULL EXPLANATION AND THE REQUESTED INFORMATION FOR ANY "YES" ANSWERS

<p>1) Has the applicant ever had an application denied by any state or federal regulatory authority? (If yes, provide details including the type of application, the identity of the authority which issued the denial, the reasons for the denial and an explanation of any subsequent events.)</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>2) Has the applicant or any entity which is affiliated or under the same general management, interlocking directorate or ownership as the applicant ever had a Certificate of Authority or license suspended or revoked by any regulatory authority? (If yes, provide details including the type of action, the identity of the authority that took the action, the reasons for the action, a copy of the order or other such notice of the action and an explanation of any subsequent events.)</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>3) Has the applicant ever been subject to any regulatory action including cease and desist orders, fines, consent agreements or similar actions? (If yes, provide details including the type of action, the identity of the authority that took the action, the reasons for the action, a copy of the order or other such notice of the action and an explanation of any subsequent events.)</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>4) Has the applicant ever been placed into any type of regulatory supervision or rehabilitation by any regulatory authority? (If yes, provide details including the type of action, the identity of the authority that took the action, the reasons for the action, a copy of the order or other such notice of the action , an explanation of any subsequent events and an explanation of the current status.)</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>5) Is the applicant currently involved in any dispute or controversy with any regulatory authority?</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>6) Has the applicant ever been the subject of bankruptcy or liquidation proceedings? (If yes, provide the jurisdiction of the proceedings, the docket number, the current status and the date of final disposition.)</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>7) Is the applicant currently a defendant or the subject in any legal action alleging fraud, dishonesty or breach of trust on the part of the applicant or its officers, directors, trustees or members? (If yes, supply a statement giving the jurisdiction of the case, a summary of the allegations, the case style (name) and a summary of the current status of the case.)</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>8) Is the applicant a defendant in <u>any</u> lawsuit asking for a judgment that is equal to or greater than ten percent of its assets above liability?</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>9) Has the applicant or any person who is presently an officer, director or owner of 10 percent or more of the applicant ever been convicted of or pleaded guilty or nolo contendere to, or found liable of indictment or bill of information, in any jurisdiction, charging a felony or misdemeanor other than minor traffic violations?</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>10) Within the last five years, has the applicant changed its name?</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<p>11) Within the last five years, has the applicant undergone a change in domicile? (Changes of domicile address within the same state need not be included.)</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO

INTERROGATORIES – CONTINUED

12) Within the last five years, has the applicant merged or consolidated with any other entity?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
13) Within the last five years, has the applicant undergone a change in ownership (direct or indirect) of 10 percent or more? (If yes, provide a full explanation of the change in ownership and an organizational/ownership chart which clearly shows the ownership of the applicant both before and after the transaction.)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
14) Other than the transaction leading to this application, is the applicant presently negotiating or inviting negotiations or party to a counterletter which would result in a merger or consolidation with any other company or in a change ownership, direct or indirect, of ten percent or more?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
15) Has the applicant undergone a change of management or control since the date of the latest audited statement filed in support of this application?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
16) Other than those disclosed with this application, does the applicant contemplate a change in management or any transaction which would normally result in a change of management within the next 24 months?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
17) Within the last five years, has the applicant transferred or encumbered a substantial portion (more than 20%) of its assets or liabilities?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
18) Does the applicant have any plans to redomesticate the domestic insurer?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
19) Other than changes disclosed in this application, does the applicant have any plans to change the officers and/or directors of the domestic insurer within 24 months of the transaction leading to this application?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
20) Does the applicant or any entity which is affiliated or under the same general management, interlocking directorate or ownership as the applicant currently have any application pending with any Department of Insurance for a Certificate of Authority?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
21) Is the applicant owned, operated or controlled, directly or indirectly, by any other state or province, district, territory or nation or any governmental subdivision or agency?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
22) Has the applicant or any entity which is affiliated or under the same general management, interlocking directorate or ownership as the applicant operated in any capacity in Louisiana for which it would be required to be licensed by or registered with the Louisiana Department of Insurance without having first obtained the necessary license?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
23) Is the applicant currently undergoing an examination or audit (whether routine, targeted or otherwise) being conducted by any state or federal regulatory authority?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
24) Is the applicant part of an insurance holding company group? (If yes, provide the holding company group code assigned by the NAIC _____.)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
25) Does the regulatory authority governing the applicant in the state or country of domicile have any statutes or regulations that might prohibit or restrict in any way the disclosure of information concerning the applicant to the Louisiana Department of Insurance?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
26) Does the applicant purchase investment securities through any investment banking or brokerage house or firm from whom any of the applicant's officers, directors, trustees, investment committee, owners of 10% or more of the applicant or the family members thereof receive a commission or salary or any form of compensation?	<input type="checkbox"/> YES	<input type="checkbox"/> NO

INTERROGATORIES – CONTINUED

27) Within the last five years, has the applicant made a loan to an entity owned or controlled directly or indirectly by one or more of the applicant's officers, directors, trustees, investment committee or any owner of 10% or more of the applicant?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
28) Within the last five years, has the applicant sold or transferred any of its assets or property, real or personal, to any entity owned directly or indirectly by one or more of the applicant's officers, directors, trustees, investment committee members or owners of 10% or more of the applicant?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
29) Within the last five years, has the applicant purchased securities, assets or property of any kind from an entity owned or controlled directly or indirectly by one or more of the applicant's officers, directors, trustees, investment committee members or any owner of 10% or more?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
30) If any of questions 26, 27, 28 or 29 were answered yes, did any officer, director, trustee, investment committee member or owner of ten percent or more of the applicant company receive any money or valuable thing for negotiating, procuring, recommending or aiding in such transaction?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
31) In association with this transaction or subsequent to it, will the domestic insurer become party to any reinsurance contracts which in effect provide that the domestic insurer will reimburse or indemnify the reinsurer for losses payable thereunder?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
32) Does the applicant utilize or plan to utilize the services of third party administrators or managing general agents for the domestic insurer? (If yes, provide the name and Louisiana license number of the entity.)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
33) Has the applicant filed with its domiciliary state any amendments or restatements of its most recent annual financial statement?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
34) Is the applicant affiliated with or concurrently operating as a bank, bank holding company, subsidiary or affiliate?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
35) Is the applicant affiliated with any insurers which are authorized or approved to do business in this state?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
36) Is the applicant licensed as an insurance producer in any jurisdiction? (If yes, provide the jurisdiction(s) and license numbers.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
37) Does the applicant have any outstanding unexercised stock options? (If yes, attach a full explanation of who holds these options and the number of shares subject thereto.)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
38) Does the applicant have pending or plan to file any other applications, exemption requests or other such filings for acquisition of insurers in any jurisdiction in association with this or any other transaction? (If yes, identify the states in which the filing is made and specifically indicate whether or not the applicant is seeking a consolidated public hearing pursuant to La. R.S. 22:691.4 E(3).)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
39) As a result of this transaction will the domestic insurer(s) become party to any management, tax sharing, investment, reinsurance or other agreements? (If yes, supply copies of all such agreements).	<input type="checkbox"/> YES	<input type="checkbox"/> NO
40) After the transaction leading to this application, will the domestic insurer be able to satisfy the requirements for the issuance of a license to write the lines of insurance for which it is presently licensed?	<input type="checkbox"/> YES	<input type="checkbox"/> NO

INTERROGATORIES – CONTINUED

41) Will the effect of the transaction leading to this application be to substantially lessen competition in insurance in Louisiana or tend to create a monopoly therein?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
42) Is the financial condition of the applicant such as is might jeopardize the financial stability of the domestic insurer or prejudice the interest of the policyholders?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
43) Are any plans or proposals which the applicant has in regard to the domestic insurer unfair or unreasonable to policyholders of the insurer or not in the public interest?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
44) Are the competence, experience and integrity of those persons who will control the operation of the domestic insurer such that it would not be in the interest of policyholders of the insurer and of the public to permit the transaction leading to this application?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
45) Is the transaction leading to this application likely to be hazardous or prejudicial to the insurance buying public?	<input type="checkbox"/> YES	<input type="checkbox"/> NO

INTERROGATORIES

FULL EXPLANATIONS FOR "YES" ANSWERS

Response to Interrogatory #3 - Has Elevance Health, Inc. ever been subject to any regulatory action including cease and desist orders, fines, consent agreements or similar actions? (If yes, provide details including the type of action, the identity of the authority that took the action, the reasons for the action, a copy of the order or other such notice of the action and an explanation of any subsequent events.)

Yes. In February 2015, Elevance Health, Inc. (f/k/a Anthem, Inc.) (“Elevance”) reported that it was the target of a sophisticated external cyber-attack during which the attackers gained unauthorized access to certain of its information technology systems and obtained personal information related to many individuals and employees. To date, there is no evidence that credit card or medical information was accessed or obtained. Upon discovery of the cyber-attack, Elevance took immediate action to remediate the security vulnerability and has continued to implement security enhancements since this incident.

Federal and state agencies, including state insurance regulators, state attorneys general, and the Health and Human Services Office of Civil Rights and the Federal Bureau of Investigation investigated events related to the cyber-attack, including how it occurred, its consequences and Elevance’s responses. Elevance has resolved all investigations related thereto. Attached as Exhibit 3(A) is an Assurance of Voluntary Compliance involving Elevance and a multi-state group of attorneys general. As part of the settlement, Elevance has undertaken commitments that align with Elevance’s ongoing and consistent focus to protect information, in addition to a monetary payment of \$39.5 million. Additionally, attached as Exhibit 3(B) is a Resolution Agreement involving Elevance and the Health and Human Services Office of Civil Rights, including a Corrective Action Plan that sets forth certain obligations of Elevance to address its security management and other related processes, in addition to a monetary payment of \$16 million.

Response to Interrogatory #4 - Has Elevance Health, Inc. ever been placed into any type of regulatory supervision or rehabilitation by any regulatory authority? (If yes, provide details including the type of action, the identity of the authority that took the action, the reasons for the action, a copy of the order or other such notice of the action , an explanation of any subsequent events and an explanation of the current status.)

Yes. Please see Interrogatory #3 response immediately above.

Response to Interrogatory #5 - Is Elevance Health, Inc. currently involved in any dispute or controversy with any regulatory authority

Yes. Please see Elevance Health Inc.’s Quarterly Report on Form 10-Q (for the period ended September 30, 2023), Note 11 – “Commitments and Contingencies - *Litigation and Regulatory Proceedings*” of the Notes to the Consolidated Financial Statements (included in Part I, Item 1 of the Form 10-Q).

Response to Interrogatory #7 - Is Elevance Health, Inc. currently a defendant or the subject in any legal action alleging fraud, dishonesty or breach of trust on the part of the applicant or its officers, directors, trustees or members? (If yes, supply a statement giving the jurisdiction of the case, a summary of the allegations, the case style (name) and a summary of the current status of the case.)

Yes. In March 2020, the U.S. Department of Justice (“DOJ”) filed a civil lawsuit against Elevance Health, Inc. (f/k/a Anthem, Inc.) in the U.S. District Court for the Southern District of New York (the “New York District Court”) in a case captioned United States v. Anthem, Inc. The DOJ’s suit alleges, among other things, that Elevance falsely certified the accuracy of the diagnosis data Elevance submitted to the Centers for Medicare and Medicaid Services (“CMS”) for risk-adjustment purposes under Medicare Part C and knowingly failed to delete inaccurate diagnosis codes. The DOJ further alleges that, as a result of these purported acts, Elevance caused CMS to calculate the risk-adjustment payments based on inaccurate diagnosis information, which enabled Elevance to obtain unspecified amounts of payments in Medicare funds in violation of the False Claims Act. The DOJ filed an amended complaint in July 2020, alleging the same causes of action but revising some of its allegations. In September 2020, Elevance filed a motion to transfer the lawsuit to the Southern District of Ohio, a motion to dismiss part of the lawsuit, and a motion to strike certain allegations in the amended complaint. In an opinion and order issued October 3, 2022, the New York District Court denied Elevance’s motions, and the case will now proceed in such court. Elevance intends to continue to vigorously defend this suit, which Elevance believes is without merit; however, the ultimate outcome cannot be presently determined. Attached as Exhibit 7 is copy of the Amended Complaint (filed on July 2, 2020). *See also the Form 10-Q of Elevance filed with the Securities Exchange Commission on September 30, 2023*

Response to Interrogatory #10 - Within the last five years, has Elevance Health, Inc. changed its name?

Yes. Elevance Health, Inc. changed its name from Anthem, Inc., effective June 27, 2022.

Response to Interrogatory #35 – Is Elevance Health, Inc. affiliated with any insurers which are authorized or approved to do business in this state?

Yes, Elevance Health, Inc. is affiliated with the following insurers/HMOs authorized to do business in Louisiana:

- (a) Amerigroup Insurance Company
- (b) Anthem Insurance Companies, Inc.;
- (c) Anthem Life Insurance Company
- (d) UniCare Life & Health Insurance Company; and
- (e) Community Care Health Plan of Louisiana, Inc.

Response to Interrogatory #37 - Does Elevance Health, Inc. have any outstanding unexercised stock options? (If yes, attach a full explanation of who holds these options and the number of shares subject thereto.)

Yes. Please see Elevance Health Inc.'s Quarterly Report on Form 10-Q (for the period ended September 30, 2023), Note 15 – “Capital Stock – *Stock Incentive Plans*” of the Notes to the Consolidated Financial Statements (included in Part I, Item 1 of the Form 10-Q).

Response to Interrogatory #38 - Does Elevance Health, Inc. have pending or plan to file any applications, exemption requests or other such filings for acquisition of insurers in any jurisdiction in association with this or any other transaction? (If yes, identify the states in which the filing is made and specifically indicate whether or not Elevance, Inc. is seeking a consolidated public hearing pursuant to La. R.S. 22:691.4 E(3).)

On January 27, 2023, Elevance Health, Inc. filed a Form A Statement and Form E Exemption Letter with the Arkansas Insurance Department and the Mississippi Insurance Department. The Arkansas Insurance Commissioner issued an Approval Order on April 25, 2023. The Mississippi Insurance Commissioner issued an Approval Order on May 9, 2023.

Response to Interrogatory #40 – After the transaction, will the domestic insurer be able to satisfy the requirements for the issuance of a license to write the lines of insurance for which it is presently licensed?

Yes, after the transaction, all Domestic Insurers/HMOs will continue to satisfy the requirements for the issuance of a license to write the business for which it is presently licensed.

Exhibit 3(A)
ASSURANCE OF VOLUNTARY COMPLIANCE

This Assurance of Voluntary Compliance (“Assurance”)¹ is entered into by the Attorneys General of Alaska, Arizona, Arkansas, Colorado, Connecticut, the District of Columbia, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New York, Nevada, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, Washington, West Virginia, and Wisconsin (collectively, “Attorneys General”) and Anthem, Inc. (“Anthem”) to resolve the Attorneys General’s investigation into the criminal cyberattack on Anthem’s systems, which Anthem publicly announced on February 4, 2015 (collectively, the “Parties”).²

In consideration of their mutual agreements to the terms of this Assurance, and such other consideration as described herein, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

I. INTRODUCTION

This Assurance constitutes a good faith settlement and release between Anthem and the Attorneys General of claims under state law and the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and its implementing regulations, 45 C.F.R. §§ 160, 162, and 164 (“HIPAA”) related to a data breach, publicly announced by Anthem on February 4, 2015, in which a criminal cyber-attacker gained unauthorized access to its network and infiltrated an internally hosted enterprise data warehouse, which contained the personal information (“PI”) and/or protected health information (“PHI”) of Anthem plan members and other

¹ This Assurance of Voluntary Compliance shall, for all necessary purposes, also be considered an Assurance of Discontinuance.

² The State of California has simultaneously entered into a settlement with Anthem in a form consistent with California law.

individuals (the “Data Breach”). Anthem discovered the unauthorized access that caused the Data Breach on or about January 29, 2015. The Data Breach affected approximately 78,800,000 individuals nationwide. The information accessed in unencrypted form by the cyber-attacker included names, dates of birth, Social Security numbers, healthcare identification numbers, home addresses, email addresses, phone numbers, and employment information, including income data.

II. DEFINITIONS

1. For purposes of this Assurance, the following definitions shall apply:
 - A. “Anthem” shall mean Anthem, Inc., its wholly owned, integrated, and operated affiliates, subsidiaries, and divisions, successors, and assigns, directors and officers, and employees doing business in the United States.
 - B. “Anthem Network” shall mean the networking equipment, databases or data stores, applications, servers, and endpoints that are capable of using and sharing software, data, and hardware resources and that are owned and/or operated by Anthem.
 - C. “Business Associate” shall be defined in accordance with 45 C.F.R. § 160.103 and is a person or entity that provides certain services to or performs functions on behalf of covered entities, or other business associates of covered entities, that require access to PHI.
 - D. “Consumer Protection Acts” shall mean the State citations listed in Appendix A.
 - E. “Covered Entity” shall be defined in accordance with 45 C.F.R. § 160.103 as a health plan, health care clearinghouse, or health care provider that transmits protected health information in electronic form in connection with

a transaction for which the U.S. Department of Health and Human Services has adopted standards.

- F. “Covered Systems” shall mean components, such as servers, workstations, and devices, within the Anthem Network that are routinely used to collect, process, communicate, and/or store PI and/or PHI.
- G. “Data Breach” shall mean the security incident discovered by Anthem on or about January 29, 2015, and publicly announced on February 4, 2015, in which a malicious cyber-attacker gained unauthorized access to portions of the Anthem Network that stored PI and/or PHI, and which impacted approximately 78,800,000 individuals nationwide.
- H. “Data Breach Notification Law” shall mean the State citations listed in Appendix B.
- I. “Effective Date” shall be October 30, 2020.
- J. “Encrypt,” “Encrypted,” or “Encryption” shall refer to the transformation of data at rest or in transit into a form in which meaning cannot be assigned without the use of a confidential process or key. The manner of Encryption shall conform to existing industry standard.³
- K. “Minimum Necessary Standard” shall refer to the requirements of the Privacy Rule that, when using or disclosing Protected Health Information or when requesting Protected Health Information from another Covered Entity or Business Associate, a Covered Entity or Business Associate must

³ For the purposes of this Assurance, the term “existing industry standard” applies to what the standard may become as the industry changes over time. As of the Effective Date, the existing industry standard shall be defined pursuant to Federal Information Processing Standards Publication 140-2.

make reasonable efforts to limit Protected Health Information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request as defined in 45 C.F.R. § 164.502(b) and § 164.514(d).

- L. “Multi-factor Authentication” means authentication through verification of at least two of the following authentication factors: (i) knowledge factors, such as a password; or (ii) possession factors, such as a token, connection through a known authenticated source, or a text message on a mobile phone; or (iii) inherent factors, such as biometric characteristics.
- M. “Personal Information” or “PI” shall mean the data elements in the definition of personal information set forth in the Data Breach Notification Law and/or Personal Information Protection Act listed in Appendix B.
- N. “Personal Information Protection Act” shall mean the State citations listed in Appendix B.
- O. “Privacy Rule” shall refer to the HIPAA Regulations that establish national standards for safeguarding individuals’ medical records and other Protected Health Information, including electronic PHI, that is created, received, used, or maintained by a Covered Entity or a Business Associate, specifically 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E.
- P. “Protected Health Information” or “PHI” shall be defined in accordance with 45 C.F.R. § 160.103, including electronic protected health information.
- Q. “Security Event” shall mean any compromise that (i) results in the unauthorized access, acquisition, or exfiltration of electronic PI or PHI

collected, processed, transmitted, stored, or disposed of by Anthem, or (ii) causes lack of enterprise availability of electronic PI or PHI of at least 500 U.S. consumers held, processed, or stored by Anthem.

- R. “Security Rule” shall refer to the HIPAA Regulations that establish national standards to safeguard individuals’ electronic Protected Health Information that is created, received, used, or maintained by a Covered Entity or Business Associate that performs certain services on behalf of the Covered Entity, specifically 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and C.

III. ASSURANCES

A. Compliance with State and Federal Law

2. Anthem shall not misrepresent the extent to which Anthem maintains and protects the privacy, security, or confidentiality of any PI or PHI collected from or about consumers.

3. If a Security Event does not trigger the Data Breach Notification Law, Anthem shall create a report that includes a description of the Security Event and Anthem’s response to that Security Event (“Security Event Report”). The Security Event Report shall be made available for inspection by the Third-Party Security Assessor as described in Paragraph 27.

B. Information Security Program

4. Anthem shall develop, implement, and maintain a written information security program (“Information Security Program”) that is reasonably designed to protect the security, integrity, and confidentiality of PI and PHI that Anthem collects, stores, transmits, maintains, and/or destroys. The Information Security Program shall, at a minimum, include the specific information security requirements set forth in Paragraphs 5 through 25 of this Assurance.

a. The Information Security Program shall comply with any applicable requirements under state or federal law, and shall contain administrative, technical, and physical safeguards appropriate to: (i) the size and complexity of Anthem's operations; (ii) the nature and scope of Anthem's activities; and (iii) the sensitivity of the PI and PHI that Anthem collects, stores, transmits and/or maintains.

b. The Information Security Program shall be written and modified to allow access to PHI consistent with the Minimum Necessary Standard. Anthem shall consider and adopt where reasonably feasible the principles of zero trust architecture throughout the Anthem Network. As used herein, zero trust architecture means Anthem will:

i. Regularly monitor, log, and inspect network traffic, including log-in attempts, through the implementation of hardware, software, or procedural mechanisms that record and evaluate such activity;

ii. Authorize and authenticate relevant device, user, and network activity within the Anthem Network; and

iii. Require appropriate authorization and authentication prior to any user's access to the Anthem Network.

c. Anthem may satisfy the requirements of this Assurance, including the implementation of the Information Security Program through the review, maintenance, and, if necessary, updating of an existing information security program or existing safeguards, provided that such existing program or safeguards meet the requirements set forth in this Assurance.

d. Anthem shall review not less than annually the Information Security Program.

e. Anthem shall employ an executive or officer who shall be responsible for implementing, maintaining, and monitoring the Information Security Program (“Chief Information Security Officer” or “CISO”). The CISO shall have the background and expertise in information security appropriate to the level, size, and complexity of her/his role in implementing, maintaining, and monitoring the Information Security Program.

f. The role of the CISO will include regular and direct reporting to the Chief Executive Officer (“CEO”), Executive Staff, and Board of Directors concerning Anthem’s security posture, the security risks faced by Anthem, and the security implications of Anthem’s business decisions. The CISO shall meet with and provide a report to: (1) the Board of Directors on at least a semi-annual basis and (2) the CEO on at least a quarterly basis. The CISO shall report to the CEO within twenty-four (24) hours of a confirmed Security Event impacting 500 or more consumers residing in the United States. The CISO shall include such Security Events in its annual report to the Board of Directors.

g. Anthem shall provide notice of the requirements of this Assurance to the employees of Anthem’s Information Security organization and shall implement training on the requirements of this Assurance to those employees. Anthem shall provide the training required under this paragraph to such employees within ninety (90) days of the Effective Date of this Assurance or prior to their starting their responsibilities for implementing, maintaining, or monitoring the Information Security Program.

h. As part of its Information Security Program, Anthem shall develop, implement, and maintain a written incident response plan to prepare for and respond to Security Events. Anthem shall revise and update this response plan, as necessary, to adapt to any material changes that affect the security of PI and PHI. Such a plan shall, at a minimum, identify and

describe the following phases: (i) Preparation; (ii) Detection and Analysis; (iii) Containment; (iv) Notification and Coordination with Law Enforcement; (v) Eradication; (vi) Recovery; (vii) Consumer and Regulator Notification and Remediation; and (viii) Post-Incident Analysis.

i. Anthem shall budget such that its Information Security Program receives the resources and support reasonably necessary to function as intended.

j. Anthem shall take reasonable efforts, using a reasonable and documented risk-based approach, to evaluate whether vendors that routinely handle PI or PHI have safeguards in place to protect such information and that such vendors will notify Anthem promptly of any potential compromise to the confidentiality, integrity, or availability of PI or PHI held, stored, or processed by the vendors on behalf of Anthem.

C. Specific Information Security Requirements

5. **Data Collection & Retention:** Anthem shall develop, implement, and maintain reasonable policies and procedures governing its collection, use, and retention of PI and PHI. Anthem shall limit its use, disclosure of, and requests for PHI in accordance with the Minimum Necessary Standard, and to fulfill all applicable regulatory, legal, and contractual obligations.

6. **Segmentation:** Anthem shall develop, implement, and maintain reasonable policies and procedures designed to reasonably segment the Anthem Network. At a minimum, within ninety (90) days, Anthem shall develop a timetable to implement:

- a. segmentation of its VOIP servers; and
- b. segmentation of its development and production environments.

On a semiannual basis, Anthem will report to the Board of Directors regarding the implementation timetable progress, as well as document any significant delays or revisions to the timetable.

7. **Cyber Security Operations Center (“C-SOC”)**: Anthem shall maintain the existence and operation of its C-SOC or a reasonably equivalent technology. The C-SOC shall be staffed continuously to provide comprehensive monitoring of servers and other technologies to identify improper use of data, including PI and/or PHI. The C-SOC’s analytic capabilities shall be deployed to detect, analyze, and respond to potential and confirmed Security Events.

8. **Logging & Monitoring**: Anthem shall develop, implement, and maintain reasonable policies and procedures designed to properly log and monitor the Anthem Network. At a minimum:

a. Anthem shall employ tools, such as a Security Information and Event Monitoring solution (“SIEM”) (or a reasonably equivalent technology), among others, to log and monitor network traffic to detect and respond to Security Events.

b. Anthem shall take reasonable steps to properly configure, and regularly update or maintain the SIEM (or a reasonably equivalent technology) used pursuant to subsection (a) and shall take reasonable steps to adequately log system activity and identify potential Security Events for review. Using the SIEM (or a reasonably equivalent technology), Anthem shall actively review and analyze in real-time the logs of system activity and take appropriate follow-up with respect to Security Events.

c. Anthem shall maintain logs in conformance with industry standards and all applicable laws.

d. In addition to the requirements set forth in subparagraphs (a) through (c) of this Paragraph, Anthem shall develop, implement, and maintain defined and specific policies and procedures with respect to logging and monitoring of the internal data warehouse involved in the Data Breach and any database (or set of databases) that collects, processes, transmits, and/or stores

PI and/or PHI of similar volume as the internal data warehouse involved in the Data Breach. At a minimum:

i. Anthem shall deploy an appropriate database activity monitoring tool or a reasonably equivalent technology in the internal data warehouse involved in the Data Breach and any similar database (or set of databases) that Anthem uses to collect, process, transmit, and/or store PI and/or PHI of similar volume as the internal data warehouse involved in the Data Breach, to the extent it is commercially feasible.

ii. The monitoring of such database(s) shall include commercially reasonable query categories available in a database activity monitoring tool or reasonable equivalent issued to the relevant database(s).

iii. The monitoring of such database(s) shall be performed by appropriately trained or experienced personnel.

e. Anthem shall create a formalized procedure to track Security Events and alerts on privileged user queries on a regular basis and document identified issues and necessary action items.

9. **Antivirus Maintenance:** Anthem shall implement and maintain current, up-to-date antivirus protection programs or a reasonably equivalent technology on the Anthem Network components that require antivirus software, which shall be at the highest technical level available within Anthem-approved antivirus products that can be supported on such components, subject to any reasonable and documented security exceptions.

10. **Access Controls:** Anthem shall implement and maintain appropriate controls to manage access to and use of all accounts with access to PI or PHI, including individual accounts, administrator accounts, service accounts, and vendor accounts. Such controls shall include a means

to regularly review access and access levels of users and remove network and remote access within twenty-four (24) hours of notification of termination for any employee whose employment has ended or any non-associate whose term has ended.

11. **Authentication:** Anthem shall implement and maintain reasonable policies and procedures requiring the use of authentication in accordance with industry standards, where commercially feasible, including as appropriate under industry standards, the use of strong passwords, password rotation, and ensuring that stored passwords are protected from unauthorized access.

12. **Privileged Account Management:** Anthem shall implement and maintain reasonable controls to secure use of privileged credentials, such as through a Privileged Access Management tool or reasonably equivalent technology that vaults and rotates elevated credentials in places where privileged access credentials are required. Administrators shall be required to use Multi-factor Authentication or reasonably equivalent technology to gain access to their safe within the vault to retrieve their credentials.

13. **Remote Access/ Multi-factor Authentication:** Anthem shall require the use of Multi-factor Authentication or reasonably equivalent technology for end-user remote access to the Anthem Network that are servers. Additionally, Anthem will require during vendor security assessments business record documentation that demonstrates the vendor deploys Multi-factor Authentication or reasonably equivalent technology for end-user remote access to the Anthem Network via any business-to-business connection.

14. **Encryption:** Anthem shall develop, implement, maintain, regularly review, and revise policies and procedures to Encrypt PI and PHI at rest and in transit as reasonable and appropriate, and in accordance with applicable law.

15. **Asset Inventory:** Anthem shall develop, maintain, and regularly update a reasonable inventory of the assets that primarily comprise the Anthem Network and assign criticality ratings to such assets, as feasible.

16. **Risk Assessments:** Anthem shall develop, implement, and maintain a risk assessment program to identify, address, and, as appropriate, remediate risks affecting its Covered Systems. At a minimum, Anthem shall have an annual risk assessment performed by an independent third party. The assessment shall include assessment of all reasonably anticipated, internal and external risks to the security, confidentiality, or availability of PI and PHI collected, processed, transmitted, stored, or disposed of by Anthem, excluding legal documents and analyses that Anthem reasonably asserts are exempt from disclosure under legally-recognized privilege. Such reports shall be maintained by the CISO and be made available for inspection by the Third-Party Assessor described in Paragraph 27 of this Assurance.

17. **Vulnerability Management:** Anthem shall commit to continuing its current practices related to vulnerability scanning or a reasonably equivalent technology and remediation.

18. **Penetration Testing:** Anthem shall develop, implement, and maintain a penetration testing program designed to identify, assess, and remediate security vulnerabilities within the Anthem Network, which shall include annual external penetration tests or a reasonably equivalent technology and appropriate remediation of vulnerabilities revealed by such testing. Anthem shall develop, implement, and maintain an internal penetration testing program through the use of its Adversary Simulation Team or a reasonably equivalent group, who shall perform biannual internal penetration tests. The reports of such external and internal penetration tests shall be maintained by the CISO for a period of not less than six (6) years and be made available for inspection by the Third-Party Assessor described in Paragraph 27 of this Assurance.

19. **Email Filtering and Phishing Solutions:** Anthem shall maintain email protection and filtering solutions for all Anthem email accounts, including email SPAM, phishing attacks, and anti-malware or a reasonably equivalent technology.

20. **Employee Training:** In addition to the requirements set forth in Paragraph 4(g) above, Anthem shall conduct an initial training for all new employees and, on at least an annual basis, train existing employees concerning its information privacy and security policies, the proper handling and protection of PI and PHI, and disciplinary measures for violation, up to and including termination. At a minimum:

a. Anthem's new employee and annual training shall cover social engineering schemes, such as phishing;

b. Anthem shall conduct annual mock phishing exercises and all employees who fail must successfully complete additional training; and

c. Anthem shall document such trainings and the results of the mock phishing exercises.

21. **Network Sensors:** Anthem shall deploy network sensors or a reasonably equivalent technology to detect attempts to communicate from the Anthem Network to known malicious IP addresses.

22. **Endpoint Detection and Response:** Anthem will implement, maintain, and monitor controls designed to provide real-time notification of malicious systems modifications and anomalous systems activity in the Covered Systems.

23. **Intrusion Detection and Prevention Solution(s):** Anthem shall develop, implement, and maintain an intrusion detection and prevention solution to assist in detecting and preventing unauthorized access to the Anthem Network.

24. **Data Loss Prevention:** Anthem shall develop, implement, and maintain a data loss prevention technology or a reasonably equivalent technology to detect and prevent unauthorized data exfiltration from the Anthem Network.

25. **Whitelisting:** Anthem shall implement and maintain controls designed to identify applications permitted to be on the Covered Systems while blocking and/or preventing the execution of unauthorized applications (i.e., applications not on the whitelist) on critical servers.

D. Information Security Program Assessment

26. Anthem shall obtain an initial and annual information security assessment of its policies and practices pertaining to the collection, storage, maintenance, transmission, and disposal of PI and PHI, from an independent third-party professional (“Third-Party Assessor”) within one year of the Effective Date of this Assurance and then once a year thereafter for a total period of three (3) years.

27. The Third-Party Assessor must be an organization that employs at least one individual to perform the assessment that is: (a) qualified as a Certified Information System Security Professional (“CISSP”) or as a Certified Information Systems Auditor (“CISA”), or a similar qualification; and (b) has at least five (5) years of experience evaluating the effectiveness of computer systems or information system security.

28. Anthem may satisfy the initial assessment by providing a copy of the Assessment Report performed for calendar year 2019 pursuant to the settlement of *In re Anthem Inc. Data Breach Litig.*, MDL 2617. For the remaining two assessments, the Third-Party Assessor shall review this Assurance and the Security Event Report, risk assessments, and penetration test reports provided by Anthem as set forth in Paragraphs 3, 16, and 18, respectively. The Third-Party Assessor shall prepare a formal report (“Security Report”) that shall confirm Anthem’s

development, implementation, and maintenance of a written Information Security Program with security controls and processes that meet the requirements of this Assurance related to: segmentation, antivirus maintenance, access controls including privileged access management and multi-factor authentication, vulnerability scanning and remediation, logging and monitoring, encryption, application whitelisting, e-mail filtering, and information system activity review and detection. The Security Report shall also confirm that Anthem has complied with the provisions of this Assurance related to the employment of a CISO or equivalent officer, maintenance of a C-SOC facility, and performance of internal and external penetration tests and information security training. In preparing each Security Report, the Third-Party Assessor may rely on the Assessment Report performed for calendar years 2020 and 2021 for *In re Anthem Inc. Data Breach Litig.*, MDL 2617, for security controls and processes addressed by both that Assessment Report and this Assurance.

29. The Security Report shall be provided to the Connecticut Attorney General no later than ten (10) days after its completion. Anthem will also provide the Risk Assessment, as set forth in Paragraph 16, and a SOC 2 Type 2 Assessment, as referenced in Paragraph 31 to the Connecticut Attorney General on an annual basis during the three-year term.

a. Confidentiality: The Connecticut Attorney General's Office shall, to the extent permitted by state law, treat each Security Report as exempt from disclosure as applicable under the relevant public records laws.

b. State Access: The Connecticut Attorney General's Office may provide a copy of each Security Report to any other of the Attorneys General upon request, and each requesting Attorney General shall, to the extent permitted by state law, treat such report as exempt from disclosure as applicable under the relevant public records laws.

30. Upon receipt of each Security Report, Anthem will review and evaluate whether to revise its current policies and procedures based on the findings of the Security Report. Within sixty (60) days of Anthem's receipt of each Security Report, Anthem shall forward to the Connecticut Attorney General a description of any action they plan to take, or if no action is taken, a detailed description why no action is necessary, in response to each Security Report.

E. Information Security Program Audit

31. Anthem shall provide to the Connecticut Attorney General an annual SOC 2 Type 2 Assessment for calendar year 2019 and then once a year thereafter for a total period of three (3) years. At a minimum, this Assessment shall include the trust service principles of Security and Confidentiality.

IV. PAYMENT TO THE STATES

32. Anthem shall pay a total amount of Thirty-Nine Million and Five Hundred Thousand Dollars (\$39,500,000.00). Said payment shall be divided and paid by Anthem directly to each of the Attorneys General in an amount to be designated by the Attorneys General and communicated to Anthem by the Connecticut Attorney General, along with instructions for such payments.⁴ Payment shall be made in full within thirty (30) business days of the Effective Date and receipt of payment instructions by Anthem from the Connecticut Attorney General, except that where state law requires judicial or other approval of the Assurance, payment shall be made no later than thirty (30) days after notice from the relevant Attorney General that such final approval for the Assurance has been secured.

⁴ Payment to the State of California pursuant to its settlement with Anthem will be a portion of the total amount paid as set forth in this Paragraph.

33. Of the total amount, Anthem shall pay two million, seven hundred and fifteen thousand, four hundred and ninety-five dollars and 21 cents (\$2,715,495.21) to the New York Attorney General.

34. Also out of the total amount, as set forth above, Anthem will make payment to the NAGTRI Endowment Fund maintained in trust by the National Association of Attorneys General within thirty (30) days of the Effective Date, in an amount designated and communicated to Anthem by the Connecticut Attorney General.

V. RELEASE AND EXPIRATION

35. Release: Following full payment of the amounts due by Anthem under this Assurance, the Attorneys General shall release and discharge Anthem from all civil claims that the Attorneys General could have brought under the Consumer Protection Acts, Personal Information Protection Acts, Security Breach Notification Acts, HIPAA, and any common law claims concerning unfair, deceptive, or fraudulent trade practices based on Anthem's conduct related to the Data Breach. Nothing contained in this paragraph shall be construed to limit the ability of the Attorneys General to enforce the obligations that Anthem, its officers, subsidiaries, affiliates, agents, representatives, employees, successors, and assigns, have under this Assurance. Further, nothing in the Assurance shall be construed to create, waive, or limit any private right of action.

36. Notwithstanding any term of this Assurance, any and all of the following forms of liability are specifically reserved and excluded from the release in Paragraph 35 as to any entity or person, including Anthem:

a. Any criminal liability that any person or entity, including Anthem, has or may have to the States.

b. Any civil or administrative liability that any person or entity, including Anthem, has or may have to the States under any statute, regulation, or rule giving rise to any and all of the following claims:

- i. State or federal antitrust violations;
- ii. State or federal securities violations; or
- iii. State or federal tax claims.

37. Expiration: The obligations and other provisions of this Assurance set forth in Paragraphs 4(b), 6-13, 15, 17-19, and 21-25 shall expire at the conclusion of the five (5) year period after the Effective Date of this Assurance. The obligations and other provisions of this Assurance set forth in Paragraphs 14, 16, 20(a)-(c), 47, and 48 shall expire at the conclusion of the seven (7) year period after the Effective Date of the Assurance, unless they have expired at an earlier date pursuant to their specific terms. Provided, however, that nothing in this Paragraph shall be construed as excusing or exempting Anthem from complying with any state or federal law, rule, or regulation, nor shall any of the provisions of this Assurance be deemed to authorize or require Anthem to engage in any acts or practices prohibited by any law, rule, or regulation.

VI. GENERAL PROVISIONS

38. Meet and Confer: If any Attorney General determines that Anthem has failed to comply with any of the terms of this Assurance, and if in the Attorney General's sole discretion the failure to comply does not threaten the health or safety of the Attorney General's State and/or does not create an emergency requiring immediate action, the Attorney General will notify Anthem in writing of such failure to comply and Anthem shall have thirty (30) days from receipt of such written notice to provide a good faith response to the Attorney General's determination. The response shall include: (A) a statement explaining why Anthem believes it is in full compliance

with this Assurance; or (B) a detailed explanation of how the alleged violation(s) occurred, and either (i) a statement regarding whether the alleged violation(s) has been addressed and how, or (ii) a statement regarding whether the alleged violation cannot be reasonably addressed within thirty (30) days receipt of the notice, but, if (B)(ii) then also a statement (a) indicating whether Anthem has begun to take corrective action(s) to address the alleged violation(s), (b) stating what corrective action(s) Anthem is pursuing, and (c) providing the Attorneys General with a reasonable timetable for addressing the alleged violation(s). Nothing herein shall prevent an Attorney General from agreeing in writing to provide Anthem with additional time beyond the thirty (30) day period to respond to the notice referenced in this Paragraph. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Assurance after the Effective Date or compromise the authority of the Attorney General to initiate a proceeding for any failure to comply with this Assurance.

39. Any failure by the Attorneys General to insist upon Anthem's compliance with any of the provisions of this Assurance shall not be deemed a waiver of any of the provisions hereof, and the Attorneys General, notwithstanding that failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Assurance to be performed by Anthem.

40. If any clause, provision, or section of this Assurance shall, for any reason, be held illegal, invalid, or unenforceable, such illegality, invalidity, or unenforceability shall not affect any other clause, provision, or section of this Assurance and this Assurance shall be construed and enforced as if such illegal, invalid, or unenforceable clause, section, or provision had not been contained herein.

41. Nothing contained in this Assurance shall be construed to waive or limit any right of action by any consumer, person or entity, or by any local, state, federal or other governmental entity, except as provided by the Release herein.

42. Nothing in this Assurance shall prevent or restrict the use of this Assurance by the State in any action against Anthem for failure to comply with any of its provisions, or in the event that Anthem is in default of any of its terms and conditions. A default on the part of Anthem shall include any material breach of any of the terms or requirements of this Assurance. Nothing in this Assurance shall be construed to (i) exonerate any failure to comply with any of its provisions after the Effective Date of this Assurance, (ii) compromise or limit the authority of the State to initiate a proceeding for any failure to comply, or (iii) compromise the authority of the Court or any other court of competent jurisdiction to impose any applicable remedies for any violation of this Assurance.

43. Nothing in this Assurance is intended to be and shall not be construed or deemed to be an admission or concession or evidence of any liability or wrongdoing whatsoever on the part of Anthem or of any fact or violation of any law, rule, or regulation. This Assurance is made without trial or adjudication of any alleged issue of fact or law and without any finding of liability of any kind.

44. Anthem hereby acknowledges that its undersigned representative or representatives are authorized to enter into and execute this Assurance. Anthem has been represented by legal counsel and has been advised by their legal counsel of the meaning and legal effect of this Assurance.

45. This Assurance shall bind Anthem and its subsidiaries, affiliates, successors, future purchasers, acquiring parties, and assigns.

46. Within thirty (30) days of the Effective Date, Anthem will deliver a copy of this Assurance to (a) its Chief Executive Officer, Chief Information Officer, Chief Information Security Officer, and its General Counsel, and (b) its Board of Directors. In the event that any person assumes the role of Chief Executive Officer, Chief Information Officer, Chief Information Security Officer, and its General Counsel, or becomes a member of the Board of Directors and such person has not been previously delivered a copy of this Assurance, Anthem shall deliver a copy of this Assurance to such person within thirty (30) days from which such person assumes such role or becomes a member of the Board of Directors and maintain a record of such.

47. With respect to existing subsidiaries and affiliates, which do not yet fall under the definition of Anthem as set forth in Paragraph 1(A), but which are wholly owned and Anthem intends to integrate and operate, Anthem shall within one hundred and eighty (180) days following the Effective Date of this Assurance develop a reasonable and appropriate implementation timetable for those subsidiaries and affiliates to achieve compliance with the provisions of this Assurance. For purposes of this provision, implementation shall mean (i) that Anthem or its subsidiaries and affiliates have taken the relevant measure(s) where technologically feasible and otherwise reasonable, or have taken alternative measure(s) that alone or in the aggregate provide for substantially equivalent security, or (ii) that Anthem or its wholly owned, integrated, and operated subsidiaries and affiliates have developed a reasonable and appropriate plan to evaluate the technological and operational feasibility of the provisions of this Assurance. On a semiannual basis, Anthem will report to the Board of Directors regarding the implementation timetable progress, as well as document any significant delays or revisions to the timetable.

48. In the event that (1) Anthem acquires or merges with a subsidiary or affiliate after the Effective Date, (2) the subsidiary is wholly owned by Anthem, and (3) Anthem determines that

it intends to wholly integrate and operate that subsidiary following the completion of an integration assessment, Anthem shall have one-hundred twenty (120) days from the date Anthem completes the integration assessment to develop and then implement an integration timetable regarding compliance with the terms of this Assurance. For purposes of this provision, implementation shall mean (i) that Anthem or its wholly owned, integrated, and operated subsidiaries and affiliates have taken the relevant measure(s) where technologically feasible and otherwise reasonable, or have taken alternative measure(s) that alone or in the aggregate provide for substantially equivalent security, or (ii) that Anthem or its wholly owned, integrated, and operated subsidiaries and affiliates have developed a reasonable and appropriate plan to evaluate the technological and operational feasibility of the provisions of this Assurance. On a semiannual basis, Anthem will report to the Board of Directors regarding the implementation timetable progress, as well as document any significant delays or revisions to the timetable.

49. The settlement negotiations resulting in this Assurance have been undertaken by the Parties in good faith and for settlement purposes only, and no evidence of negotiations or communications underlying this Assurance shall be offered or received in evidence in any action or proceeding for any purpose.

50. In states where statute requires that this Assurance be filed with and/or approved by a court, Anthem consents to the filing of this Assurance and its approval by the court, and authorizes the Attorneys General in such states to represent that Anthem does not object to court approval of the Assurance. Anthem further consents to the jurisdiction of each such court for the purpose of approving or enforcing this Assurance. To the extent there are any court costs associated with the filing of this Assurance (if legally required), Anthem agrees to pay such costs.

51. This Assurance does not constitute an approval by the Attorneys General of any of Anthem's past or future practices, and Anthem shall not make any representation to the contrary.

52. Anthem shall not participate directly in any activity to form or proceed as a separate entity or corporation for the purpose of engaging in acts prohibited in this Assurance. Anthem shall not knowingly cause, permit, or encourage any other persons or entities acting on its behalf, to engage in practices prohibited by this Assurance.

VII. NOTICES UNDER ASSURANCE

53. Any notices or other documents required to be sent to the Parties pursuant to the Assurance shall be sent to the following address via first class and electronic mail, unless a different address is specified in writing by the party changing such address:

For the Attorney General:

Bureau Chief
Bureau of Internet and Technology
New York State Attorney General's Office
28 Liberty Street
New York, NY 10005
ifraud@ag.ny.gov

For Anthem:

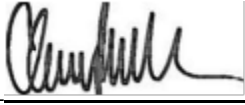
Office of the General Counsel
Anthem, Inc.
220 Virginia Avenue
Indianapolis, IN 46204
Tel.: (800) 331-1476

with a copy to:

Craig Hoover
Michelle Kisloff
Allison Holt Ryan
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004
Tel.: (202) 637-5600
craig.hoover@hoganlovells.com
michelle.kisloff@hoganlovells.com
allison.holt-ryan@hoganlovells.com

APPROVED:

ATTORNEY GENERAL, THE STATE OF NEW YORK

By:  _____ Date: September 30, 2020

Clark Russell
Deputy Bureau Chief
Bureau of Internet and Technology

Exhibit 3B
RESOLUTION AGREEMENT

I. Recitals

1. Parties. The Parties to this Resolution Agreement (“Agreement”) are:

- A. The United States Department of Health and Human Services, Office for Civil Rights (“HHS”), which enforces the Federal standards that govern the privacy of individually identifiable health information (45 C.F.R. Part 160 and Subparts A and E of 45 C.F.R. Part 164, the “Privacy Rule”), the Federal standards that govern the security of electronic individually identifiable health information (45 C.F.R. Part 160 and Subparts A and C of 45 C.F.R. Part 164, the “Security Rule”), and the Federal standards for notification in the case of breach of unsecured protected health information (45 C.F.R. Part 160 and Subparts A and D of 45 C.F.R. Part 164, the “Breach Notification Rule”). HHS has the authority to conduct compliance reviews and investigations of complaints alleging violations of the Privacy, Security, and Breach Notification Rules (the “HIPAA Rules”) by covered entities and business associates, and covered entities and business associates must cooperate with HHS compliance reviews and investigations. *See* 45 C.F.R. §§ 160.306(c), 160.308, and 160.310(b).
- B. Anthem, Inc. (“Anthem”), which is a business associate, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. Anthem is a publicly traded corporation. It provides administrative services as a business associate to the Anthem Affiliated Covered Entities (Anthem ACE) and is one of the nation’s leading health benefits companies, with health plans in more than a dozen states and customers in other states through its subsidiaries.
- C. HHS and Anthem shall together be referred to herein as the “Parties.”

2. No Admission. This Agreement is not an admission, concession, or evidence of liability by Anthem.

3. No Concession. This Agreement is not a concession by HHS that Anthem is not in violation of the HIPAA Rules and that Anthem is not liable for civil money penalties (“CMPs”).

4. Intention of Parties to Effect Resolution. This Agreement is intended to resolve HHS Transaction Number: 01-15-204066 and any potential violations of the HIPAA Rules related to the Covered Conduct specified in section I.5 of this Agreement. In consideration of the Parties’ interest in avoiding the uncertainty, burden, and expense of further investigation and formal proceedings, the Parties agree to resolve this matter according to the Terms and Conditions below.

5. Factual Background and Covered Conduct.

On February 13, 2015, HHS opened a compliance review of Anthem based on February 5, 2015 media reports and information on Anthem's website that Anthem had experienced a "sophisticated external cyber attack." On March 13, 2015, HHS received notification from Anthem that cyber-attackers gained impermissible access to the electronic protected health information (ePHI) of 78,800,000 individuals maintained on Anthem's enterprise data warehouse. On February 23, 2015, HHS notified Anthem of its investigation regarding Anthem's compliance with the HIPAA Rules. HHS' investigation indicated potential violations of the following provisions ("Covered Conduct"):

- A. The requirement to conduct an accurate and thorough risk analysis of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of all ePHI held by Anthem (*see 45 C.F.R. § 164.308 (a)(1)(ii)(A)*).
- B. The requirement to implement sufficient procedures to regularly review records of information system activity (*see 45 C.F.R. § 164.308 (a)(1)(ii)(D)*).
- C. The requirement to identify and respond to detections of the security incident leading to this breach (*see 45 C.F.R. § 164.308 (a)(6)(ii)*).
- D. The requirement to implement sufficient technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4) (*see 45 C.F.R. § 164.312(a)*).
- E. The requirement to prevent unauthorized access to the ePHI of 78,800,000 individuals whose information was maintained in Anthem's enterprise data warehouse (*see 45 C.F.R. § 164.502(a)*).

II. Terms and Conditions

6. Payment. HHS has agreed to accept, and Anthem has agreed to pay HHS, the amount of \$16,000,000 ("Resolution Amount"). Anthem agrees to pay the Resolution Amount on October 15, 2018 by automated clearing house transaction pursuant to written instructions to be provided by HHS.

7. Corrective Action Plan. Anthem has entered into and agrees to comply with the Corrective Action Plan ("CAP"), attached as Appendix A, which is incorporated into this Agreement by reference. If Anthem breaches the CAP, and fails to cure the breach as set forth in the

CAP, then Anthem will be in breach of this Agreement and HHS will not be subject to the Release set forth in section II.8 of this Agreement.

8. Release by HHS. In consideration of and conditioned upon Anthem's performance of its obligations under this Agreement, HHS releases Anthem from any actions it may have against Anthem under the HIPAA Rules arising out of or related to the Factual Background and Covered Conduct identified in section I.5 of this Agreement. HHS does not release Anthem from, nor waive any rights, obligations, or causes of action other than those arising out of or related to the Covered Conduct and referred to in this paragraph. This release does not extend to actions that may be brought under section 1177 of the Social Security Act, 42 U.S.C. § 1320d-6.

9. Agreement by Released Parties. Anthem shall not contest the validity of its obligation to pay, nor the amount of, the Resolution Amount or any other obligations agreed to under this Agreement. Anthem waives all procedural rights granted under Section 1128A of the Social Security Act (42 U.S.C. § 1320a- 7a) and 45 C.F.R. Part 160 Subpart E, and HHS claims collection regulations at 45 C.F.R. Part 30, including, but not limited to, notice, hearing, and appeal with respect to the Resolution Amount.

10. Binding on Successors. This Agreement is binding on Anthem and its successors, heirs, transferees, and assigns.

11. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

13. Execution of Agreement and Effective Date. The Agreement shall become effective (*i.e.*, final and binding) upon the date of signing of this Agreement and the CAP by the last signatory ("Effective Date").

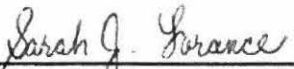
14. Tolling of Statute of Limitations. Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a CMP must be imposed within six (6) years from the date of the occurrence of the violation. To ensure that this six-year period does not expire during the term of this Agreement, Anthem agrees that the time between the Effective Date of this Agreement (as set forth in Paragraph 13) and the date the Agreement may be terminated by reason of Anthem's breach, plus one-year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the violations which are the subject of this Agreement. Anthem waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Conduct identified in section I.5 that is filed by HHS within the time period set forth above, except to the extent that such defenses would have been available had an administrative action been filed on the Effective Date of this Agreement.

15. Disclosure. HHS places no restriction on the publication of the Agreement.

16. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

17. Authorizations. The individual(s) signing this Agreement on behalf of Anthem represent and warrant that they are authorized by Anthem to execute this Agreement. The individual(s) signing this Agreement on behalf of HHS represent and warrant that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.


For Anthem, Inc.



Sarah J. Lorange
Senior Vice President & Chief Compliance Officer
Anthem, Inc.

10/15/2018
Date

For Department of Health and Human Services



Susan M. Pezzullo Rhodes
Regional Manager, New England Region
Office for Civil Rights

10/15/18
Date

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ANTHEM, INC.

I. Preamble

Anthem, Inc. (hereinafter known as "Anthem") hereby enters into this Corrective Action Plan ("CAP") with the United States Department of Health and Human Services, Office for Civil Rights ("HHS"). Contemporaneously with this CAP, Anthem is entering into a Resolution Agreement ("Agreement") with HHS, and this CAP is incorporated by reference into the Resolution Agreement as Appendix A. Anthem enters into this CAP as part of consideration for the release set forth in section II.8 of the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

Anthem has identified the following individual as its authorized representative and contact person regarding the implementation of this CAP and for receipt and submission of notifications and reports:

Sarah J. Lorance
Senior Vice President & Chief Compliance Officer
700 Broadway
Denver, CO 80273
Telephone: (303) 764-7277
Sarah.j.lorance@anthem.com

HHS has identified the following individual as its authorized representative and contact person with whom Anthem is to report information regarding the implementation of this CAP:

Susan M. Pezzullo Rhodes
Office for Civil Rights, New England Region
U.S. Department of Health and Human Services
JFK Federal Building, Room 1875
Boston, MA 02203
Telephone: 617-565-1347
Fax: 617-565-3809

Anthem and HHS agree to promptly notify each other of any changes in the contact persons or the other information provided above.

B. Proof of Submissions. Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, overnight mail, or hand delivery, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

III. Effective Date and Term of CAP

The Effective Date for this CAP shall be calculated in accordance with paragraph II.13 of the Agreement ("Effective Date"). The period for compliance ("Compliance Term") with the obligations assumed by Anthem under this CAP shall begin on the Effective Date of this CAP and end two (2) years from the Effective Date, unless before the end of this two (2) year period, HHS has notified Anthem under section VIII.B. hereof of its position that Anthem has breached this CAP. In the event of such a notification by HHS under section VIII.B. hereof, the Compliance Term shall not end until HHS either (1) notifies Anthem that it has determined that the breach has been cured or (2) notifies Anthem under section VIII.D. hereof that it will seek imposition of a CMP. After the Compliance Term ends, Anthem shall still be obligated to submit the final Annual Report as required by Section VI and comply with the document retention requirement in Section VII.

IV. Time

In computing any period of time prescribed or allowed by this CAP, all days referred to shall be calendar days. The day of the act, event, or default from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day which is not one of the aforementioned days.

V. Corrective Action Obligations

Anthem agrees to the following:

A. Security Management Process

1. Anthem shall conduct an accurate and thorough Risk Analysis of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) held by Anthem. Within ninety (90) days of the Effective Date, Anthem shall provide to HHS a Statement of Work (SOW) for the Risk Analysis. Within thirty (30) days of its receipt of Anthem's Risk Analysis SOW, if HHS identifies deficiencies in the Risk Analysis SOW, HHS shall provide Anthem with written technical assistance, as necessary, such as through suggested edits to the SOW, so that Anthem may revise its SOW accordingly. Within thirty (30) days of HHS providing such written technical assistance, if any, the Parties shall meet and confer in good faith to determine the deadline by which Anthem shall submit a

revised SOW for HHS review. Within thirty (30) days of Anthem submitting any such revised SOW, the Parties shall meet and confer in good faith to determine the deadline by which HHS shall review the revised SOW and provide Anthem with written technical assistance, if any. This submission and review process shall continue until HHS approves the SOW.

2. Anthem shall provide the Risk Analysis, consistent with section V.A.1, to HHS within two-hundred ten (210) days of HHS's approval of the Risk Analysis SOW, as required by section V.A.1, for HHS' review. Anthem may submit a Risk Analysis currently underway or previously completed for consideration by HHS for compliance with this provision. Within thirty (30) days of its receipt of Anthem's Risk Analysis, HHS will inform Anthem whether it has any technical assistance to provide for the submitted Risk Analysis. Upon receiving any recommended changes to the Risk Analysis to confirm compliance with the SOW and the Security Rule, Anthem shall have thirty (30) days to revise the Risk Analysis and provide the revised Risk Analysis to HHS for review. This process shall continue until HHS determines the Risk Analysis has been completed in accordance with the SOW and the Security Rule. Anthem will within one-hundred fifty (150) days then incorporate the results of the Risk Analysis into its existing process for implementing security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level as required by the Security Rule and will provide such documentation to HHS upon request.

B. Policies and Procedures

1. Anthem shall review and revise, as necessary, the written policies and procedures addressing the Minimum Content set forth in Section V.D. to confirm compliance with the Federal standards that govern the security of individually identifiable health information (45 C.F.R. Part 164, Subpart C) (the "Security Rule").

2. Anthem shall provide the policies and procedures identified in section V.B.1 above to HHS for review within one-hundred fifty (150) days of the Effective Date. Within sixty (60) days of its receipt of Anthem's submitted policies and procedures, HHS will inform Anthem whether it has any feedback on the submitted policies and procedures. Upon receiving any recommended changes to such policies and procedures from HHS to confirm compliance with the Security Rule, Anthem shall have forty-five (45) days to revise such policies and procedures and provide the revised policies and procedures to HHS for review. This process shall continue until HHS confirms that such policies and procedures comply with the requirements of the Security Rule.

3. Anthem shall adopt any necessary amendments to its policies and procedures pursuant to section V.B.2 within ninety (90) days of receipt of HHS' final feedback.

C. Distribution of Policies and Procedures

1. Anthem shall make available, for example through publication on its intranet, the policies and procedures identified in section V.B. to members of the Anthem's workforce subject to those policies and procedures who use or disclose ePHI within thirty (30) days of Anthem's adoption of such policies and procedures, and thereafter to new members of the workforce who

will be subject to those policies and procedures and who will use or disclose ePHI within thirty (30) days of their becoming a member of the workforce.

D. Minimum Content of the Policies and Procedures

The Policies and Procedures subject to this CAP shall include and be limited to policies and procedures that address the following Security Rule provisions:

1. Information System Activity Review – 45 C.F.R. § 164.308(a)(1)(ii)(D), including a process(es) for the regular review of records of information system activity collected by Anthem and processes for evaluating when the collection of new or different records needs to be included in the review;

2. Access Control – 45 C.F.R. § 164.312(a)(1), with respect to provisions to address access between Anthem systems containing ePHI, such as network or portal segmentation, and provisions to enforce password management requirements, such as password age.

E. Reportable Events

1. During the Compliance Term, in the event that Anthem receives information that a workforce member subject to the policies and procedures adopted by Anthem under section V.B.3 may have failed to comply with those policies and procedures, Anthem shall promptly investigate this matter. If Anthem determines, after such investigation, that during the Compliance Term a member of its Workforce subject to the policies and procedures adopted by Anthem under section V.B.3 failed to comply with those policies and procedures, and such failure was material (e.g., a violation that results in a presumed Breach of Unsecured PHI), Anthem shall notify HHS in writing within sixty (60) days. Such violations shall be known as Reportable Events. The report to HHS shall include the following information:

a. A description of the event, including the relevant facts, the role(s) of the persons involved, and the provision(s) of the policies and procedures under section V.B. implicated; and

b. A description of the actions taken and any further steps Anthem plans to take to address the matter to mitigate any harm, and to prevent it from recurring, including sanctions, if any.

2. If no Reportable Events occur within the Compliance Term, Anthem shall so inform HHS in its Annual Report as specified in section VI below.

VI. Implementation Report and Annual Reports

A. Implementation Report. Within one-hundred and twenty (120) days after HHS finalizes its review of the Policies and Procedures specified in section V.B. above, Anthem shall submit a written report with the documentation described below to HHS (“Implementation Report”). The Implementation Report shall include:

1. An attestation signed by an officer of Anthem attesting that the policies and procedures submitted to HHS under section V.B. are being implemented;

2. An attestation signed by an officer of Anthem attesting that he or she has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes, based upon such inquiry, that the information is accurate and truthful.

B. Annual Reports. The one-year period beginning on the Effective Date and each subsequent one-year period during the course of the Compliance Term shall be referred to as "the Reporting Periods." Anthem shall submit to HHS an Annual Report with respect to the status of and findings regarding Anthem's compliance with this CAP. Anthem shall submit the Annual Report to HHS no later than sixty (60) days after the end of each corresponding Reporting Period. The Annual Report shall include:

1. A summary of Reportable Events (defined in Section V.E.1) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

2. An attestation signed by an owner or officer of Anthem attesting that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VII. Document Retention

Anthem shall maintain for inspection and copying, and shall provide to HHS, upon request, all documents and records relating to compliance with this CAP for six (6) years from the Effective Date.

VIII. Breach Provisions

Anthem is expected to fully and timely comply with all provisions contained in this CAP.

A. Timely Written Requests for Extensions

Anthem may, in advance of any due date set forth in this CAP, submit a timely written request for an extension of time to perform any act required by this CAP. A "timely written request" is defined as a request in writing received by HHS at least five (5) days prior to the date such an act is required or due to be performed.

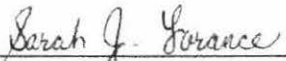
B. Notice of Breach of this CAP and Intent to Impose Civil Money Penalty. The Parties agree that a breach of this CAP by Anthem constitutes a breach of the Agreement. Should HHS believe that Anthem has breached this CAP, HHS will notify Anthem of: (1) its belief that Anthem has breached the agreement and the basis thereof; and (2) HHS' intent to impose a CMP pursuant to 45 C.F.R. Part 160 for the Covered Conduct set forth in section I.5 of the Agreement ("Notice of Breach and Intent to Impose CMP"), including the amount of such CMP.

C. Anthem's Response. Anthem shall have thirty (30) days from the date of receipt of the Notice of Breach and Intent to Impose CMP to demonstrate to HHS' satisfaction that:

1. Anthem is in compliance with the obligations of the CAP that HHS cited as the basis for the breach;
2. The alleged breach has been cured; or
3. The alleged breach cannot be cured within the thirty (30) day period, but that:
(a) Anthem has begun to take action to cure the breach; (b) Anthem is pursuing such action with due diligence; and (c) Anthem has provided HHS a reasonable timetable for curing the breach.

D. Imposition of CMP. If at the conclusion of the thirty (30) day period, Anthem fails to meet the requirements of section VIII.C. of this CAP to HHS' satisfaction, HHS may seek imposition of a CMP against Anthem pursuant to 45 C.F.R. Part 160 for any violations of the HIPAA Rules related to the Covered Conduct set forth in section I.5 of the Agreement. HHS shall promptly notify Anthem in writing of its determination to seek the imposition of a CMP pursuant to 45 C.F.R. Part 160. HHS must offset any CMP amount levied under this section by the amounts already paid by Anthem in lieu of CMPs under the Resolution Agreement. Any such offset will apply only to Covered Conduct up to and including the Effective Date.

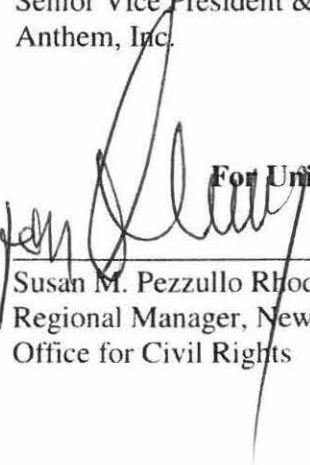
For Anthem, Inc.



Sarah J. Lorance
Senior Vice President & Chief Compliance Officer
Anthem, Inc.

10/15/2018
Date

For United States Department of Health and Human Services



Susan M. Pezzullo Rhodes
Regional Manager, New England Region
Office for Civil Rights

10/15/18
Date

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York
By: LI YU
PETER ARONOFF
RACHAEL DOUD
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----	X	
UNITED STATES OF AMERICA,	:	20 Civ. 2593 (ALC)
	:	
Plaintiff,	:	<u>AMENDED</u>
	:	<u>COMPLAINT</u>
v.	:	
	:	
ANTHEM, INC.,	:	JURY TRIAL DEMANDED
	:	
Defendant.	:	
-----	X	

The United States (the “Government”), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, alleges as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by the Government against defendant Anthem, Inc. (“Anthem”) to recover treble damages sustained by, and civil penalties and restitution owed to, the Government as result of Anthem’s violations of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.* As set forth below, Anthem knowingly disregarded its duty to ensure the accuracy of the risk adjustment diagnosis data that it submitted to the Centers for Medicare and Medicaid Services (“CMS”) for hundreds of thousands of Medicare beneficiaries covered by the Medicare Part C plans operated by Anthem. By ignoring its duty to delete thousands of inaccurate diagnoses, Anthem unlawfully obtained and retained from CMS millions of dollars in payments under the risk adjustment payment system for Medicare Part C.

2. As a Medicare Advantage Organization (“MAO”), Anthem was responsible for covering the cost of services rendered by healthcare providers like hospitals and doctors’ offices for the Medicare beneficiaries enrolled in Anthem’s Part C plans. Anthem, in turn, received monthly capitated payments from CMS for providing such coverage. *See infra* ¶¶ 21-39.

3. Anthem understood that CMS calculated the payments to Anthem pursuant to a risk adjustment system, under which the amounts of those payments were based directly on the number and the severity of the diagnosis data — in the form of ICD diagnosis codes — that Anthem submitted to CMS. *See infra* ¶¶ 27-44. In most cases, Anthem submitted the diagnosis codes reported by providers in the claims and data that the providers submitted to Anthem to seek payments for treating Medicare beneficiaries enrolled in Anthem’s Part C plans.

4. Anthem knew that, because the diagnosis codes it submitted to CMS affected payment directly, it had an obligation to ensure that its data submissions were accurate and truthful, including by complying with the ICD coding guidelines adopted by CMS regulations. *See infra* ¶¶ 45-50. Indeed, Anthem expressly promised CMS that it would “research and correct” any “discrepancies” in its “risk adjustment data” submissions and that it would comply with CMS’s regulatory and contractual requirement that diagnosis codes for risk adjustment purposes must be substantiated by beneficiaries’ medical records. *See infra* ¶¶ 79-82. In addition, Anthem repeatedly attested to CMS that its risk adjustment diagnosis data submissions were “accurate, complete, and truthful” according to its “best knowledge, information and belief.” *See infra* ¶¶ 83-90. As Anthem knew, the promises and attestations it made to CMS placed on Anthem an obligation to make good faith efforts to delete inaccurate diagnosis codes. *See infra* ¶¶ 57-61, 70-78, 137-140.

5. Anthem’s actual practices between early 2014 and early 2018 (the “relevant period”), however, were in direct contravention of its promises and attestations to CMS.

Specifically, Anthem implemented a “retrospective chart review” program using a vendor, pursuant to which they obtained medical records from providers concerning services they provided to beneficiaries enrolled in Anthem’s Part C plans and the vendor then reviewed those medical records to identify all the diagnosis codes supported by the records.¹ This process was “retrospective” because it typically occurred at least several months after Anthem had submitted to CMS the diagnosis codes reported by providers. Anthem knew that the results of chart review could indicate whether or not the diagnosis codes Anthem previously submitted to CMS were accurate. More specifically, Anthem knew that the diagnosis codes it previously submitted to CMS, but which could not be substantiated by Anthem’s retrospective chart review, had likely been reported inaccurately. *See infra* ¶¶ 120-133.

6. To persuade providers to supply records for review, Anthem told providers that Anthem’s chart review process was an “oversight activity” that “will help ensure that the ICD9 codes have been reported accurately” and in accordance with “proper coding guidelines.” *See infra* ¶¶ 111-119. That was not true. Instead, Anthem used chart reviews only to submit additional diagnosis codes to CMS while turning a blind eye to negative results where chart reviews could not substantiate the diagnosis codes that Anthem had previously submitted to CMS.

7. More specifically, although the Medicare Revenue and Reconciliation (“Medicare R&R”) group at Anthem could have readily written a computer algorithm to find inaccurately reported diagnosis codes by comparing previously-submitted codes against chart review results, Anthem made no effort to do so during the relevant period. This was because Anthem viewed its chart review program only as a means to find “new revenue generating [diagnosis] codes” so that Anthem could obtain higher Medicare payments. Finding and deleting inaccurate diagnosis

¹ In 2018, Anthem made significant changes to its chart review procedures. Specifically, it began comparing the diagnosis codes it previously submitted to CMS against the chart review results to identify potential inaccuracies.

codes, by contrast, would have reduced Anthem’s revenue from Medicare. *See infra* ¶¶ 120-133.

8. Anthem made “revenue enhancement” the sole purpose of its chart review program, while disregarding its obligation to find and delete inaccurate diagnosis codes, because Anthem prioritized profits over compliance. Specifically, Anthem’s one-sided chart review program, *i.e.*, focusing solely on finding additional codes to submit to CMS without also identifying and deleting inaccurate codes, often generated \$100 million or more a year in additional revenue for Anthem. Indeed, as the head of the Medicare R&R group at Anthem recognized, the one-sided chart review program was “a cash cow” for Anthem because it consistently produced a “return on investment” of up to 7:1. *See infra* ¶¶ 141-152.

9. Ultimately, the extraordinary profits that Anthem obtained through its one-sided chart review program came at the expense of the public fisc. By knowingly breaching its promises and attestations to CMS, and by knowingly disregarding its regulatory and contractual obligation to correct inaccuracies in its diagnosis data submissions, Anthem improperly obtained or retained millions of dollars from CMS in violation of three FCA provisions — 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), and (a)(1)(G) – and under the common law. *See infra* ¶¶ 158-178.

THE PARTIES

10. Plaintiff is the United States. Through its Department of Health and Human Services (“HHS”), and more specifically through CMS, a component agency within HHS, the Government administers the Medicare Program, including, as relevant here, the risk adjustment payment system for Medicare Part C.

11. Defendant Anthem, Inc., formerly known as WellPoint, is an Indiana corporation with its headquarters at 220 Virginia Avenue in Indianapolis, Indiana. During the times relevant to this action, Anthem maintained three geographic divisions — East, Central, and West. Further, Anthem, through its subsidiaries and affiliates, operated dozens of Medicare Part C

plans across the United States. In New York, for example, Anthem operated Empire MediBlue Plus (the “Empire MediBlue Plan”) – a Medicare Part C plan with the contract number H3370 – through its subsidiaries Empire HealthChoice HMO, Inc. and Empire HealthChoice Assurance, Inc. (collectively *d/b/a* Empire BlueCross BlueShield). A table of the plans operated by Anthem that are relevant to this action, the contract numbers for those plans, and the Anthem subsidiaries involved with those plans is attached as Exhibit 1 hereto.²

JURISDICTION AND VENUE

12. This Court has jurisdiction over the claims under the FCA pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and it has jurisdiction over the common law claims pursuant to 28 U.S.C. § 1345.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because Anthem transacted business in this District and because a substantial part of the events giving rise to the claims herein occurred within this District. For example, Anthem enrolled thousands of residents of this District in Empire MediBlue Plus — one of Anthem’s largest Medicare Part C plans. As relevant here, Anthem also maintained a regional office at One Liberty Plaza in Manhattan, through which Anthem sought and obtained records from healthcare providers in this District for its retrospective chart review program.

14. This Court may exercise personal jurisdiction over Anthem pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process.

² The subsidiaries and affiliate that Anthem used to operate the Medicare Part C plans at issue and during the relevant period include, but are not limited to: Anthem Blue Cross Life & Health Insurance Co., Anthem Health Plans, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of Maine, Inc., Anthem Health Plans of Virginia, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross Blue Shield of Georgia, Community Insurance, Co., Compmore Health Services Insurance Corp.; Empire Healthchoice HMO, Inc., Empire Healthchoice Assurance, Inc., Healthkeepers, Inc., HMO Colorado, Inc., HMO Missouri, Inc., Rocky Mountain Hospital & Medical Services, Inc., and Unicare Life & Health Insurance Co.

THE FALSE CLAIMS ACT

15. The False Claims Act was originally enacted in 1863 to address fraud on the Government in the midst of the Civil War, and it reflects Congress’s objective to “enhance the Government’s ability to recover losses as a result of fraud against the Government.” *See* S. Rep. No. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266.

16. As relevant here, the FCA establishes treble damages liability to the Government where an individual or entity:

- i. “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval[;]”
- ii. “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[;]” or
- iii. “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government[.]”

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

17. “Knowingly,” within the meaning of the FCA, is defined to include a defendant acting in reckless disregard or deliberate indifference of the truth or falsity of information, as well as actual knowledge of such falsity by the defendant. *See id.* § 3729(b)(1). Further, “no proof of specific intent to defraud” is required to establish liability under the FCA. *Id.*

18. For purposes of section 3729(a)(1)(B), the FCA defines “material” as “having a natural tendency to influence, or capable of influencing, the payment or receipt of money or property.” *Id.* § 3729(b)(4).

19. The FCA also defines “obligation” in section 3729(a)(1)(G) – the reverse false claims provision – to include any “established duty, whether or not fixed, arising from an express or implied contractual ... relationship, from a fee-based or similar relationship, from statute or

regulation, or from the retention of an overpayment.” *Id.* § 3729(b)(3). This broad definition reflects Congress’s intent for the reverse false claims provision to apply to non-fixed duties to pay or repay the Government. *See* S. Rep. 111-10 at 14 (2009). In 2010, Congress further reinforced the duty on Medicare program participants like MAOs to return overpayments in a timely manner. Specifically, as part of the Patient Protection and Affordable Care Act of 2010, *see* 124 Stat. 119, 753-56 (2010), Congress added a provision to the Social Security Act that obligates MAOs like Anthem to report and return overpayments made by Medicare within sixty days of the identification of the overpayments. *See* 42 U.S.C. § 1320a-7k(d)(2). Under this provision, if an MAO makes a late report or repayment—that is a report or repayment after 60 days—it is still liable to pay treble damages and penalties under the FCA.

20. Finally, in addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.³ *See* 31 U.S.C. § 3729(a)(1).

THE MEDICARE ADVANTAGE PROGRAM AND ITS RISK ADJUSTMENT PAYMENT SYSTEM

A. Medicare Advantage and the Role of Part C MAOs

21. Medicare is a federally-operated health insurance program administered by CMS benefiting individuals 65 and older and the disabled. *See* 42 U.S.C. § 1395c *et seq.*

22. Parts A and B of the Medicare Program are commonly known as “traditional” Medicare. Part A covers inpatient and institutional care, while Part B covers physician, hospital, outpatient, and ancillary services and durable medical equipment. Under Medicare Parts A and B, CMS reimburses healthcare providers (*e.g.*, hospitals and physicians’ offices) directly using a fee-for-service system. Specifically, healthcare providers submit claims to CMS for medical

³ As adjusted by applicable laws and regulations, the range of civil penalties for FCA violations occurring between September 29, 1999, and November 1, 2015, is \$5,500 to \$11,000, *see* 28 U.S.C. § 2461 (notes); 64 Fed. Reg. 47,099, 47,103 (1999); and the range of civil penalties for FCA violations occurring after November 1, 2015, is \$10,781 to \$21,563, *see* 82 Fed. Reg. 9,131–9,136 (2017).

services actually rendered. CMS, in turn, pays the providers directly for each service based on payment rates established by the Government.

23. On the other hand, Medicare Part C, which is at issue in this case, involves Medicare beneficiaries who have elected to receive Part A and Part B benefits through a Medicare Advantage plan (“Part C plan” or “MA plan”). *See* 42 U.S.C. §§ 1395w-21 to 1395w-28. The MA plans, in turn, are operated and managed by MAOs, which are private insurers like Anthem. *See* 42 C.F.R. §§ 422.2, 422.503(b)(2).

24. Under Medicare Part C, beneficiaries receive healthcare services managed by those plans. More specifically, when a healthcare provider furnishes medical services to a Medicare beneficiary enrolled in an MA plan, the provider submits claims and encounter data to the MAO that operates the MA plan in order to receive payment from the MAO, instead of CMS.

25. Congress expressly delegated authority to CMS to issue rules to implement and regulate Medicare Part C. *See* 42 U.S.C. § 1395w-26(b). Pursuant to that delegation, CMS has promulgated regulations that, *inter alia*, define the MAOs’ obligations and responsibilities. *See generally* 42 C.F.R. Part 422. As discussed more fully below, *see infra* ¶¶ 57-61, CMS’s Part C regulations require MAOs like Anthem to implement compliance procedures and programs and to make annual attestations.

26. In addition to issuing regulations, CMS also has defined the MAOs’ obligations contractually. For example, in order to participate in Medicare Part C, MAOs must execute a written agreement or a renewal of the written agreement with CMS on an annual basis for each of the Part C plans they operate. As relevant here, Anthem executed such agreements or renewals annually for all of the Part C plans it operated from 2013 to 2018.⁴ Further, the terms

⁴ Examples of such agreements are the annual Part C agreements executed by Anthem in 2014 and 2015 for its Empire MediBlue Plan, which are attached here as Exhibits 2 and 3.

and conditions in the Part C annual agreements/renewals that are relevant here have remained the same during that period.

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. A central and distinguishing feature of Medicare Part C is how CMS determines the amount of the payments to which each MAO is entitled for providing healthcare coverage to a beneficiary enrolled in one of the MAO’s Part C plans. Instead of compensating an MAO on a fee-for-service basis for specific medical services for a beneficiary, CMS makes monthly payments to the MAO in a fixed, capitated (per beneficiary enrollee in each Part C plan) amount for providing coverage for each of the Medicare beneficiaries enrolled in the Part C plan.

28. Unlike under Parts A and B, the per-member, per-month payments that CMS makes to MAOs under Medicare Part C do not depend on the amount of services provided to a specific beneficiary. Instead, the capitated rate is determined based on how the bid submitted by an MAO compares to an administratively set benchmark established under the Part C statute. *See* 42 U.S.C. § 1395w-23(a)(1)(B); 42 C.F.R. §§ 422.254, 425.304.

29. Within this system, which Congress has mandated since 2000, *see* 42 U.S.C. § 1395w-23(a)(1)(C) (directing CMS to adjust the capitated payments for each MA plan enrollee based on each enrollee’s demographic factors and health status), CMS uses its risk adjustment payment system to determine the capitated payments based on the expected risk of each beneficiary.⁵

⁵ Because CMS calculates and makes the monthly capitated payments to MAOs in a given payment year before CMS necessarily has received all the diagnosis data relevant to the risk-adjustment calculation, CMS also engages in a “reconciliation process” *after* the conclusion of each payment year. *See* 42 C.F.R. § 422.310(g)(2).

Through this process, CMS may conclude that “adjustments to payments are necessary” based on subsequently-submitted diagnosis data, which may result in CMS making an additional reconciliation payment to an MAO or seeking a reconciliation refund from the MAO. *See id.*

30. More specifically, CMS calculates, for each beneficiary enrolled in a Part C plan, a risk score – also known as the risk adjustment factor or “RAF” — which acts as a multiplier for purposes of determining the capitated payment for that enrollee. *See* 42 C.F.R. § 422.308(e).⁶ In other words, CMS pays MAOs more for beneficiaries with certain serious illnesses or chronic medical conditions and, thus, higher risk scores, than for beneficiaries without those conditions and, thus, lower risk scores.

31. Since 2004, CMS has employed a hierarchical condition category (“HCC”) model to calculate the risk score for Medicare beneficiaries enrolled in Part C plans. As directed by Congress, the HCC model takes into account both the demographic factors and health status of Medicare beneficiaries. *See* 42 C.F.R. § 422.2.

32. Clinically, HCCs are categories of related medical diagnoses including major, severe, and/or chronic illnesses. *See id.* Between 2004 and 2013, there were 70 HCCs in CMS’s Part C risk adjustment model. Starting in 2014, and after CMS revised its model, the number of HCCs increased to 79.

33. Each HCC correlates with the marginal predicted cost of medical expenditures for that set of medical conditions based on CMS’s data from administering the traditional Medicare Fee-For-Service program. Some examples of HCC codes are HIV/AIDS (HCC 1), metastatic cancer and leukemia (HCC 8), congestive heart failure (HCC 80), and ischemic stroke (HCC

⁶ To determine the *base* monthly payment amount for Medicare beneficiaries enrolled in a specific Part C plan, CMS uses a bidding process in which each Part C Plan, through its MAO, submits a bid amount. That bid is then compared to an administratively set benchmark set by CMS. *See* 42 C.F.R. Part 422, subparts F and G.

100).⁷ Higher relative values (also sometimes referred to as relative factors, or coefficients) are assigned to HCCs that include diagnoses with greater disease severity and treatment costs.

34. A single Medicare beneficiary may have none, one, or multiple HCCs, which affect the risk adjustment payment calculated by CMS according to the relative values of those HCCs and the base payment amount for a specific Medicare beneficiary.

35. To illustrate, assume that adding HCC 8 (metastatic cancer and leukemia) to a hypothetical Medicare beneficiary's list of HCCs in 2014 would have increased that beneficiary's overall risk score from 0.7 to 2.77, *i.e.*, by 2.07; and further assume that the base payment amount for this beneficiary was \$10,000. In these circumstances, adding HCC 8 would have caused CMS to pay out \$20,700 more in risk adjustment payments for that beneficiary in 2014.

36. To determine which HCCs are applicable to each Medicare beneficiary, CMS's HCC model relies on the diagnoses – more specifically ICD diagnosis codes – documented by medical encounters that Medicare beneficiaries have with authorized healthcare providers (*e.g.*, a visit to a doctor's office or an inpatient stay at a hospital). In other words, the ICD diagnosis codes submitted by MAOs are used by CMS to calculate the risk adjustment payment.

37. HHS has adopted the ICD Guidelines for Coding and Reporting as the standard for medical record documentation. *See* 45 C.F.R. § 162.1002(c)(2) and (c)(3) (“The Secretary [of HHS] adopts ... the official ICD-10-CM Guidelines for coding and reporting”). CMS regulations, therefore, required MAOs to “submit data that conform to” the ICD coding guidelines. *See* 42 C.F.R. § 422.310(d)(1) (requiring MAOs to submit data in conformity with “all relevant national standards”).

⁷ HCC numerical codes changed between the 2004–2013 model (known as Version 12) and the 2014 model (known as Version 22). The numerical examples of HCC codes cited herein are from the Version 22 model.

38. Practically, the ICD coding and classification system allows healthcare providers, insurance carriers and public health agencies to use alphanumeric codes to represent diagnoses. Each disease, injury, infection and symptom has its own ICD code. During the relevant times, the applicable standards for ICD coding have been set forth in two systems — first, up to October 1, 2015, the International Classification of Diseases, Ninth Revision, Clinical Modification (“ICD-9”); and thereafter, the International Classification of Diseases, Tenth Revision, Clinical Modification (“ICD-10”).

39. Finally, the HCC model is prospective, meaning that it relies on risk-adjusting diagnosis codes from dates of service by a provider in one year (the “DOS year” or “date of service year”) to determine payments in the following year (the “payment year”). In other words, CMS calculates the risk score for each Medicare beneficiary enrolled in Part C anew for each payment year based on the ICD codes from medical encounters that occurred in the immediately preceding year. As illustrated by the hypothetical example in paragraph 35 above, the higher a Part C beneficiary’s risk score, the higher the payments by CMS to the MAO operating that beneficiary’s Part C plan.

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

40. In most cases, the ICD diagnosis codes reported to CMS for risk adjustment purposes originate from healthcare providers who treat Part C beneficiaries. In this scenario, the risk adjustment data is typically generated and reported in five steps.

41. First, based on a face-to-face encounter between a healthcare provider and a Part C beneficiary, the provider (the physician or a nurse) would document the encounter in the beneficiary’s medical records, including the characteristics of the beneficiary’s illnesses or medical conditions. Next, the provider – or, often, a coder working for the provider – would assign the diagnosis codes reflecting the beneficiary’s illnesses or medical conditions in the

provider's records for the beneficiary. Third, MAOs like Anthem would receive diagnosis codes from the provider. Healthcare providers can transmit diagnosis codes to an MAO when they submit claims for payment from the MAO for treating the beneficiary, in encounter records reporting the services rendered, or by alternative means (for purposes of this Complaint, diagnosis codes reported by providers to MAOs like Anthem are referred to as "provider-reported codes"). Fourth, the MAO would in turn submit those diagnosis codes to CMS using the risk adjustment data reporting systems provided by CMS. Finally, CMS maps each beneficiary's diagnosis codes to HCCs and then calculates each beneficiary's risk score to apply to the payment calculation.

42. During the years relevant to this action, CMS utilized two electronic systems for collecting risk adjustment diagnosis data — the Risk Adjustment Processing System ("RAPS") and the Encounter Data Processing System ("EDPS"). Up to 2014, CMS calculated risk adjustment payments based solely on the RAPS-submitted diagnosis data. Starting in 2015, CMS has calculated risk adjustment payments using a combination of RAPS and EDPS-submitted diagnosis data. The RAPS data submissions (and, after 2015, the EDPS data submissions) were claims for payment from CMS because the reported diagnosis codes factored directly into CMS's risk adjustment calculations.

43. More specifically, the data that MAOs submit through the RAPS system have several components. For example, the component known as AAA identifies the submitter, while the component known as BBB identifies the MAO. As relevant here, the CCC component contains the Medicare identification number for a particular beneficiary as well as up to ten diagnostic clusters for that beneficiary. Each cluster, in turn, contains the date on which the medical treatment occurred, the type of provider, a diagnosis code from the medical encounter,

and a “Delete Indicator.”⁸ Because each diagnostic cluster includes a distinct diagnosis that can increase a beneficiary’s risk score, each cluster is, for purposes of the FCA, a separate claim for payment.⁹

44. During the relevant period, CMS calculated the risk adjustment payments to be made to MAOs in three phases. First, CMS made an initial calculation based on the diagnosis data reported by MAOs for the 12-month period ending in the June before a given payment year (*e.g.*, diagnosis data from July 2011 through June 2012 for payment year 2013). *See* 42 C.F.R. § 422.310(g) (requiring MAOs to submit such diagnosis data by September). This initial calculation determined the interim monthly payments that CMS made to MAOs in the first six months of the payment year. Next, CMS recalculated the risk scores for beneficiaries enrolled in an MAO’s plans based on diagnosis data for medical encounters during the year immediately preceding the payment year (*e.g.*, diagnosis data from January and December 2012 for payment 2013). Based on that recalculation, CMS would make retroactive adjustments to payments made in the first half of the payment year and also update the interim payments for the second half of the payment year. Finally, after the payment year ended, CMS provided a further opportunity for MAOs like Anthem to submit or correct the diagnosis data. Based on the additional submissions or corrections, CMS recalculated the risk scores again “to determine if adjustments to payments are necessary.” 42 C.F.R. § 422.310(g)(2). If such adjustments were necessary, CMS would make the adjustments as part of the annual reconciliation process to ensure that the final payments

⁸ As discussed more fully below, this indicator allows MAOs to correct or withdraw a false cluster by advising CMS to delete the inaccurate diagnosis code in that cluster.

⁹ In the EDPS system, MAOs similarly submit data with a number of components, known as “loops.” ICD diagnosis codes are among the data that MAOs are required to submit to CMS using EDPS. Further, like the RAPS system, the EDPS system has mechanisms designed for MAOs to notify CMS to delete certain diagnosis codes so that CMS would not use those codes for purposes of calculating risk-adjustment payments.

to the MAOs were accurate. This might involve CMS making an additional payment to an MAO if the MAO submitted additional diagnosis data by the final submission deadline or involve CMS seeking a recoupment from the MAO if the MAO deleted inaccurate diagnosis codes.

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

45. Because the accuracy and integrity of CMS’s calculation of Part C risk adjustment payments depend on the accuracy of the diagnosis codes MAOs submit to CMS, CMS promulgated regulations regarding the coding and medical record documentation standards for risk adjustment diagnosis data. More specifically, as noted above, CMS required MAOs to “submit [diagnosis] data that conform to” the ICD coding guidelines. *See* 42 C.F.R. § 422.310(d)(1) (requiring MAOs to submit data in conformity with “all relevant national standards,” which, pursuant to 42 C.F.R. § 162.1002(c), included the ICD coding guidelines); *accord* Medicare Managed Care Manual (“MMC Manual”), Chap. 7, Ex. 30 (Aug. 2004) (instructing MAOs to follow the ICD coding guidelines in submitting diagnosis codes); *see also infra* ¶ 64.

46. As relevant here, the ICD coding guidelines consistently provided that “accurate coding cannot be achieved” in the absence of “complete documentation in the medical record.” *See, e.g.*, ICD-10-CM Official Guidelines for Coding and Reporting FY 2014 (the “2014 ICD-10 Coding Guidelines”) at 1. This coding standard is widely understood by MAOs like Anthem, and they commonly refer to it as the risk adjustment “medical record documentation” requirement. Under this standard, a diagnosis code can be considered accurate and valid for risk adjustment purposes if it is documented in and supported by medical records for a particular encounter between a patient and a healthcare provider. *See* 2014 ICD-10 Coding Guidelines at 112 (“For accurate reporting of ICD-10[] diagnosis codes, the documentation should describe the patient’s condition, using terminology which includes specific diagnoses, as well as symptoms,

problems, or reasons for the encounter”).

47. In addition, the ICD coding guidelines also specified that a diagnosis code should not be applied if a condition is documented in the medical records as only “probable,” “suspected,” “questionable,” one that the provider is trying to “rule out,” or characterized by “other similar terms indicating uncertainty.” *See id.* at 113.

48. CMS has repeatedly provided training and instructions to MAOs on how to implement the medical record documentation requirement under the ICD coding guidelines. For example, CMS issued public guidance to emphasize to MAOs that they were responsible for submitting “risk adjustment data that are substantiated by the physician or provider’s full medical record,” *see* MMC Manual Chap. 7, § 111.8 (Aug. 2004), and to ensure that “[a]ll diagnosis codes submitted [are] documented in the medical record,” *see* MMC Manual Chap. 7, § 40 (June 2013). Likewise, provisions in the MMC Manual advised MAOs that they should not submit diagnosis codes for risk adjustment purposes if the condition at issue was only probable or suspected, or questionable. *See* MMC Manual Chap. 7, Ex. 30 (Aug. 2004).

49. In addition, CMS offered trainings to MAOs on how to implement this regulatory requirement starting as early as 2003. *See* 2003 Regional Risk Adjustment Training for MAOs Participant Guide § 4.1 (MAOs “must submit risk adjustment data that are substantiated by the patient’s medical record). To emphasize the importance of this requirement, and to ensure that MAOs understood it, CMS continued to provide training on this regulatory requirement in 2004, 2005, 2006, 2007, 2008, 2012, 2013, and 2014. *See* 2004 Regional Risk Adjustment Training for MAOs Participant Guide, §§ 5.1, 5.5, 6.1.3; 2005 Risk Adjustment Data Basic Training Participant Guide §§ 4.1, 5, 5.1, 5.5, 8.7.3, 9.1, 9.2; 2006 Risk Adjustment Data Basic Training for MAOs Participant Guide §§ 5.1, 5.4, 5.5, 7.7.3, 8.1, 8.2; 2007 Risk Adjustment Data Training for MAOs Participant Guide §§ 6.1, 6.4, 7.1, 7.2, 8.7.3; 2008 Risk Adjustment

Technical Assistance Participant Guide §§ 5.6, 6, 6.1, 6.4, 6.5, 7.1, 7.2; 2012 Regional Technical Assistance Participant Guide § 2.2; Risk Adjustment 101 Participant Guide §§ 3.2.4; 4.3 (2013); Risk Adjustment Webinar at p. 48 (July 1, 2014).¹⁰

50. Further, as MAOs do not directly provide medical care to Part C beneficiaries directly, CMS trained them to “take steps to ensure that they have, or have access to, the proper medical documentation to support diagnoses being submitted for risk adjustment.” *See* 2005 Risk Adjustment Data Basic Training for MAOs § 8.7.3. More specifically, CMS explained that MAOs “are responsible for the accuracy of the data they submit to CMS” and “[w]here necessary, should obtain the proper documentation to support diagnoses and maintain an efficient system for tracking diagnoses back to medical records.” *Id.* CMS reiterated those instructions to MAOs regarding their responsibility for ensuring proper medical record documentation during trainings conducted in 2005, 2006, 2007, 2008, and 2012.

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

51. CMS recognized that MAOs may subsequently obtain information showing that diagnosis codes that the MAOs previously submitted were not valid for risk adjustment purposes, such as because such codes are not supported by medical record documentation. The duties imposed by the risk adjustment regulations, including the duty to exercise due diligence and good faith in ensuring data accuracy, 42 C.F.R. § 422.504(l), and the duty to detect and correct non-compliance with CMS’s program requirements, *id.* § 422.503(b)(4)(vi), required MAOs to delete unsupported diagnosis codes.

52. CMS also recognized that, unless such codes were deleted or withdrawn, the inclusion of the inaccurate diagnosis codes would cause CMS to calculate – and make – higher

¹⁰ These trainings are available at: <https://www.csscooperations.com/internet/cssc4.nsf/docsCatHome/CSSC%20Operations> (last visited July 2, 2020).

risk adjustment payments to MAOs that it would not have made but for the submission of the inaccurate data. This, in turn, would result in the MAOs violating their regulatory and contractual obligations, as well as attestations, to ensure the accuracy of their risk adjustment data submissions. *See infra* ¶¶ 58-90. Accordingly, CMS implemented a function in each of the risk adjustment data reporting systems – RAPS and EDPS – for MAOs to use to delete inaccurate diagnosis codes.

53. In addition to implementing the delete functions in RAPS and EDPS to enable MAOs to fulfill their regulatory obligation and attestations, CMS also provided instructions and training to MAOs on their responsibility to use this function to delete inaccurate diagnosis codes that they had submitted for risk adjustment purposes. For example, CMS instructed MAOs that if “upon conducting an internal review of submitted diagnosis codes,” they “determine[] that any ICD[] diagnosis codes that have been submitted do not meet risk adjustment submission requirements,” they are “responsible for deleting the submitted ICD[] diagnosis codes as soon as possible.” MMC Manual, Chap. 7 § 40 (June 2013).

54. CMS also repeatedly emphasized the obligation to delete inaccurate diagnosis codes that had been submitted during trainings for MAOs. For example, in 2003, CMS provided training to MAOs that if they “identif[y] incorrect or invalid information that has been submitted, [they] must delete that information.” Likewise, in 2005, CMS trained MAOs on their “responsibilities for deletions.” Specifically, CMS explained that the “reasons to delete” includes where any of the “data fields” in a diagnosis code cluster submitted to RAPS “are incorrect.” *See* 2005 Risk Adjustment Data Basic Training for MAOs Participant Guide §§ 4.12 to 4.16. CMS also told the MAOs that they “must delete a diagnosis [data] cluster [in RAPS] when any data in that cluster are in error.” *Id.* To ensure that MAOs understood their responsibilities for making deletions, CMS provided similar trainings for MAOs in 2006, 2007, 2008, and again in

2014. *See* 2006 Risk Adjustment Data Basic Training for MAOs Participant Guide §§ 4.12 to 4.16; 2007 Risk Adjustment Data Training Participant Guide §§ 4.12 to 4.16; 2008 Risk Adjustment Technical Assistance Participant Guide §§ 4.12 to 4.16; CMS June 2014 Risk Adjustment Webinar.¹¹

55. More specifically, and as CMS explained to MAOs like Anthem, it is important for the MAOs to timely report deletions of inaccurate diagnosis codes because deletions can directly affect the accuracy of CMS's final reconciliation calculation for each payment year. As noted above, *see supra* ¶ 44, as part of its reconciliation process, CMS may make an additional payment to an MAO based on additional diagnosis codes reported before the final submission deadline or seek a recoupment if the MAO deleted inaccurate diagnosis codes.

56. Finally, to ensure that MAOs can fulfill their obligation to delete inaccurate diagnosis code submissions, CMS also promulgated regulations and configured its risk adjustment data reporting systems to allow MAOs to submit deletions both before and after the final deadline for RAPS and EDPS data submissions. *See* 42 C.F.R. § 422.310(g)(2)(ii). In other words, while MAOs ordinarily were required to make final risk adjustment diagnosis data submissions by a specific deadline prior to receiving their final reconciliation payments for a given payment year, CMS required MAOs to delete inaccurate diagnosis codes that had been previously submitted even *after* that deadline. This, in turn, enabled CMS to recover risk adjustment payments associated with the deleted diagnoses as part of CMS's risk score rerun processes. In the Medicare Part C context, diagnosis deletions reported before the deadline are known among the MAOs as "open-period deletes," while diagnosis deletions reported after the deadline are known as "closed-period deletes."

¹¹ These trainings are available at: <https://www.cssoperations.com/internet/cssc4.nsf/docsCatHome/CSSC%20Operations> (last visited July 2, 2020).

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. CMS promulgated regulations and annual agreements to define the obligations of MAOs under Medicare Part C. As set forth below, among the most important regulatory and contractual obligations of the MAOs are those pertaining to their responsibilities for ensuring the accuracy of the risk adjustment diagnosis data that they submit to CMS and for deleting inaccurate data that they previously submitted.

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

58. Throughout the relevant period, CMS required MAOs to implement effective compliance programs and defined this requirement as a prerequisite to MAOs obtaining and retaining payments under Part C. *See* 42 U.S.C. § 422.503(a). As CMS explained as early as June 2000, one purpose of requiring MAOs to implement compliance programs is to ensure that the information they submit to CMS is accurate and truthful. *See* 65 Fed. Reg. 40170-01 at 40264 (June 29, 2000).

59. At the outset, CMS’s Part C regulations require MAOs – including Anthem – to “[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with [] program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse.” 42 C.F.R. § 422.503(b)(4)(vi).

60. CMS’s Part C regulations specify that the compliance program that MAOs like Anthem are required to implement “must, at a minimum, include [certain] core requirements,” which include, as relevant here:

- To establish and implement “an effective system for routine monitoring and identification of compliance risks,” which “should include internal monitoring and audits and, as appropriate, external audits,” to evaluate the MAO’s

“compliance with CMS requirements and the overall effectiveness of the compliance program.”

- To establish and implement “procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.”

Id. § 422.503(b)(4)(vi)(E)-(F).

61. In the event that an MAO like Anthem uncovers “evidence of misconduct related to payment,” CMS’s Part C regulations require the MAO to “conduct a timely, reasonable inquiry into that conduct” and to undertake “appropriate corrective action,” including “repayment of overpayments” in response. *Id.* § 422.503(b)(4)(vi)(G). CMS’s Part C regulations also required Anthem and other MAOs to “have procedures to voluntarily self-report potential fraud or misconduct related to [the Part C] program to CMS or its designee.” *Id.*

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. In addition to being subject to regulatory requirements, MAOs like Anthem also agreed in their Part C annual agreements to be responsible to CMS for ensuring the accuracy of their risk adjustment diagnosis data submissions.

63. As relevant here, each time Anthem executed a Part C annual agreement, it affirmatively accepted the obligation to ensure that “the risk adjustment data it submits to CMS [for Part C purposes] are accurate, complete, and truthful.” *See* Ex. 2, Art. IV.D.2; *see also* Ex. 3, Art. IV.D.2 (same). Relatedly, and in accordance with CMS regulations, *see* 42 C.F.R. § 422.510, the Part C annual agreement also specified that CMS could terminate Anthem’s participation in Medicare Part C if CMS determined that Anthem had submitted false data or

“fail[ed] to provide CMS with valid risk adjustment data.” *See* Ex. 2, Art. VIII.B.1(a).

64. By executing Part C annual agreements, Anthem and other MAOs also agreed to comply with CMS’s requirements relating to the submission of diagnosis codes.¹² Specifically, Anthem agreed to operate its MA plans “in compliance with the requirements of [] applicable Federal statutes, regulations, and policies” and to “implement a compliance plan in accordance with [42 C.F.R.] § 422.503(b)(4)(vi).” *See, e.g.*, Ex. 2, Art. II.A and Art.III.F. The Part C annual agreements further define the applicable federal policies as including, among other things, the “Medicare Managed Care Manual.” *Id.* Art. II.A

65. In other words, by executing its Part C annual agreements, Anthem affirmatively assumed the obligation not only to follow CMS regulations requiring compliance with the ICD coding guidelines, including the medical record documentation standard, but also to comply with the requirement that MAOs affirmatively assess the accuracy of their diagnosis data submissions against the ICD coding guidelines and the medical record documentation standard.

66. During the relevant period, Anthem was well aware of its contractual obligation to submit diagnosis data in accordance with CMS’s requirements. For example, in August 2010, Anthem distributed an “outreach and education” bulletin to physicians and other healthcare providers entitled “Risk Adjustment 101.”¹³ In that bulletin, Anthem explained that “CMS uses documentation from [beneficiary’s] medical record to validate that the appropriate ICD-9 code has been assigned” and that “[i]f the medical record does not support the reported ICD-9 code, CMS may adjust [] payments” to the Part C plans. *See* Ex. 4. Anthem further explained that

¹² In this regard, the Part C annual agreement further specified that “[a]s a condition of receiving a monthly payment under” the agreement, MAOs like Anthem would “request payment ... on the forms attached” to the contract, including “Attachment B,” which required the MAO to certify the “accuracy, completeness, and truthfulness” of the risk adjustment data submitted to CMS. *See* Ex. 2, Article IV.C.

¹³ A copy of this bulletin is attached here as Exhibit 4.

providers could “help [it] meet [its] reporting requirements and obligations to CMS” by “supplying Anthem with the most accurate and complete diagnosis coding[.]” *Id.*

67. Anthem also understood that relevant sections of the MMC Manual and CMS’s trainings reflected the controlling requirement for risk adjustment diagnosis coding. When it issued an internal coding manual in 2015, for example, Anthem instructed its staff that “when coding medical records on behalf of Anthem (formerly WellPoint) for Medicare Advantage Risk Adjustment purposes,” they should “refer to” the “Official ICD ... Coding Guidelines,” “CMS 2008 Risk Adjustment Participant Guide,” CMS’s 2013 “Risk Adjustment 101 Participant Guide,” “Chapter 7 [of] the Medicare Managed Care Manual,” and one other training as the sources of “official coding rules and regulations.” *See Medicare Advantage Risk Adjustment Programs (the “2015 Anthem Coding Manual”)* at 4 (relevant excerpts from this internal Anthem manual are attached here as Exhibit 5).

68. More specifically, Anthem knew that the ICD coding guidelines required particular types of evidence in the medical records to support specific medical conditions like diabetes with complications or active forms of cancer. For example, because providers “may document cancer in historical terms,” proper coding requires a determination of “whether the malignancy should be coded [as] history, using a V-code, or [as] current.” *See 2015 Anthem Coding Manual (Ex. 5)* at 18. To “code current malignancy,” therefore, required medical record documentation that “show clear presence of current disease.” *Id.*

69. Similarly, the 2015 Anthem Coding Manual also specified that “in order to select a code from HCC categories 15-18,” which represent diabetes with various types of complications, there “must be a documented cause-and-effect relationship between diabetes and the associated manifestation.” *Id.* at 21. Accordingly, if the medical record “documentation

does not properly link the two conditions,” a coder must “default to diabetes without complication code 250.0x (HCC 19).” *Id.*

70. In addition, by executing the Part C annual agreements, Anthem agreed to abide by CMS’s requirement for MAOs to delete inaccurate diagnosis codes that they previously submitted. *See* Ex. 3, Art. II.A. As discussed above, *see supra* ¶¶ 51-56, CMS issued public guidance to Anthem and other MAOs that, as part of their regulatory obligation to ensure the accuracy of risk adjustment data, they were “responsible for deleting the submitted ICD[] codes as soon as possible” whenever they “determine[] that any IC[] diagnosis codes that have been submitted do not meet risk adjustment submission requirements.” *See* MMC Manual, Chap. 7 § 40 (June 2013).

71. Anthem, in turn, understood both how to use the delete function in the RAPS and EDPS reporting systems and when it was appropriate for Anthem to delete diagnosis codes.

72. In the first regard, Anthem implemented procedures that allowed it to implement deletions of previously-submitted RAPS and EDPS diagnosis data submissions and to track the status of such deletion efforts. For example, as described in a report from Anthem’s Internal Audit department, the “management” of the Medicare R&R group at Anthem “created delete files for submission [to CMS]” when they decided to make certain deletes in response to an audit by CMS in 2013.

73. In the second regard, and as Anthem’s chief compliance officer acknowledged, Anthem understood that it would “be appropriate to submit deletes” of diagnosis codes previously submitted to CMS “if Anthem became aware that one of the codes ... was not supported by the medical record.”

74. More specifically, based on trainings from CMS as well as its own experience as a major health insurance company, Anthem was well aware of several circumstances that could

lead to the presence, in the claims that Anthem received from providers, of inaccurate diagnosis codes that were unsubstantiated by medical record documentation.

75. For example, Anthem knew that many of the diagnosis codes in the claims data it received from providers were likely to be inaccurate due to the high frequency of provider coding errors. In a November 2012 e-mail, for example, a compliance manager in Anthem's Medicare R&R group explained to a senior Anthem executive that "we also know that physicians do not always code accurately" and that "the assignment of improper dx [diagnosis] codes" was one of the "[c]ommon errors."

76. Further, Anthem's own coding policies and procedures identified a number of specific medical conditions as ones that were generally known to be subject to frequent inaccurate coding. In an internal policy from 2014, for example, Anthem referred to several conditions and HCCs – including, for example, "Cancer (HCC 7/8, 8/9, 9/10, 10/11, 11/12)" and "DM [diabetes mellitus] with Complication" – as "Red Flag HCCs." According to Anthem, this classification was applied because those "are conditions targeted by CMS or that have a high probability of coding error."

77. In addition, Anthem also had so-called "capitated reimbursement" relationships with certain healthcare providers during the relevant period. Under these arrangements, which also are known as "revenue-sharing" or "profit-sharing" relationships, Anthem shared a percentage of its Medicare Part C risk adjustment payments with the contracted providers. To illustrate, if Anthem had a capitated relationship with a physicians' group with a 50-50 revenue split, and Anthem received \$100,000 in risk adjustment payments from CMS based on the diagnosis codes submitted by the physicians group, Anthem would then pay \$50,000 to that physicians group pursuant to their arrangement.

78. Anthem understood that its “capitated” or “profit-sharing” relationships with providers created a strong financial incentive for those providers to over-report diagnosis codes both in terms of the number and the severity of reported medical conditions for Part C beneficiaries. Thus, Anthem’s internal risk assessments during the relevant period – such as the “2015 Risk Chart” for its Medicare R&R group – identified the “capitated” provider relationships as a “key” reason for classifying the risk of Anthem’s “submitting diagnosis data for risk adjustment that is not accurate and/or supported in the medical record” as “High.”

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. As a condition for using the RAPS and EDPS systems to submit risk adjustment diagnosis data to CMS for risk adjustment payments, MAOs must execute Electronic Data Interchange (“EDI”) agreements with CMS.

80. In these agreements, Anthem and other MAOs expressly agree to assume a number of specific obligations relating to their risk adjustment data submissions, including the obligation to “research and correct risk adjustment data discrepancies.” *See* EDI Enrollment Form stamped May 23, 2004 (“A. The Eligible Organization Agrees: ... 11. That it will research and correct risk adjustment data discrepancies.”) (attached as Exhibit 6).

81. During the relevant period, executives at Anthem executed multiple EDI agreements in which Anthem expressly agreed to “research and correct risk adjustment data discrepancies.” *See* EDI agreement dated October 11, 2013; EDI agreement dated December 2, 2015 (attached as Exhibits 7 and 8).

82. Further, according to its chief compliance officer, Anthem understood that the types of “data discrepancies” that it was responsible for researching and correcting pursuant to its EDI agreements included situations where medical record review indicated Anthem had submitted a diagnosis code that inaccurately depicted a beneficiary’s medical condition, such as

a mis-transcription resulting in switched digits in an ICD code (*e.g.*, 250 vs. 205).

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. Medicare Part C regulations require MAOs like Anthem to submit annual attestations to CMS for each of their Part C plans that, among other things, certify the accuracy of the risk adjustment diagnosis data they submitted for the relevant payment year. *See* 42 C.F.R. § 422.504(l). The Part C regulations further specify that the MAO’s submission of their annual attestations is “a condition for receiving the monthly [capitated] payment” from CMS. *Id.*

84. In addition to being a regulatory requirement, the MAOs’ obligation to submit annual attestations regarding the accuracy and truthfulness of their risk adjustment diagnosis data is also specified in the Part C annual agreements that they execute with CMS. *See, e.g.*, Ex. 3, Art. IV.D.2

85. Here, Anthem understood that its receipt of risk adjustment payments from CMS was conditioned on its submission of the annual attestations to CMS in compliance with the Part C regulations and the annual agreement provisions.

86. In 2015, for example, the director of regulatory compliance for Anthem’s Medicare R&R group approved a policy to “document the process related to the submission of the annual Risk Adjustment Attestation as required by [CMS].” The policy explained that “CMS requires that each MAO attest to the validity and accuracy of [its] Risk Adjustment Data for the previous Payment Year.” This Anthem policy also recognized that submission of the attestation is a prerequisite “[i]n order for [Anthem’s] Risk Adjustment data to be included in CMS’s run of the Risk Adjustment Model,” which determines the final payment to Anthem.

87. During the relevant period, senior Anthem executives – including the then-president of Anthem’s Medicare business – signed and submitted annual attestations to CMS

each year for the Part C plans operated by Anthem. Anthem submitted those annual attestations after the final submission deadline for reporting diagnosis data for each payment year.

88. In each of these annual attestations, the executives certified that Anthem understood that the risk adjustment information it submitted to CMS “directly affects the calculation of CMS payments to [Anthem]” and that “misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.” *See* Attestation of Risk Adjustment Data dated June 26, 2015 (attached hereto as Exhibit 9). Having “acknowledge[d]” that understanding, the Anthem executives further certified that “all information submitted to CMS” by Anthem for risk adjustment payment purposes “is accurate, complete, and truthful” according to Anthem’s “best knowledge, information, and belief.” *Id.*

89. As CMS repeatedly notified MAOs since June 2000, the purpose of the annual attestation requirement is to place the responsibility on MAOs like Anthem to make “good faith efforts to certify the accuracy” of the risk adjustment data they submitted. *See* 65 Fed. Reg. 40,170, 50,268 (June 29, 2000); *see also* MMC Manual Chap. 7, § 111.7 (2004) (“CMS expects [MAOs] to design and implement effective systems to monitor the accuracy, completeness, and truthfulness of risk adjustment data and to exercise due diligence in reviewing the information provided to CMS”).

90. Anthem, in turn, understood its obligation to make “good faith efforts” and “exercise due diligence” to ensure the accuracy of its risk adjustment diagnosis data submissions to CMS. In July 2010, for example, Anthem distributed a “provider announcement” to hospitals and physicians acknowledging that “CMS requires that we [Anthem] perform oversight activities related to the collection and reporting of [beneficiary] diagnosis data which must be supported by medical record documentation.”

**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. Since the early 2000s, CMS has conducted audits of diagnosis codes submitted by MAOs, known as Risk Adjustment Data Validation (“RADV”) audits.

92. In 2001, CMS alerted MAOs that they were “required to submit medical records for validating encounter data” and that “[m]edical record reviews of a sample of hospital encounters may be audited to ensure the accuracy of diagnostic information.” *See* MMC Manual, Chapter 7, § 110.3 (October 2001). In 2004, CMS updated its public guidance to MAOs by explaining that “[a] sample of risk adjustment data used for making payments may be validated against hospital inpatient, hospital outpatient, and physician medical records to ensure the accuracy of medical information. Risk adjustment data will be validated to the extent that the diagnostic information justifies appropriate payment under the risk adjustment model.” *See* MMC Manual, Chapter 7, § 111.8 (August 13, 2004).

93. To facilitate its audit of risk adjustment diagnosis data, CMS promulgated a regulation to require MAOs as well as healthcare providers who render care to Part C beneficiaries to supply the underlying medical records to CMS for use in RADV audits of risk adjustment diagnosis code submissions. *See* 42 C.F.R. § 422.310(e).

94. For each audit, CMS selected a *sample* of enrollees in an MAO’s Part C plans and reviewed the medical records for those enrollees to determine if the diagnosis codes submitted by the MAOs were supported by those records.

95. For the payment year 2007 audits, CMS calculated the amounts by which the Part C MA plans were overpaid as result of the inaccuracies and sought refunds from the plans. *See, e.g.,* Medicare Advantage RADV Audits Fact Sheet at 1 (“CMS recouped \$13.7 million in overpayments associated with sampled beneficiaries” as result of its RADV audits of Part C MA

plans for payment year 2007).¹⁴

96. As relevant here, CMS has conducted RADV audits of Part C MA plans operated by Anthem. For payment year 2007, RADV audits of four such MA plans resulted in Anthem refunding CMS more than \$800,000 in overpayments. *See id.* at 2 (refunds associated with plans H0540, H0564, H1849, and H3655).¹⁵

97. In addition to allowing CMS to recoup overpayments, the RADV audits also highlighted for Anthem and other MAOs that a material percentage of the diagnosis codes they submitted to CMS were inaccurate. For example, as an internal Anthem report shows, CMS's payment year 2012 RADV audits showed Anthem that its risk adjustment diagnosis code submissions to CMS had an error rate of 9.6%, which was higher than the national error rate.

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

98. Because the accuracy of risk adjustment diagnosis data submissions directly impacts the integrity of the risk adjustment payment system, the Government also has sought to enforce the requirement for data accuracy by actively pursuing legal remedies against both MAOs that have knowingly submitted inaccurate and untruthful diagnosis data to CMS and healthcare providers that knowingly caused MAOs to submit inaccurate and untruthful diagnosis data to CMS.

99. In August 2012, for example, the Government obtained \$3.82 million in settlement from SCAN Health Plan, a Long Beach, California-based managed care company, based on allegations that SCAN had used outside vendors to review medical charts of SCAN's

¹⁴ This fact sheet is available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Fact-Sheet-2013.pdf> (last visited July 2, 2020).

¹⁵ As noted above, CMS selected a *sample* of diagnosis codes for each RADV audit. RADV audits did not, and are not intended to, review all or significant percentage of the diagnosis codes submitted by MAOs to CMS.

Part C beneficiaries to identify new diagnosis codes for SCAN to submit to CMS, but had failed to disclose to CMS that chart review results also indicated that some of the previously-submitted diagnosis codes might need to be deleted, which enabled SCAN to improperly obtain higher risk adjustment payments from CMS.

100. Further, in May 2017, the Government obtained a \$32.5 million settlement from Freedom Health, Inc., a Tampa-based MAO, in connection with a *qui tam* action involving allegations that Freedom Health had submitted unsupported diagnosis codes to CMS on behalf of two Part C plans and thereby obtained inflated risk adjustment payments. In addition to paying the Government to settle these allegations, Freedom Health also agreed to be subject to a Corporate Integrity Agreement that included procedures for “determin[ing] whether Freedom properly submitted risk adjustment eligible diagnoses to CMS in accordance with CMS’s rules and criteria under the Medicare Advantage Program.” *See* Corporate Integrity Agreement, App. C at 1 (available at <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>).

101. In addition, in October 2018, the Government obtained a \$270 million settlement from DaVita Medical Holdings LLC, a healthcare provider. This settlement was based in part on allegations that DaVita had given improper coding guidance to its employees so that they would record inaccurate diagnosis codes to MAOs in order to boost its payments under revenue-sharing or capitated arrangements with MAOs and that DaVita had hired coding companies to perform retrospective chart reviews to identify new diagnosis codes to report to MAOs for submission to CMS, but did not take corrective action with respect to previously submitted codes that could not be substantiated by chart review. More specifically, DaVita’s alleged misconduct caused CMS to overpay the MAOs based on inaccurate diagnosis codes from DaVita and, in turn, enabled DaVita to receive higher cost-sharing payments from the MAOs.

102. Likewise, in August 2019, the Government obtained a settlement against Beaver Medical Group, L.P., a California-based physician group, based on allegations that, to increase its payments from MAOs pursuant to revenue-sharing arrangements, Beaver had knowingly submitted diagnoses that were not supported by the medical records, and thereby caused CMS to calculate risk adjustment payments based on inaccurate diagnosis data.

103. As relevant here, Anthem was well aware of the Government's active efforts to pursue legal remedies in order to enforce Medicare Part C's risk adjustment data accuracy requirement. The Medicare R&R group and the compliance staff at Anthem routinely monitored the status of the Government's enforcement activities relating to risk adjustment data accuracy.

104. In September 2012, for example, executives in Anthem's Medicare compliance group exchanged e-mails concerning the impact of the SCAN Health settlement on Anthem's Medicare "risk adjustment reporting methodology." Specifically, an Anthem compliance manager forwarded a report about this settlement and highlighted a passage suggesting that the SCAN Health settlement showed "there will be greater scrutiny in connection with how retrospective reviews are performed and ... greater scrutiny for how risk adjustment payments are calculated."

105. Similarly, in February 2015, a manager in Anthem's Medicare R&R group emailed a conference presentation on "Government managed care oversight and enforcement focus areas" to the director of Anthem's Medicare compliance group. According to the Medicare R&R manager, she was sharing the presentation because it contained "informative materials." The presentation, in turn, identified "risk scores" as an area of "Government MC Oversight Focus" based on "DOJ/OIG False Claims Act cases," and cited the "SCAN Health Plan" settlement as an example of the Government's enforcement focus in the "Medicare" context.

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 relied on the diagnosis codes contained in the insurance claims submitted by healthcare providers who treated Anthem’s Part C beneficiaries as the primary source of the diagnosis data it submitted to CMS for risk adjustment purposes.

107. During the relevant period, the Medicare R&R group at Anthem referred to the provider-reported diagnosis codes as the “internal source data.” Within Anthem, the data team in the Medicare R&R group was responsible for collecting these diagnosis codes after they had been uploaded electronically to a shared site by the three geographic business divisions at Anthem — East, Central and West.

108. Once the data team in Anthem’s Medicare R&R group received the diagnosis code uploads from the business divisions, it would run computer algorithms to compare the newly-uploaded data against diagnosis data that Anthem previously submitted to CMS, to look for duplicative entries. If the computer algorithms found exact duplicates, the data team would remove those entries. The data team also was responsible for configuring the diagnosis data submissions in formats that would be accepted by the RAPS and, starting in 2012, the EDPS systems.

109. After those steps, the data team in Anthem’s Medicare R&R group submitted electronic data files, which contained the provider-reported diagnosis codes, to CMS using the RAPS and, starting in 2012, the EDPS systems.

110. During the relevant period, and as discussed above, Anthem not only understood that providers “do not always code accurately” as a general matter, but also had specific notice that its own diagnosis code submissions contained a significant percentage of inaccuracies. *See*

supra ¶¶ 74–78. Yet, Anthem did not implement any regular procedure or process during the relevant period to audit, review, or monitor whether the diagnosis codes it was submitting to CMS were in fact supported by the underlying medical records. More specifically, Anthem did not check the accuracy of its diagnosis code submissions before sending them to CMS, and Anthem did not have any regular procedure for checking those codes after they were submitted.

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. From 2007 to 2010, Anthem had operated a limited chart review program. In 2010, Anthem decided to significantly expand its chart review program. To that end, Anthem retained a vendor called Medi-Connect and tasked it with contacting healthcare providers to obtain the medical records to review as well as reviewing and coding these records.

112. To induce healthcare providers to supply records for chart review, executives at Anthem’s Medicare R&R group created “FAQs” (frequently asked questions), “talking points,” and “provider announcement” flyers in late June 2010. In these communications, Anthem informed providers that its chart review program was “an oversight activity” and that a key purpose of this program was to verify the accuracy of the “ICD9 codes [that] have been reported by the provider[s].”

113. For example, the FAQs told providers that Anthem’s chart review program would serve *two functions* within the Part C risk adjustment framework – one, to identify diagnosis codes that providers may have missed so that Anthem would “submit all ICD 9 codes for [its] Medicare Advantage members”; and, “in addition,” to “ensure that ICD9 codes have been reported by the provider correctly,” meaning that there was “medical record documentation support” and that “proper coding guidelines were followed.” *See* FAQ’s Regarding Retrospective Medical Record Review and Medi-Connect Global at 1 (attached as Exhibit 10).

114. To underscore Anthem's representation that its chart review program would involve verifying the *accuracy* of provider-reported ICD9 codes, the FAQs also characterized the chart review program as "an oversight activity related to" whether "the collection and reporting of [Part C beneficiaries'] diagnosis data" were "supported by medical record documentation as required by CMS." *Id.*

115. Anthem's FAQs further asserted that providers were "required to comply with [Medi-Connect's] request for medical records" pursuant to CMS's policies. *See id.* at 3. Specifically, Anthem reiterated that "the [chart] review process will help ensure that ICD9 codes have been reported *accurately.*" (emphasis added).

116. The "provider announcement" flyers that Anthem distributed to providers about its chart review program likewise touted the program as an "oversight activity" designed to improve the accuracy of diagnosis data. Specifically, the flyers represented that Anthem "engaged Medi-Connect [as a vendor] to perform retrospective review of [] medical records" to fulfill the "CMS require[ment] that [Anthem] perform oversight activities related to" whether diagnosis data reported to CMS were "supported by medical record documentation." *See* Provider Announcement dated July 1, 2010 (attached hereto as Exhibit 11). The flyers further advised providers that cooperating with Medi-Connect's "record retrieval" requests would "help[] Anthem ensure risk adjustment payment integrity and accuracy." *Id.*

117. Besides circulating flyers and FAQs to paint its chart review program as an "oversight activity" in 2010, Anthem also directed its executives to make this representation to healthcare providers who were reluctant to provide patients' medical records to Medi-Connect.

118. In 2013, for example, Anthem's Medicare R&R group became aware that Medi-Connect was not able to collect records from a major academic medical institution based in Manhattan.

119. In late November 2013, in an effort to obtain those medical records for Medi-Connect, Anthem directed a regional vice president at its New York office to schedule a meeting with that Manhattan-based academic medical institution. At that meeting, the Anthem regional vice president was instructed to tell representatives from the Manhattan-based academic medical institution that it needs to provide the records to Medi-Connect because Anthem’s chart review program was part of the “oversight activities” and “routine monitoring” that Anthem was “required to [perform]” as a “designee” of CMS.

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. Contrary to what it communicated to healthcare providers in the FAQs and flyers, Anthem did not use the results of its chart review program to verify that “ICD9 codes have been reported accurately,” *see* Ex. 10 at 3, or to “ensure risk adjustment payment integrity and accuracy,” *see* Ex. 11. Instead, Anthem treated chart review only as a “revenue enhancement program.” More specifically, Anthem used this program *solely* to find additional diagnosis codes to submit to CMS and thereby obtaining higher risk adjustment payments, and *not* – as it had told providers – to determine whether previously-submitted diagnosis codes had been reported accurately or inaccurately.

121. For example, Anthem instructed Medi-Connect to focus its chart review and coding efforts on finding “all possible new revenue generating codes” for Anthem.

122. Once Medi-Connect obtained medical records from providers to review, its instruction from Anthem was to have its certified coders conduct an initial round of “cold coding” – meaning that the coders would review the medical records and extract ICD codes without knowing what ICD codes Anthem had previously sent to CMS – of all the records.

123. What Medi-Connect did next with the codes extracted during this initial round of coding depended entirely on whether a given code could be submitted to CMS to generate an additional risk adjustment payment for Anthem. Specifically, for the “newly identified ICD codes which are new revenue-generating,” Anthem directed Medi-Connect to have its coders conduct a second round of review of the relevant medical records.

124. The purpose of this further review, as Anthem told Medi-Connect, was to check that “the initial coders did in[]fact identify all mapped HCCs.” In other words, Anthem did not want to leave out any diagnosis code that could lead to a revenue-generating HCC for itself.

125. In addition, while Anthem allowed Medi-Connect’s coders to use “issue flags” to identify documentation mistakes in the medical records they reviewed, whether those issue flags served any function again depended wholly on whether they could benefit Anthem financially for risk adjustment purposes.

126. Specifically, when “new revenue generating” codes were at stake, Anthem told Medi-Connect to conduct a second round of review of the flagged records with the goal of finding “all possible new revenue generating codes” that met the medical record documentation standard set forth in the ICD coding guidelines.

127. By contrast, if the “issue flags” did not implicate “new revenue generating codes,” Anthem did not ask Medi-Connect to take any step to determine whether the flagged records supported or would not support the diagnosis codes that Anthem had already reported to CMS for risk adjustment purposes. As Anthem was well aware, deleting inaccurate diagnosis codes that had been submitted to CMS previously not only would generate no new revenue, but also could lead CMS to lower risk adjustment payments or even seek recoupment from Anthem.

128. Besides how it defined the scope of Medi-Connect’s responsibilities within Anthem’s chart review program, Anthem also configured its internal procedures to ensure that

chart review would be used solely for revenue generation purposes.

129. Specifically, as they received the chart review results from Medi-Connect, the data team in Anthem's Medicare R&R group would run a computer algorithm in the SAS software system to compare the diagnosis information in Medi-Connect's results against the diagnosis information that Anthem had previously submitted to CMS. This comparison enabled the data team to gather all of the newly-identified diagnosis codes that could generate additional risk adjustment payments for Anthem. Anthem then had its internal coding teams review those new diagnosis codes to ensure that they satisfied CMS's submission requirements. Finally, Anthem submitted to CMS the codes that its internal coding terms found to be consistent with CMS's requirements.

130. By contrast, Anthem did *not* have any process during the relevant period to compare the diagnosis codes that Anthem previously submitted to CMS against Medi-Connect's chart review results for the same visits by the same patients, so as to identify diagnosis codes that had previously been submitted but were not identified by Medi-Connect (and thus were likely inaccurate). Anthem did not run this comparison during the relevant period even though, as the director of the data team at Anthem's Medicare R&R group admitted under oath, Anthem's programmers were fully capable of writing an SAS database algorithm to do such a comparison.

131. As Anthem understood, taking the simple step of running this comparison would have shown which of Anthem's previously-submitted diagnosis codes could not be substantiated through the chart review process. For example, such a comparison would have revealed instances where Anthem submitted to CMS diagnosis codes in provider claims that were inaccurate due to transcription errors, including when someone had mistakenly entered ICD code 250 (diabetes) as 205 (leukemia). As Anthem's Chief Compliance Officer recognized,

identifying such errors would have fulfilled the promise that Anthem made to CMS in EDI agreements to “research and correct risk adjustment data discrepancies.”

132. Similarly, by taking the simple step of comparing its previously-submitted codes against chart review results, Anthem would have identified instances where a diagnosis of diabetes with complications was inaccurate because the underlying medical record “d[id] not properly link” the patient’s diabetes with the supposed complications, *see* Ex. 5 at 21 (Anthem’s internal coding manual instructing coders to “default to diabetes without complication code” if the medical records do not show such a link), *see also infra* ¶ 154.a (example where Medi-Connect’s results identified an inaccurate diagnosis of diabetes with complications). Such a comparison also would have identified, for example, situations where an active form of cancer diagnosis in a provider claim was inaccurate because the underlying medical records did not “show clear presence of current disease,” rather than a history of cancer, *see* Ex. 5 at 18, *see also infra* ¶ 154.b (example where Medi-Connect’s results identified an inaccurate diagnosis of active cancer).

133. As Anthem knew, identifying and deleting such inaccuracies in its diagnosis code submissions could lead CMS to calculate lower risk adjustment payments to Anthem. So it did not make an effort to do so. Instead, Anthem allowed inaccuracies to remain in its diagnosis code submissions. For example, and as Anthem understood, in the scenario where a medical assistant mistakenly typed ICD9 code 250 (diabetes) as 205 (leukemia) into a claim, and where Medi-Connect’s coders correctly identified code 250, instead of 205, as the correct diagnosis, Anthem’s practice during the relevant period was to report both 205 and 250 for the same patient, instead of checking to see which code was accurate. This practice inevitably led to inflated risk adjustment payments for Anthem because caused CMS was making its calculations based on inaccurate diagnosis data.

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

134. Anthem’s failure to comply with its contractual and regulatory obligations was not due to ignorance or mistake. As detailed below, Anthem understood the structure of the risk adjustment payment system and its responsibilities as an MAO, including, specifically, (a) the direct impact that diagnosis data has on CMS’s risk adjustment payment calculations, (b) Anthem’s obligation to ensure the accuracy of its diagnosis data submissions to CMS, (c) the presence of substantial numbers of inaccuracies in the diagnosis codes that Anthem was submitting to CMS based on provider claims, (d) Anthem’s obligation to research and correct data discrepancies, and (e) Anthem’s duty to delete previously-submitted diagnosis codes that proved to be inaccurate. *See infra* ¶¶ 136–140.

135. Rather, Anthem intentionally chose to structure chart review in contravention of the representations it made to healthcare providers and its regulatory and contractual obligations because it decided to prioritize profits over its compliance obligations. Anthem saw its chart review program not as an “oversight activity” — as it had told providers —but rather as “a cash cow” for Anthem itself. *See infra* ¶¶ 141–152.

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

136. During the relevant period, Anthem was well aware of the direct effect that diagnosis data had on the risk adjustment payments that Anthem received from CMS. For example, the 2015 Anthem Coding Manual used formulas to describe the relationship among diagnosis codes, the patient’s risk score, and the risk adjustment payment amount. Specifically, it explained that the risk score was calculated using “disease data ... in the form of diagnosis codes” as follows:

$$\text{Risk Score} = (\text{demographics}) + (\text{disease}) + (\text{disease}) + (\text{disease})$$

The manual further explained that CMS, in turn, calculated the payment to Anthem using the risk score and a base payment rate:

$$\text{Total Payment} = \text{Base Payment} \times \text{Risk Score}$$

137. Anthem also understood that, as an MAO, it had the obligation to ensure the accuracy of the diagnosis data that CMS used to calculate the risk adjustment payments. For example, Anthem unequivocally acknowledged that it had the obligation to “perform oversight activities” and to “ensure risk adjustment payment integrity and accuracy” in the FAQs and flyers it created in 2010 to encourage providers to supply medical records to Medi-Connect. *See* Ex. 10 at 3, Ex. 11; *see generally supra* ¶¶ 111–119.

138. Further, Anthem was aware of the high frequency of provider coding errors. In 2012, for example, one of Anthem’s Medicare compliance managers observed that “we all know that physicians do not always code accurately” and that “improper [diagnosis] codes” are one of the “[c]ommon errors.” *See supra* ¶ 75. During the relevant time, RADV audit results also gave Anthem specific notice that a significant percentage of its diagnosis code submissions to CMS were inaccurate. Anthem’s self-assessment, moreover, concluded that the “risk level” for its “submitting diagnosis data for risk adjustment that is not accurate and/or supported in the medical record” was “high” in 2015.

139. In addition, Anthem recognized that, in accordance with the EDI agreements it executed, it had an obligation to “research and correct” any “discrepancies” in its “risk adjustment data” submissions. *See* Exs. 6, 7, 8. Specifically, as Anthem’s chief compliance officer acknowledged, the types of “data discrepancies” that Anthem would be responsible for researching and correcting pursuant to its EDI agreements with CMS would include situations where medical record review suggests that a diagnosis code previously submitted to CMS was incorrect, for example due to a mis-transcription.

140. Finally, Anthem knew that it was obligated to delete inaccurate diagnosis codes. As an MAO, Anthem was familiar with the CMS trainings on this requirement. Further, as its chief compliance officer admitted, it was understood at Anthem that one of the situations where it would “be appropriate to submit deletes” was “if Anthem became aware that one of the codes had been submitted [to CMS] was not supported by the medical record.” Indeed, during the relevant period, Anthem routinely submitted deletes for the diagnosis codes that RADV audits had determined to be inaccurate.

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. Although Anthem told providers in 2010 to supply medical records to Medi-Connect for chart review because it would be an “oversight activity” that verified the accuracy of diagnosis codes already submitted to CMS, *see* Ex. 10 at 3, internal records show that Anthem treated chart review solely as a means to obtain more risk adjustment payments from CMS.

142. For example, both before and during the relevant period, Anthem classified chart review as one of its “revenue enhancement programs.” Further, according to a 2013 internal audit report, Anthem stated the purpose of its chart review program as “to collect additional data to submit to CMS.”

143. Consistent with that goal, Anthem assessed its chart review program not on the basis of whether it enabled Anthem to improve the accuracy of its diagnosis code reporting, but instead based on how effectively it generated revenue for Anthem. Specifically, analysts in Anthem’s Medicare R&R group were tasked with constantly looking for ways to increase the return on investment (“ROI”) rate for chart review, which was calculated by dividing the amount of additional revenue generated by chart review by the cost of operating the program.

144. For example, in 2015 and 2016, Anthem had its analysts engage in a “predictive model analysis” to “predict[] which retrospective chart chases will be valuable” to Anthem. As

one of the analysts explained in an e-mail to the data team, having such a model would give Anthem a “methodology” to “improve the retrospective [chart review] ROI with little or no impact on total revenue.”

145. Anthem also closely tracked the ROI for its chart review program. According to an actuarial director in Anthem’s finance department, calculating the ROI for chart review required several of Anthem’s finance staff working together using data and algorithms in several computer programs. As result of those efforts, Anthem found that in 2015, for example, its chart review program generated over \$112 million in additional revenue while costing Anthem just under \$19 million in expenses, yielding an ROI of 6.00. *See* 2015 ROI Analysis (attached here as Exhibit 12).

146. The fact that chart review was generating five, six, or seven million dollars in revenue in return for each million dollars of expenditures was not lost on Anthem’s senior executives. For example, when there was discussion within Anthem in early 2016 about changing the chart review program, the head of the Medicare R&R group promptly raised a concern about making such changes. According to that executive, she told two of her peers in March 2016 that she was “not inclined to change” chart review in any way because “[chart review] is a cash cow” for Anthem by virtue of its having “a high ROI.”

147. A key reason that chart review was “a cash cow” was because of Anthem’s one-sided use of chart review results — only looking for additional diagnosis codes to submit and not, as Anthem had told providers and promised CMS, also to identify inaccurate codes that needed to be deleted. Anthem’s internal discussions underscore the magnitude of the financial impact that Anthem anticipated if it made the switch to using chart review to look for both additions and deletions.

148. In 2017, for example, finance executives at Anthem had a series of discussions

about this topic. According to one of Anthem's finance vice presidents at that time, he made an estimate in October 2017 that making a switch from one-sided chart review to two-way chart review could reduce the value of chart review for Anthem by 72%, which translated to an \$86 million reduction to Anthem's "chart revenue" forecast for 2017.

149. Further, the 72% estimate was not an outlier within Anthem. Specifically, earlier in 2017, another finance vice president at Anthem had suggested in discussions that making the switch from one-sided chart review to two-way chart review would reduce Anthem's revenue from its chart review program by about two thirds.

150. Anthem's strong focus on the profitability of the chart review program came at the direct expense of its compliance with its obligations as a Medicare MAO. For example, according to Anthem's 2015 internal compliance plans, the head of the Medicare R&R group was primarily responsible for mitigating the compliance risks for submitting inaccurate risk adjustment diagnosis data. Yet, Anthem never notified this executive that she had been assigned such a role. Thus, that executive believed that it "would be unreasonable" to have expected her to be responsible for ensuring that Anthem did not submit inaccurate risk adjustment diagnosis data to CMS.

151. Further, even though this executive – the head of Anthem's Medicare R&R group since 2015 – was a member of Anthem's Medicare Compliance committee, she not only never received training on Anthem's obligation to research and correct discrepancies in risk adjustment data under its Part C EDI agreement with CMS, but also had never seen a copy of an EDI agreement until August 2019.

152. Nor was the lack of attention to compliance at Anthem limited to its Medicare R&R group. The president of Anthem's Medicare business from 2013 to 2019, who also served on Anthem's Medicare Compliance committee, was likewise unfamiliar with Anthem's EDI

agreements with CMS. In addition, even though he personally signed dozens of Anthem's Part C annual attestations to CMS, this executive was not aware of any training from CMS regarding when MAOs like Anthem had the obligation to delete inaccurate diagnosis codes.

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. As set forth above, Anthem understood its obligation to submit accurate diagnosis data to CMS and to delete inaccurate diagnosis code submissions that could not be validated by the medical records. Anthem also was aware of significant rates of errors in the diagnosis codes it was submitting to CMS based on the provider claims. Further, Anthem knew that the chart review results from Medi-Connect could help it verify the accuracy of the previously-submitted diagnosis data. Finally, Anthem understood that it both had the ability and the obligation to compare the chart review results from Medi-Connect against the diagnosis codes it previously submitted to find and delete the codes that could not be validated based on the medical records.

154. Anthem, however, chose to prioritize profitability over compliance. *See supra* ¶¶ 141-152. As result of that choice, until 2018, when it finally began to use chart review results to identify both codes to delete and additional codes to submit, Anthem knowingly caused CMS to calculate the risk adjustment payments it made to Anthem on the basis of thousands, and likely tens of thousands, of inaccurate diagnosis codes. Examples of those instances include:

- a. Patient A: In connection with a visit to a provider by this beneficiary on May 13, 2014, Anthem submitted an ICD-9 diagnosis code for diabetes with ophthalmic manifestations for this beneficiary – which mapped to HCC 18 – for payment year 2015. Anthem's chart review program did not substantiate the diabetes with ophthalmic manifestations diagnosis, but instead determined that the patient had diabetes without complications, which mapped to HCC 19, instead of 18. Further, no other provider reported the diabetes with ophthalmic manifestations diagnosis (or any other diagnosis that mapped to

HCC 18) during 2014.

Anthem did not submit a delete for the diagnosis code for diabetes with ophthalmic manifestations, replace that diagnosis code with one for diabetes without complications, or otherwise notify CMS not to rely on that code for risk adjustment purposes. In the meantime, Anthem relied on chart review results to submit four additional ICD-9 codes to CMS for Patient A's visit on May 13, 2014. Due to this course of conduct, CMS used HCC 18, instead of HCC 19, to calculate Anthem's risk adjustment payment for Patient A in payment year 2015, resulting in an overpayment of \$1,680.32 to Anthem.

- b. Patient B: In connection with a visit to a provider by this beneficiary on June 23, 2014, Anthem submitted an ICD-9 diagnosis code for active lung cancer (*i.e.*, malignant neoplasm of the bronchus or lung) for this beneficiary – which mapped to HCC 8 – for payment year 2015. Anthem's chart review program did not substantiate the active lung cancer diagnosis. Further, no other provider reported such a diagnosis (or any other diagnosis that mapped to the same HCC) during 2014.

Anthem did not submit a delete for the diagnosis code for active lung cancer or otherwise notify CMS not to rely on that code for risk adjustment purposes. In the meantime, Anthem relied on chart review results to submit three additional ICD-9 codes to CMS for Patient B's visit on June 23, 2014. Due to this course of conduct, CMS used HCC 8 to calculate Anthem's risk adjustment payment for Patient B in payment year 2015, resulting in an overpayment of \$7,080.74 to Anthem.

- c. Patient C: In connection with a visit to a provider by this beneficiary on May 15, 2014, Anthem submitted an ICD-9 diagnosis code for chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation, with obstruction for this beneficiary – which mapped to HCC 31 – for payment year 2015. Anthem's chart review program did not substantiate that diagnosis. Further, no other provider reported such a diagnosis (or any other diagnosis that mapped to the same HCC) during 2014.

Anthem did not submit a delete for the peptic ulcer diagnosis code or otherwise notify CMS not to rely on that code for risk adjustment purposes. In the meantime, Anthem relied on chart review results to submit four additional ICD-9 codes to CMS for Patient C's visit on May 15, 2014. Due to this course of conduct, CMS used HCC 31 to calculate Anthem's risk adjustment payment for Patient C in payment year 2015, resulting in an overpayment of \$2,519.18 to Anthem.

- d. Patient D: In connection with a visit to a provider by this beneficiary on May 17, 2012, Anthem submitted an ICD-9 diagnosis code for bipolar disorder for this beneficiary – which mapped to HCC 55 – for payment year 2013. Anthem's chart review program did not substantiate the bipolar diagnosis. Further, no other provider reported such a diagnosis (or any other diagnosis that mapped to the same HCC) during 2012.

Anthem did not submit a delete for the bipolar diagnosis code or otherwise notify CMS not to rely on that code for risk adjustment purposes. In the meantime, Anthem relied on chart review results to submit six additional ICD-9 codes to CMS for Patient D's visit on May 17, 2012. Due to this course of conduct, CMS used HCC 55 to calculate Anthem's risk adjustment payment for Patient D in payment year 2013, resulting in an overpayment of \$2,693.27 to Anthem.

- e. Patient E: In connection with a visit to a provider by this beneficiary on August 1, 2012, Anthem submitted an ICD-9 diagnosis code for colostomy for this beneficiary – which mapped to HCC 176 – for payment year 2013. Anthem's chart review program did not substantiate the colostomy diagnosis. Further, no other provider reported such a diagnosis (or any other diagnosis that mapped to the same HCC) during 2012.

Anthem did not submit a delete for the colostomy diagnosis code or otherwise notify CMS not to rely on that code for risk adjustment purposes. In the meantime, Anthem relied on chart review results to submit five additional ICD-9 codes to CMS for Patient E's visit on August 1, 2012. Due to this

course of conduct, CMS used HCC 176 to calculate Anthem's risk adjustment payment for Patient E in payment year 2013, resulting in an overpayment of \$6,394.41 to Anthem.

- f. Patient F: In connection with a visit to a provider by this beneficiary on October 15, 2012, Anthem submitted an ICD-9 diagnosis code for chronic respiratory failure ("COPD") for this beneficiary – which mapped to HCC 79 – for payment year 2013. Anthem's chart review program did not substantiate the COPD diagnosis. Further, no other provider reported a COPD diagnosis (or any other diagnosis that mapped to the same HCC) during 2012.

Anthem did not submit a delete for the COPD diagnosis code or otherwise notify CMS not to rely on that code for risk adjustment purposes. In the meantime, Anthem relied on chart review results to submit four additional ICD-9 codes to CMS for Patient F's visit on October 15, 2012. Due to this course of conduct, CMS used HCC 79 to calculate Anthem's risk adjustment payment for Patient F in payment year 2013, resulting in an overpayment of \$4,769.37 to Anthem.

- g. Patient G: In connection with a visit to a provider by this beneficiary on August 16, 2012, Anthem submitted an ICD-9 diagnosis code for osteopathy resulting from poliomyelitis of the lower log for this beneficiary – which mapped to HCC 37 – for payment year 2013. Anthem's chart review program did not substantiate that diagnosis. Further, no other provider reported such a diagnosis (or any other diagnosis that mapped to the same HCC) during 2012.

Anthem did not submit a delete for the osteopathy resulting from poliomyelitis of the lower log diagnosis code or otherwise notify CMS not to rely on that code for risk adjustment purposes. Due to this course of conduct, CMS used HCC 37 to calculate Anthem's risk adjustment payment for Patient G in payment year 2013, resulting in an overpayment of \$5,137.89 to Anthem.

In these and thousands of other instances, Anthem's misconduct had a direct and foreseeable impact on CMS. Specifically, Anthem's misconduct not only enabled it to obtain and retain

higher risk adjustment payments from CMS, it also adversely affected the integrity and accuracy of CMS's risk adjustment payment system. In addition, by knowingly failing to delete these and thousands of other inaccurate diagnoses, Anthem knowingly and improperly avoided its obligation to repay CMS for payments it received for these inaccurate diagnoses.

155. Further, for each payment year in the relevant period – 2013, 2014, 2015, and 2016, Anthem submitted Part C annual attestations for its MA plans, which certified to CMS that all of the risk adjustment diagnosis data Anthem had submitted for those MA plans were “accurate” based on Anthem’s “best knowledge, information, and belief.” *See* Ex. 9.

156. As Anthem knew, each of those Part C attestations was false. Specifically, Anthem had information in its possession – the chart review results it received from Medi-Connect – that Anthem could have used to uncover numerous inaccuracies like the seven examples enumerated in paragraph 154 above.

157. Anthem also knew that its ongoing submission of the false annual attestations to CMS had a direct and foreseeable impact on CMS. Specifically, as Anthem’s internal policy recognized, CMS’s procedures required MAOs like Anthem to submit Part C annual attestations before CMS would proceed with the final reconciliation phase of the risk adjustment payment process. *See supra* ¶ 86. Thus, the false attestations submitted by Anthem caused CMS to move forward with final reconciliation for Anthem’s Part C plans and disburse reconciliation payments to Anthem during the relevant period.

FIRST CLAIM

Presentation of False or Fraudulent Claims

31 U.S.C. § 3729(a)(1)(A)

158. The Government incorporates by reference paragraphs 1 through 157 above as if fully set forth in this paragraph.

159. The Government seeks relief against defendant Anthem under section 3729(a)(1)(a) of the FCA, 31 U.S.C. § 3729(a)(1)(A), because Anthem knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to CMS.

160. Specifically, on account of its choice to operate its chart review program in deliberate ignorance or reckless disregard of its regulatory and contractual obligation to delete inaccurate diagnosis codes, Anthem knowingly submitted false Part C annual attestations to CMS in connection with seeking final reconciliation payments from Medicare.

161. By reason of the false annual attestations that Anthem knowingly presented, or caused to be presented, for payment or approval, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

162. If CMS had known that Anthem's attestation was false because, at the time of the attestation, Anthem knew that specific diagnosis codes it had submitted for payment and never deleted were inaccurate, CMS would have taken appropriate actions to ensure that Anthem did not receive or retain risk-adjustment payments to which it was not entitled, including by recouping payments through administrative processes, adjusting the reconciliation payments, or obtaining repayments in enforcement actions.

SECOND CLAIM

Making and Using False Statements in Violation of the FCA

31 U.S.C. § 3729(a)(1)(B)

163. The Government incorporates by reference paragraphs 1 through 157 above as if fully set forth in this paragraph.

164. The Government seeks relief against Anthem under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B), because Anthem knowingly made, used, or caused to be made

or used, a false record or statement material to a false or fraudulent claim.

165. Specifically, on account of its choice to operate its chart review program in deliberate ignorance or reckless disregard of its regulatory and contractual obligation to delete inaccurate diagnosis codes, Anthem knowingly made, used, or caused to be made or used, false Part C annual attestations in relation to seeking final reconciliation payments from Medicare.

166. By reason of these false records or statements, the Government has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

167. If CMS had known that Anthem's attestation was false because, at the time of the attestation, Anthem knew that specific diagnosis codes it had submitted for payment and never deleted were inaccurate, CMS would have taken appropriate actions to ensure that Anthem did not receive or retain risk-adjustment payments to which it was not entitled, including by recouping payments through administrative processes, adjusting the reconciliation payments, or obtaining repayments in enforcement actions.

THIRD CLAIM

Reverse False Claims — Knowingly and Improperly Avoiding an Obligation to Repay the Government

31 U.S.C. § 3729(a)(1)(G)

168. The Government incorporates by reference paragraphs 1 through 157 above as if fully set forth in this paragraph.

169. The Government seeks relief against Anthem under Section 3729(a)(1)(G) of the FCA, 31 U.S.C. § 3729(a)(1)(G), both because Anthem knowingly made or used a false record or statement material to an obligation to repay the Government and because Anthem knowingly concealed or knowingly and improperly avoided an obligation to repay the Government.

170. Specifically, on account of its choice to operate its chart review program in deliberate ignorance or reckless disregard of its regulatory and contractual obligation to delete inaccurate diagnosis codes, Anthem knowingly made, used, or caused to be made or used, false Part C annual attestations that enabled it to evade its obligation to refund CMS under the Medicare Part C's final reconciliation process.

171. Further, by deliberately or recklessly disregarding its regulatory and contractual obligation to delete inaccurate diagnosis codes, Anthem knowingly concealed its obligation to refund CMS.

172. By reason of these false records or statements, as well as Anthem's knowing concealment and avoidance, the Government has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

FOURTH CLAIM

Unjust Enrichment

173. The Government incorporates by reference paragraphs 1 through 157 above as if fully set forth in this paragraph.

174. Anthem has received money from the Government to which it was not entitled, which unjustly enriched Anthem, and for which it must make restitution. Anthem received such money by claiming and retaining Medicare Part C risk adjustment payments based on inaccurate and invalid risk adjustment data. In equity and good conscience, such money belongs to the Government and to the Medicare Program.

175. The Government is entitled to recover such money from Anthem in an amount to be determined at trial.

FIFTH CLAIM

Payment by Mistake

176. The Government incorporates by reference paragraphs 1 through 157 above as if fully set forth in this paragraph.

177. The Government paid money to Anthem as a result of a mistaken understanding. Specifically, the Government paid Anthem's claims for risk adjustment payments under the mistaken understanding that such claims were based on accurate and valid risk adjustment data. Had the Government known the truth, it would not have paid such claims. Those payments were therefore by mistake.

178. As result of such mistaken payments, the Government has sustained damages for which Anthem is liable in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the Government, requests that judgment be entered in its favor as follows:

- (a) on the First, Second, and Third Claims for relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B), and 31 U.S.C. §§ 3729(a)(1)(G)), a judgment against Anthem for treble the Government's damages, in an amount to be determined at trial, plus a civil penalty in the maximum applicable amount for each violation of the FCA by Anthem, as well as an award of costs incurred by the Government against Anthem pursuant to 31 U.S.C. § 3729(a)(3);
- (b) on the Fourth Claim for relief (unjust enrichment), a judgment against Anthem in an amount equal to the monies that Anthem obtained from the Government without right and by which Anthem has been unjustly enriched, plus costs, pre- and post-judgment interest;

- (c) on the Fifth Claim for relief (payment by mistake), a judgment against Anthem in an amount equal to the Government’s damages, plus costs, pre- and post-judgment interest; and
- (d) such further relief as is proper.

Dated: New York, New York
July 2, 2020

AUDREY STRAUSS
Acting United States Attorney

By: /s/ Li Yu
 LI YU
 PETER ARONOFF
 RACHAEL DOUD
 Assistant United States Attorneys
 United States Attorney’s Office, Civil Division
 86 Chambers Street, 3rd Floor
 New York, NY 10007
 Tel: (212) 637-2734/2697/3274
 Email: li.yu@usdoj.gov
 peter.aronoff@usdoj.gov
 rachael.doud@usdoj.gov
Attorneys for the United States

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.

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).
HI517	Anthem Medicare Preferred Core	Anthem Insurance Companies, Inc..
HI607	Anthem Medicare Preferred Standard	Anthem Insurance Companies, Inc..
HI849	Anthem Senior Advantage Value (HMO)	Anthem Health Plans Of Kentucky, Inc..
R5941	Anthem MediBlue Access (Regional PPO)	Anthem Insurance Companies, Inc..

**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 recredited) 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.

1 Liberty Plaza
165 Broadway
New York, NY 10006

Organization

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES



9/26/2013 11:18:12 AM

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

Date

**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



9/11/2014 1:10:21 PM

Date

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

Medicare Advantage Outreach and Education Bulletin



August, 2010

To: Medicare Advantage Physicians and Practitioners

Risk Adjustment 101

Did you know that Medicare Advantage plans, like Empire Blue Cross and Blue Shield (“Empire”) are required to report member diagnoses to the Centers for Medicare and Medicaid Services (“CMS”)? This information is used to risk adjust payments received by the health plan from CMS. This is referred to as the ***CMS HCC Risk Adjustment Payment Methodology***.

What is the CMS-HCC Risk Adjustment Payment Methodology?

It is the payment methodology used by CMS to adjust its payments to the plan based on the health status and demographic characteristics of a member. The result is higher payments from CMS for members who are at risk for being sicker and lower payments for members who are predicted to be healthier.

You Play a Critical Role

You, as the provider, play a critical role in facilitating the risk adjustment process. How?

- ICD-9 codes recorded on claims and encounters are reported to CMS and used to determine the risk adjusted payment;
- CMS requires that providers use the most specific code available (including secondary codes when appropriate);
- CMS uses documentation from the member’s medical record to validate that the appropriate ICD-9 code has been assigned, and may review this data at any time, including annually;
- If the medical record does not support the reported ICD-9 code, CMS may adjust health plan payments.

Your assistance and commitment to this process is critical. By supplying Anthem with the most accurate and complete diagnosis coding and medical record documentation, you will help us meet our reporting requirements and obligations to CMS.

Our goal is to help you better understand how the risk adjustment process impacts Anthem, you, as the provider, and our members. For more information related to this important subject, please contact your provider engagement representative.

Services provided by Empire HealthChoice HMO, Inc. and/or Empire HealthChoice Assurance, Inc., licensees of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield plans. The Blue Cross and Blue Shield names and symbols are registered marks of the Blue Cross and Blue Shield Association.

Medicare Advantage Risk Adjustment Programs

Rev: May 29, 2015

© Property of Anthem 2015 • Confidential Information

Contents

Part 1: Diagnostic Coding Guidance 4

Part 2: Overarching Guidance 4

Part 3: What Is Medicare Risk Adjustment? 4

 3.1 Risk Score 5

 3.2 HCC/ Diagnosis Groups 5

 3.3 CMS-HCC Risk Adjustment Model..... 5

 3.4 Provider Types..... 6

Part 4: Medical Record Documentation 7

Part 5: Physician/ Outpatient Records..... 8

 5.1 Hospital Outpatient 8

 5.2 Coding Exclusions 8

 5.3 Date of Service..... 9

 5.4 Date of Birth 9

 5.5 Physician Signature and Credentials..... 9

 5.6 Format of Records 10

 5.7 Unconfirmed Diagnosis 10

 5.8 TAMPER..... 11

 5.9 Chronic Conditions 12

 5.10 Acute/Emergency Conditions in Physician's Office 14

 5.11 Specialists..... 14

 5.12 Inferring a Diagnosis..... 14

 5.13 "History of" 15

 5.14 Problem Lists..... 15

 5.15 Status/ Status Post Codes..... 15

 5.16 Legibility..... 16

 5.17 ICD-9-CM Codes Only..... 16

Part 6: Inpatient 17

 6.1 Hospital Inpatient 17

 6.2 Inpatient Records..... 17

Part 7: Condition Specific Coding Guidance 18

 7.1 Cancer 18

 7.2 Myelodysplastic Syndrome/Myelodysplasia..... 20

 7.3 Diabetes 21

 7.4 Peripheral Neuropathy 23

 7.5 Morbid Obesity/Body Mass Index (BMI) 23

 7.6 Acute/Old Myocardial Infarction (MI) 24

 7.7 Arrhythmias 24

Medicare Advantage Risk Adjustment Programs

7.8 Hypertensive Heart Disease 25

7.9 Carotid Artery Disease 25

7.10 Chronic Kidney Disease (CKD) 25

7.11 Strokes/ Cerebrovascular Disease 26

7.12 Aneurysm 26

7.13 Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) 26

7.14 Chronic Obstructive Pulmonary Disease (COPD) 27

7.15 Fractures..... 27

7.16 Skin Ulcers..... 28

7.17 Urosepsis 28

7.18 E Codes 28

Part 8: Miscellaneous Coding Guidance 29

8.1 Scribe Utilization 29

8.2 Abbreviations 29

Part 9: CMS-HCC Models and Disease Hierarchy 34

Part 1: Diagnostic Coding Guidance

This manual provides coding guidance to be used when coding medical records on behalf of Anthem (formerly WellPoint) for Medicare Advantage Risk Adjustment purposes. This manual was created based on specific coding guidance from the following reputable resources:

- Official ICD-9 and ICD-10 Coding Guidelines
- AHA Coding Clinic
- CMS 2008 Risk Adjustment Participant Guide
- Risk Adjustment 101 Participant Guide (2013 National Technical Assistance)
- Chapter 7 Medicare Managed Care Manual

Please refer to these resources for official coding rules and regulations. This manual is intended to address common coding topics seen in the Medicare Advantage population. This manual is not all inclusive; it will be reviewed and updated annually.

Coders should also utilize (current and up-to-date) references such as:

- Medical dictionaries
- Drug references
- AMA and other Anatomy/clinical references (i.e., Merck Manual)
- AHA, AAPC, and AHIMA approved coding and billing education references (e.g., Faye Brown's Coding Handbook, Coder's Desk Reference)
- Internet access for coding and clinical research

Part 2: Overarching Guidance

The intent of all Anthem programs is to report to CMS all conditions that are properly documented and addressed in the member's medical record for each date of service. The information contained in this manual provides parameters and guidance to help achieve this ultimate goal.

Part 3: What Is Medicare Risk Adjustment?

Medicare risk adjustment is the method used to adjust bidding and payment from CMS (Centers for Medicare & Medicaid Services) to Medicare Advantage plans based on demographics (i.e., age and sex) as well as actual health status of enrollee. Medicare risk adjustment is prospective, meaning diagnoses from the previous year and demographic information are used to predict future costs and adjust payment.

The purpose of risk adjustment is to allow CMS to pay Medicare Advantage (MA) plans for the risk of the beneficiaries enrolled. By risk adjusting plan payments, CMS is able to make appropriate and accurate payment for enrollees with differences in expected costs.

3.1 Risk Score

A risk score is created in order to determine how an average member in the population compares to another member in the population. Risk score is based on a combination of demographic and disease data. The demographic data is provided to CMS by the Social Security Administration, while the disease data is submitted by the MA Organization in the form of diagnosis codes.

The formula reads:

$$\text{Risk Score} = (\text{demographics}) + (\text{disease}) + (\text{disease}) + (\text{disease})$$

CMS uses the following demographic factors when calculating a risk score:

- Age
- Sex
- Frailty
- Disability
- Original Reason for Entitlement (OREC)
- Institutionalization
- Medicaid Status

Total risk adjusted payment starts with the base payment calculated by the MA Plan that is submitted to CMS for approval as part of the Plan's annual bid process. The total payment calculation is:

$$\text{Total Payment} = \text{Base Payment} \times \text{Risk Score}$$

3.2 HCC/ Diagnosis Groups

The Hierarchical Condition Category (HCC) is a diagnosis grouping with a single relative factor assigned to it for each model segment. The diagnosis grouping consists of clinically related ICD-9 codes that have similarly projected costs. MA plans are paid based on the member's diagnoses codes that map to an HCC. These HCC-related diagnosis codes must be reported at least once during each calendar year for risk adjusted payment. Codes are reported to CMS via the Risk Adjustment Processing System (RAPS). RAPS will be replaced with Enterprise Data Processing System (EDPS) in the near future.

Over 3,100 ICD-9 codes map to 2013 CMS-HCC and/or 2014 CMS-HCC risk adjustment model. There are over 8,700 ICD-10 codes that map to the 2014 CMS-HCC risk adjustment model.

[2013 & 2014 CMS-HCC Model Spreadsheet](#)
[Preliminary ICD-10-CM Mapping to CMS-HCC Model](#)

3.3 CMS-HCC Risk Adjustment Model

For 2014 payment year, CMS implemented an updated, clinically revised CMS-HCC risk adjustment model. The risk scores for payment year 2014 and 2015 were calculated by blending the 2013 CMS-HCC model and the revised 2014 CMS-HCC model.

For 2016 payment year (2015 dates of service), CMS fully implemented the 2014 CMS-HCC Risk Adjustment Model. For more details on the CMS-HCC models, please refer to CMS' Advance Notice and Final Call Letters.

Medicare Advantage Risk Adjustment Programs

3.4 Provider Types

For risk adjustment purposes, MA organizations must collect data from the following provider types:

- Hospital outpatient facilities
- Hospital inpatient facilities
- Physicians (refer to table below for acceptable physician specialty types)

**Acceptable Physician Specialty Types for
2015 Payment Year (2014 Dates of Service)
Risk Adjustment Data Submission**

CODE	SPECIALTY	CODE	SPECIALTY	CODE	SPECIALTY
1	General Practice	25	Physical Medicine And Rehabilitation	67	Occupational Therapist
2	General Surgery	26	Psychiatry	68	Clinical Psychologist
3	Allergy/Immunology	27	Geriatric Psychiatry	72*	Pain Management
4	Otolaryngology	28	Colorectal Surgery	76*	Peripheral Vascular Disease
5	Anesthesiology	29	Pulmonary Disease	77	Vascular Surgery
6	Cardiology	33*	Thoracic Surgery	78	Cardiac Surgery
7	Dermatology	34	Urology	79	Addiction Medicine
8	Family Practice	35	Chiropractic	80	Licensed Clinical Social Worker
9	Interventional Pain Management (IPM)	36	Nuclear Medicine	81	Critical care (intensivists)
10	Gastroenterology	37	Pediatric Medicine	82	Hematology
11	Internal Medicine	38	Geriatric Medicine	83	Hematology/Oncology
12	Osteopathic Manipulative Medicine	39	Nephrology	84	Preventive Medicine
13	Neurology	40	Hand Surgery	85	Maxillofacial Surgery
14	Neurosurgery	41	Optometry	86	Neuropsychiatry
15	Speech Language Pathologist	42	Certified Nurse Midwife	89*	Certified Clinical Nurse Specialist
16	Obstetrics/Gynecology	43	Certified Registered Nurse Anesthetist	90	Medical Oncology
17	Hospice And Palliative Care	44	Infectious Disease	91	Surgical Oncology
18	Ophthalmology	46*	Endocrinology	92	Radiation Oncology
19	Oral Surgery	48*	Podiatry	93	Emergency Medicine
20	Orthopedic Surgery	50*	Nurse Practitioner	94	Interventional Radiology
21	Cardiac Electrophysiology	62*	Psychologist	97*	Physician Assistant
22	Pathology	64*	Audiologist	98	Gynecologist/Oncologist
23	Sports Medicine	65	Physical Therapist	99	Unknown Physician Specialty
24	Plastic And Reconstructive Surgery	66	Rheumatology	C0	Sleep Medicine

* Indicates that a number has been skipped.

Part 4: Medical Record Documentation

Medical record documentation is the historical account of the patient/provider encounter and serves as the basis for coding of all diagnoses and services provided to patients. The medical record documentation is required to record pertinent facts, findings, and observations about an individual's health history including past and present illnesses, examinations, tests, treatments, and outcomes. The medical record chronologically documents the care of the patient and is an important element contributing to high quality care. Consistent, current and complete documentation in the medical record is an essential component of quality patient care. The documentation should be clear and concise to communicate the condition(s) and treatment rendered to the patient.

Medical record documentation assists physicians and other health care professionals in evaluating and planning the patient's immediate treatment and monitoring the patient's health care over time. It is also the basis for collecting data and coding for risk adjustment.

Carefully review the medical record to ensure the following guidelines are met for HCC validation:

- Each coded date of service (DOS) should be able to stand on its own.
- CMS recommends that the patient's name and DOS appear on each page of the record.
 - If the patient's name and DOS do not appear on each page of the record, it is acceptable for coding as long as it is evident that each page of the record is for the same patient and DOS. Coders should carefully review the entire record for context using their best judgment.
- Diagnosis must result from a face-to-face visit either with an acceptable physician specialty or from an acceptable facility.
- Diagnosis must be supported by appropriate medical record documentation that demonstrates TAMPER (refer to section 5.15, Status/Status Post codes, for exceptions).
- Diagnosis must be submitted at least once during a reporting period.
- The provider's signature and credential must comply with CMS requirements (refer to section 5.5, Physician Signature and Credentials, for more details)
- Conditions coded must be stated in the medical record using text. Conditions documented using only numerical ICD-9 codes are not acceptable for risk adjustment per CMS (refer to section 5.16, ICD-9-CM Codes Only, for more details).

The entire medical record should be reviewed at the time of coding to ensure complete code capture of the condition(s) documented by the provider in accordance with the Official Coding Guidelines.

There are regulatory and accreditation directives that require providers to supply documentation in order to support code assignment. Providers need to have the ability to specifically document the patient's diagnosis, condition and/or problem. It is the provider's responsibility to provide clear and legible documentation of a diagnosis, which is then translated to a code for external reporting purposes. (AHA Coding Clinic for ICD-9-CM, 2012, Q1, Volume 29, Number 1, pg 6)

Part 5: Physician/ Outpatient Records

5.1 Hospital Outpatient

Hospital outpatient services are therapeutic and rehabilitative services provided for sick or injured persons who do not require inpatient hospitalization or institutionalization. Covered and non-covered hospital outpatient facilities are listed below.

Covered Facilities

- Short-term (general and specialty) Hospitals
- Medical Asst. Facilities/Critical Access Hospitals
- Community Mental Health Centers
- Federally Qualified Health Centers
- Religious Non-Medical Health Care Institutions
- Long-term Hospitals
- Rehabilitation Hospitals
- Children's Hospitals
- Psychiatric Hospitals
- Rural Health Clinic (Free-standing & Provider-based)

Non-Covered Facilities*

- Free-standing Ambulatory Surgical Centers
- Home Health Care
- Free-standing Renal Dialysis Facilities

Non-Covered Services

- Laboratory Services
- Ambulance
- Durable Medical Equipment
- Prosthetics
- Orthotics
- Supplies
- Radiology Services**

* These are examples of non-covered facilities and are not a comprehensive list.

** Regardless of the type of diagnostic radiology bill (outpatient department or physician component), this hospital outpatient service is not acceptable for risk adjustment because it typically does not contain confirmed diagnoses.

5.2 Coding Exclusions

Documentation acceptable for risk adjustment purposes must be from a face-to-face visit with an acceptable provider type (reference section 3.4 for listing). Do not code the following from Table 5A.

Table 5A Coding Exclusions List, Do Not Code

Lab	Phone calls	Dialysis
Radiology	Physician orders	Prosthetics/orthotics
Ambulance	Charge slips/ Superbills	Ambulatory surgery center
DME/Supplies	Rx scripts	Letters not for a face-to-face visit
Diagnostic/Electro-diagnostic Reports	Nursing notes/Nurse Only Visits	Consultation requests
Chemotherapy only	Infusion Therapy	Visits between provider and family
Skilled Nursing Facility (SNF)		

5.3 Date of Service

The Date of Service (DOS) defines when a beneficiary received medical treatment from a physician or medical facility. For outpatient and physician services, the DOS has to be clear and legible including the month, day, and year. The DOS submitted to CMS must be within the data collection year.

Do not guess or use a default date. Do not interpret the signature date, Date Dictated (DD), Date Transcribed (DT), vitals date or finalized date as the DOS. Exercise extreme caution with progress notes. Do not code the record if the DOS is missing or illegible.

5.4 Date of Birth

The Date of Birth (DOB) does not have to be listed on each date of service. Look for conflicts in comparison that would invalidate the medical record. It is important that coders use their best judgment when reviewing the medical record for DOB. Implement the following best practices when the member's DOB is missing on the date of service:

- Look for patient's age to subtract from the year in the medical record. If the total corresponds with the DOB year in Chart Navigator (based on calculation), the record may be coded.
 - For example: For DOS 05/01/2014, the record states patient's age is 78. Subtract patient's age from the year in the date of service, $2014-78= 1936$. The DOB in Chart Navigator is 02/01/1936.
- If the DOB is referenced in other documents within the medical record (e.g., lab or x-ray), the coder may use that DOB for validation. If DOB corresponds, the record may be coded.
- If there is no reference to DOB throughout the entire medical record and the patient's age is not listed, allow the record and code as usual.

Conflicts:

- If there is a modest conflict (i.e., one or two digits, one or two days) in either the DOB or age calculation, allow the record and code as usual.
- If there is a major conflict in the DOB or the member age, do not code the record.

5.5 Physician Signature and Credentials

For risk adjustment purposes, the provider of service for face-to-face encounters is appropriately identified on the medical record via signature and physician specialty credentials.

Examples of acceptable physician signature, including credentials, are:

- Handwritten signature or initials
- Electronic signature with authentication by the respective provider

If electronic signatures are used as a form of authentication, the system must authenticate the signature at the end of each note. Examples of acceptable electronic signatures are: "Electronically signed by," "Authenticated by," "Approved by," "Completed by," "Finalized by," and "Validated

Medicare Advantage Risk Adjustment Programs

by" including the practitioner's name, credentials, and date of authentication. If the provider signature is missing at the time of audit, CMS allows for submission of a completed CMS-Generated Attestation for the specific encounter date for an outpatient/physician record. Flag missing signatures appropriately in Chart Navigator.

5.6 Format of Records

Conditions can be coded from *any* part of the medical record provided the condition is documented and appropriately supported with TAMPER (see section 5.8). The two most common documentation formats are:

SOAP

- **S**ubjective - HPI, chief complaint (patient's own words), ROS, reason for the visit
- **O**bjective – physical exam, review of systems, vitals, weight etc.
- **A**ssessment – final impression, symptoms, relevant concurrent problems
- **P**lan - refill meds, order test, refer to specialists, order lab work, treatment plan

CHEDDAR

- **C**hief Complaint – presenting problem(s) in patient's own words
- **H**istory – social, medical, surgical, family histories
- **E**xam – physical examination of the patient
- **D**etails of Problem – details of the complaints or symptoms
- **D**rugs/ Dosages – current medications and dosages
- **A**ssessment – assessment of the diagnostic process and final impressions
- **R**ecommendations – return to clinic, refer to specialist, treatment plan

Keep in mind, not all records follow these formats. Category titles in the medical record vary. For instance, a category titled "History" may indicate past medical history (PMH) or history of present illness (HPI). The main goals are to verify that each encounter is a face-to-face visit with an acceptable provider and that each condition coded has supportive documentation.

5.7 Unconfirmed Diagnosis

For physician and hospital outpatient records, do not code conditions documented as "consistent with," "probable," "possible," "questionable," "rule out," "likely," "suspected," "suspicious for," "working," or other uncertain language. Rather, code the condition(s) to the highest degree of certainty for that encounter such as symptoms, signs, abnormal test results, or other reason for the visit. Refer to the Official ICD-9-CM Guidelines for Coding and Reporting Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services for additional guidance.

The Official Guidelines for Coding and Reporting for Outpatient Services, state, "Chronic diseases treated on an ongoing basis may be coded and reported as many times as the patient receives treatment and care for the condition(s)."

5.8 TAMPER/Coding Guidelines per Section

Coders will apply TAMPER guidelines when analyzing each diagnosis and deciding whether that diagnosis meets reporting criteria for each DOS. Coders will look for evidence of treatment as explained by the TAMPER guidelines below.

Treatment: Can be, but not limited to, the following:

- Considered to be Medications
- Education

Assessment: Can be, but not limited to, the following:

- Included as part of the final assessment
- Part of the Assessment with other notation (i.e., "stable", "active", "present")

Monitoring: Can be, but not limited to, the following:

- Laboratory Orders/Results
- Routine follow up visits
- Home monitoring

Plan Can be, but not limited to, the following:

- Decrease medication/increase medication
- Routine follow up visits
- Home monitoring
- Case Management
- Disease Management

Evaluate: Can be, but not limited to, the following:

- Evaluation of current medical regimen
- Physical Examination
- Evaluation for treatment
- Vaccine Titers
- Diagnostics for effectiveness of care and resolution of disease
- Monofilament testing for disease detection

Referral Can be, but not limited to, the following:

- Referral to specialist for treatment
- Referral to dietician

If any one of the above actions is documented, coders should capture and report the diagnosis code(s). Every diagnosis and date of service must stand alone. See below for coding guidelines pertaining to each section of the medical record.

HPI (History of Present Illness) and Chief Complaint

- Conditions documented under HPI or as the chief complaint should be coded as long as there is evidence that the condition is current and confirmed by the provider (i.e, not documented as probable or as hearsay from the patient).

Medicare Advantage Risk Adjustment Programs

PMH (Past Medical History)/Problem Lists

- Chronic conditions in these areas require TAMPER in order to be extracted for risk adjustment. If no TAMPER exists then the code should not be extracted.

ROS (Review of Systems)

- Conditions documented under ROS should be coded as long as there is evidence that the condition is current and confirmed by the provider (i.e., not documented as probable or as hearsay from the patient). Conditions (with the exception of status codes) in these areas require TAMPER in order to be extracted for risk adjustment.

Physical Exam

- The physical exam is considered TAMPER. Current conditions documented here should be captured as they are the objective findings from the face-to-face encounter with the patient. Conditions here should only be coded if they are documented as a confirmed diagnosis and not just a description (i.e., patient appears hypoxic).

Assessment/Plan

- All conditions listed here are considered to meet TAMPER and should generally be coded. Chronic conditions listed under the assessment/plan are considered to meet TAMPER and should be coded. Keep in mind that some conditions, such as cancer, require current treatment in order to be coded as active and not history of. Acute conditions (e.g., stroke, fracture, MI, etc.) will always require TAMPER.

5.9 Chronic Conditions

Below are examples of chronic conditions that can be extracted from HPI, ROS, Physical Exam, and Assessment/Plan.

Table 5B Chronic Conditions (not an all inclusive list)

Atrial Fibrillation	Chronic Osteomyelitis	End Stage Liver Disease	Peripheral Vascular Disease
Bipolar Disorder	Chronic Pancreatitis	Epilepsy	Pulmonary Heart Disease
Cardiomyopathy	Chronic Resp. Failure	HIV/AIDS	Quadriplegia
Cerebral Palsy	Chronic Skin Ulcer	Ischemic Heart Disease	Rheumatoid Arthritis
Chronic Bronchitis	Cirrhosis of the Liver	Major Depressive Dis.	Schizophrenia
Chronic Hepatitis	Congestive Heart Failure	Multiple Sclerosis	Systemic Lupus Erythem.
Chronic Kidney Disease	Crohn's Disease	Muscular Dystrophy	Ulcerative Colitis
Chronic Nephritis	Cystic Fibrosis	Paraplegia	
Chronic Leukemia	Diabetes Type 1 & 2	Parkinson's Disease	
COPD	Emphysema	Peripheral Neuropathy	

Medicare Advantage Risk Adjustment Programs

Medical history alone may not be used as a source of diagnoses for risk adjustment purposes. For a chronic condition to be accepted for risk adjustment, the patient must have a face-to-face visit each year with a provider/physician who assesses and documents that condition. (2013 National Technical Assistance, RA 101 Part Guide, Pg 17)

5.10 Acute/Emergency Conditions in Physician's Office

Patients with life threatening conditions are not likely to be treated in the physician's office. Upon review, it is often discovered that documentation is describing the historical event rather than a current (acute) condition. Use the following list as a guide if it appears that an acute, emergent event has been documented in the office visit. Keep in mind that historical conditions that have no bearing on current care are not coded. TAMPER applies to all acute conditions.

Table 5C Coding Acute Conditions (not an all-inclusive list)

Code	Acute Condition(s)	Coder Action
411.1	Unstable Angina, Acute Coronary Syndrome	Assign a code for the underlying condition if documentation supports, such as CAD.
434.xx 436	Occlusion of cerebral arteries Acute, but ill-defined, cerebrovascular disease	Assign code V12.59 for history of CVA if no residual conditions remain. If the provider documents a late effect and cause (e.g., hemiplegia due to CVA) then use the late effects category 438.xx.
410.x1 410.x0	Acute Myocardial Infarction (initial episode of care) Acute Myocardial Infarction (unspecified episode of care)	Look for the date of the event. If the patient is \leq 8 weeks status post MI, it is acceptable to code 410.x2 for subsequent follow up care. Assign code 412 if the patient had an MI > 8 weeks ago.
518.5 518.81 518.82 518.84	Pulmonary insufficiency following trauma and surgery Acute respiratory failure Other pulmonary insufficiency, NOS Acute on chronic respiratory failure	Assign a code for the underlying pulmonary condition with supporting documentation, such as COPD.

5.11 Specialists

For specialist (Cardiologist, Ophthalmologist, Endocrinologist, etc.) encounters, all confirmed conditions documented in the HPI, ROS, Exam, and/or assessment that pertains to the specialist's field should be captured as long as there is no evidence of contradiction in the medical record. The specialist is following up on conditions that the PCP does not. They perform specific examinations and tests that would constitute as TAMPER for those conditions related to the specialist's field. It would also be appropriate to code co-existing conditions as long as there is supportive documentation for that condition. As a reminder, do not code from PMH alone without TAMPER.

5.12 Inferring a Diagnosis

Coder's must be careful to not infer a diagnosis that has not been stated by the provider. For example, Coumadin is listed as a current medication but the condition for which Coumadin is being taken is not stated. It would be incorrect for the coder to infer that the patient has atrial fibrillation based solely on the medication. Also, coders must not assign diagnoses based solely on findings (lab, x-ray, etc.). **The provider must specifically state the condition in the documentation in order for it to be coded.**

5.13 “History of”

According to ICD-9-CM, the phrase “history of” means the patient no longer has the condition and the diagnosis often indexes to a V-code not in the HCC models. However, physicians often use this phrase to indicate the length of time for which a member has been treated for a condition. Use the context of the entire medical record to determine whether the condition is active with current treatment or historically resolved.

5.14 Problem Lists

Problem lists rarely contain the required elements as described by CMS. In general, it is felt that they should be avoided as a source of diagnosis coding. **Do not code from the problem list or PMH unless there is TAMPER that can be attributed to the condition.** Carefully review the documentation, including dates (if listed) to ensure that the condition is not historically resolved.

Although the term “problem list” is commonly used with regard to ambulatory medical record documentation, a universal definition does not exist. The problem list is generally used by a coder to gain an overall clinical picture of a patient’s condition(s). Problem lists are usually supported by other medical record documentation such as SOAP notes (subjective, objective, assessment, plan), progress notes, consultation notes, and diagnostic reports.

For CMS’ risk adjustment data validation purposes, an acceptable problem list must be comprehensive and show evaluation and treatment for each condition that relates to an ICD-9 code on the date of service, and it must be signed and dated by the physician or physician extender. (2008 Risk Adjustment Participant Guide, 7-17, p172)

5.15 Status/ Status Post Codes

Per ICD-9 Guidelines, “Status codes indicate that a patient is a carrier of a disease, has the sequelae or residual of a past disease or condition, or has another factor influencing a person’s health status. This includes such things as the presence of prosthetic or mechanical devices resulting from past treatment. A status code is informative, because the status may affect the course of treatment and its outcome. A status code is distinct from a history code. The history code indicates that the patient no longer has the condition.” The status code may not affect the course of treatment indicating an exception to the TAMPER criteria.

Status codes may be coded from any part of the medical record as long as there is evidence of the condition. Coders are again cautioned with coding from PMH alone; validate that the condition and/or presence of device is a current status and not historical when able. Typically ostomies, amputations, and devices are documented in the physical exam for confirmation of current status.

Listed below are status/status post codes that link to an HCC:

- organ transplant status such as lung, liver, stem cell, etc.
- HIV status
 - Note: Per ICD-9 Guidelines, “V08 Asymptomatic human immunodeficiency virus [HIV]

Medicare Advantage Risk Adjustment Programs

infection is to be applied when the patient without any documentation of symptoms is listed as being "HIV positive;" "known HIV;" "HIV test positive;" or similar terminology. Do not use this code if the term "AIDS" is used or if the patient is treated for any: HIV-related illness or is described as having any condition(s) resulting from his/her HIV positive status; use 042 in these cases. Patients previously diagnosed with any HIV illness (042) should never be assigned to 795.71 or V08."

- heart assists devices/artificial heart
- renal dialysis
 - Note: Must be documented as currently receiving dialysis in order to code V45.11 for renal dialysis status. Assign the renal dialysis status code for the presence of an AV (arterial-venous) shunt only when documentation specifies it is for dialysis.
- ventilator status
- long term use of insulin
 - Note: Use only as secondary to type II diabetes.
- old Myocardial Infarction (refer to Table 7B for common terms associated with MI)
- artificial/stoma openings such as tracheostomy, gastrostomy, etc.
 - Note: Must be documented as currently present. Look for words such as "takedown" or "reanastomosis" to indicate the ostomy no longer exists.
- amputations of lower extremity such as toe, BKA, and AKA
 - Note: Traumatic amputation should only be coded for acute treatment. If the patient had a traumatic amputation of the lower extremity in the past, correct coding would fall under the V49.7x category
- hemiplegia/ hemiparesis
 - Note: If late effect of CVA, must be documented with linking verbiage

5.16 Legibility

Documentation should be clear and legible. Do not assume or guess a diagnosis. Only code the conditions that are clearly documented and supported in the medical record.

At a minimum the following items must be clear and legible:

- DOS including month, day, and year
- Member's first and last name
- Diagnosis
- Supportive TAMPER

If in doubt, please have another coder/supervisor review the record for legibility.

5.17 ICD-9-CM Codes Only

Some physician records contain only ICD-9-CM codes without the code's description. For risk adjustment purposes, there must be documentation of the condition elsewhere on that DOS. If the record does not document the condition (other than just listing the ICD-9-CM code), do not code.

Remember: The clinician must document the condition in the medical record in order for code assignment. Refer to ICD-9 coding guidelines and other reputable resources previously listed for further guidance.

Part 6: Inpatient

6.1 Hospital Inpatient

Hospital inpatient services include those for which the patient is admitted to the facility for at least one overnight stay. Covered and non-covered hospital inpatient facilities are listed below.

Covered Facilities:

- Short-term (general and specialty) Hospitals
- Religious Non-Medical Health Care Institutions
- Long-term Hospitals
- Rehabilitation Hospitals
- Children's Hospitals
- Psychiatric Hospitals
- Medical Assistance Facilities/ Critical Access Hospitals

* These are examples of non-covered facilities and not a comprehensive list.

Non-Covered Facilities*:

- Skilled Nursing Facilities (SNFs)
- Hospital Inpatient Swing Bed Components
- Intermediate Care Facilities
- Respite Care
- Hospice

6.2 Inpatient Records

In order to code an encounter as an inpatient record there must be a valid discharge summary containing both the admission and discharge dates. Per ICD-9-CM Inpatient Coding Guidelines, "If the diagnosis documented at the time of discharge is qualified as "probable", "suspected", "likely", "questionable", "possible", or "still to be ruled out", code the condition as if it existed or was established. The bases for these guidelines are the diagnostic workup, arrangements for further workup or observation, and initial therapeutic approach that correspond most closely with the established diagnosis." Additionally, diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded.

Listed below are a few rules to consider when coding for Inpatient Records:

- A discharge summary is considered a valid document to code for an inpatient record if both the admission and discharge dates are listed. Use inpatient coding guidelines.
- CMS has strict guidelines for submitting History & Physical (H&P) as stand-alone documentation. Refer to 2008 CMS Risk Adjustment Participant Guide section 6.4.3.1 History and Physical (H&P), and Lab and Pathology Reports- Guidance for more details.
- Emergency room visits on the day of admission, operative reports, inpatient consults, H&P, and inpatient progress notes may be coded:
 - In combination with a valid discharge summary using inpatient coding guidelines, or
 - Separately using outpatient coding guidelines

Inpatient Coding Advise: Chronic conditions such as, but not limited to, hypertension, Parkinson's disease, COPD, and diabetes mellitus are chronic systemic diseases that ordinarily should be coded even in the absence of documented intervention or further evaluation. Some chronic conditions affect the patient for the rest of his or her life and almost always require some form of continuous clinical evaluation or monitoring during hospitalization, and therefore should be coded. (AHA Coding Clinic for ICD-9-CM, 2007, 3Q, p14).

Part 7: Condition Specific Coding Guidance

7.1 Cancer

If documentation is not clear whether a neoplasm is benign or malignant, use the alphabetic index to find the morphological term used to describe the behavior of the neoplasm. For example, the term leiomyosarcoma is indexed to malignant neoplasms while lipoblastoma is indexed to benign neoplasms in the ICD-9-CM code book.

7.1.1 Current Cancer vs. History

Clinicians may document cancer in historical terms. Coders must refer to the entire document for each DOS to determine whether the malignancy should be coded history, using a V-code, or current. **Documentation must show clear presence of current disease to code current malignancy.** Instances in which the malignancy should be coded as current are noted below.

1. Document indicates either the patient or physician chose not to treat the cancer (e.g. choosing not to continue treatment of a terminal disease) OR
2. Document shows evidence of current/ongoing treatment of the disease:
 - Chemotherapy (e.g. antineoplastic medications)
 - Radiation therapy (e.g. including radioactive seed implantation to provide continuous ambulatory radiation)
 - Suppressive therapy (e.g. hormonal therapy, like Lupron for advanced prostate cancer)
 - Surgical treatment (e.g. a preoperative examination prior to colectomy)
 - Immunotherapy/Biological therapy (e.g. Herceptin therapy for breast cancer)
 - Other Adjuvant therapies
3. Documentation shows that current treatment is being temporarily stopped for the following reasons :
 - To determine an appropriate or alternate treatment plan for the patient's cancer
 - To allow the patient to rest clinically from the effects of treatment (chemo/radiation)
 - To transfer of care where treatment is to be continued by another provider

For coding purposes, cancer is considered "history of" after definitive surgical treatment and/or completion of treatment regimen **unless there is documented evidence of residual disease/treatment.** Reference chapter 2 of the ICD-9 Coding Guidelines for more specific details for coding neoplasms.

Per RADV Medical Record Checklist and Guidance, "Pay special attention to cancer diagnoses. A notation indicating 'history of cancer,' without an indication of current cancer treatment, may not be sufficient documentation for validation."

7.1.2 Primary vs. Secondary**Metastatic from = Primary**

For Example: Malignancy of the colon metastatic from prostate.

- Prostate cancer is primary.
- Colon cancer is secondary.

Metastatic to = Secondary

For Example: Breast cancer with metastasis to the mediastinal lymph nodes.

- Breast cancer is primary.
- Mediastinal lymph nodes cancer is secondary.

If the documentation only states "metastatic" assign the primary malignancy along with code 199.1 for secondary malignancy of unspecified site. (Faye Brown's ICD-9-CM Coding Handbook 2011, pg. 381)

For coding purposes, if a malignancy is not specified as primary or secondary it is assumed to be primary. The following sites are exceptions; they are classified as secondary when not otherwise specified in the documentation:

- | | | |
|-------------|---------------|-------------------|
| • Bone | • Liver | • Peritoneum |
| • Brain | • Lymph nodes | • Pleura |
| • Diaphragm | • Mediastinum | • Retroperitoneum |
| • Heart | • Meninges | • Spinal cord |

The liver has 3 possible morphological designations:

- Liver, primary – code 155.0 (HCC 8/9*)
- Liver, secondary – code 197.7 (HCC 7/8)
- Liver, not specified as primary or secondary – code 155.2 (HCC 8/9)

* Note: HCC 2013/HCC 2014

7.1.3 In Remission

The following definitions of "remission" are provided by the National Cancer Institute:

- Remission – a decrease in or disappearance of signs and symptoms of cancer
- Partial Remission – some, but not all, signs and symptoms of cancer have disappeared
- Complete Remission – all signs and symptoms of cancer have disappeared, although cancer may be in the body

Lymphoma patients who are "in remission" are still considered to have lymphoma and should be assigned the appropriate code from categories 200-202 (AHA Coding Clinic for ICD-9-CM, 1992, 2Q, p3).

Medicare Advantage Risk Adjustment Programs

When coding cancer, ICD-9 guidelines state that there must be current treatment aimed at the malignancy in order to assign a current cancer code. Lymphoma “*in remission*” represents an exception to that rule. Lymphoma stated as “*in remission*” is coded as current from categories 200-202 per AHA Coding Clinic reference above. It is inappropriate to assign a history code for lymphoma when specified as “*in remission*.”

Do not to confuse lymph node metastasis with lymphoma. Physicians may document lymph node involvement in a patient with lymphoma. It is incorrect to assign category 196 (secondary and unspecified malignant neoplasm of lymph nodes) in this case.

When coding other hematopoietic neoplasms/malignancies classified to codes 203-208 (i.e. plasma cell leukemia) assign the correct fifth digit to indicate the appropriate stage of the disease based on documentation in the medical record.

Table 7A Fifth Digit Classification

Fifth digit	For use with ICD-9 categories 203-208
0	Without mention of having achieved remission
1	In remission
2	In relapse

7.1.4 In-Situ

A neoplasm described as in-situ (codes 230-234) has not metastasized or spread to any other area of the body. The ICD-9-CM coding guidelines offer specific guidance via the index. **A neoplasm described as both in-situ and secondary, represents a conflict in the medical documentation.** Use sound coding judgment and context to determine the appropriate behavior of the neoplasm based on past medical history and treatment (surgical/ radiation/ chemotherapy) documented along with TAMPER to support the chosen code.

- **Dysplasia** – earliest form of pre-cancerous lesion recognizable in a biopsy by a pathologist. Dysplasia can be low grade or high grade. The risk of low-grade dysplasia transforming into cancer is low. Per ICD-9 index reference the term dysplasia, followed by the correct anatomical site.
- **Carcinoma in situ** – neoplasm that has stayed in the place where it began and has not spread to neighboring tissues (e.g., squamous cell carcinoma in situ). The term is synonymous with high-grade dysplasia in most organs.

7.2 Myelodysplastic Syndrome/Myelodysplasia

Myelodysplastic Syndrome, code 238.75 (HCC 44/46), is sometimes confused with congenital myelodysplasia of the spine, code 742.59 (HCC 69/72), a birth defect. Myelodysplastic syndrome (MDS, myelodysplasia) is a group of blood disorders associated with low blood count; it is more common among the elderly population versus the congenital spine defect. Use context and coding judgment to determine correct code.

7.3 Diabetes

Coding for diabetes is a four-step process in which coders must have key pieces of information in order to make accurate code selections:

- Type of Diabetes – type 1 (juvenile) or type 2 (adult onset)
 - Default is type 2 if unspecified
- Status of Control – controlled vs. uncontrolled
- Associated Manifestations – complications or manifestations of diabetes must be documented with linking verbiage to display causality
- Insulin Use – code *only* as secondary to type II diabetes
 - Code as secondary to type I DM, if desired. Type 1 diabetics must use insulin because their pancreas does not produce insulin naturally. Thus, unnecessary to assign V58.67.

Note: Coder's should never assign a code for diabetes 250.xx when the physician documents abnormal glucose, impaired fasting glucose, or impaired glucose tolerance test. A laboratory test showing one reading of high blood sugar is not considered sufficient "clinical evidence" of diabetes. These conditions are laboratory findings and have designated codes for reporting 790.21 – 790.29. Additionally, the diagnosis of "pre-diabetes" also falls under code 790.29.

7.3.1 Demonstrating Causality

Conditions listed with a diagnosis of diabetes mellitus or in a diabetic patient are not necessarily complications of the diabetes (AHA Coding Clinic, 1991, Q3, p7-8)

Diabetic complications require two or more codes to fully describe the conditions. **Assign a code for both "diabetes with ___ manifestation" in addition to the specific diabetic complication as instructed by ICD-9 coding guidelines.**

There must be a documented cause-and-effect relationship between diabetes and the associated manifestation in order to select a code from HCC categories 15-18. If documentation does not properly link the two conditions, default to diabetes without complication code 250.0x (HCC 19).

Look for linking verbiage such as:

- Diabetic coma
- Gastroparesis in diabetes
- Foot ulcer associated with diabetes
- Nephropathy due to diabetes
- Blindness of diabetes

** This is not an all-inclusive list of terms. The cause-and-effect relationship must be clearly documented with supportive TAMPER*

Gangrene and osteomyelitis are exceptions to the cause-and-effect rule above. ICD-9-CM assumes a causal relationship between osteomyelitis/gangrene and diabetes when both conditions are present, unless the physician has indicated in the medical record that the acute osteomyelitis or gangrene is totally unrelated to the diabetes (AHA Coding Clinic, 2004, Q1, p 14-15)

7.3.2 Diabetes "with"

Question: What are the code assignments for a diagnostic statement of diabetes with neuropathy?

Answer: Assign code 250.6X, Diabetes with neurological manifestations, and code 357.2, polyneuropathy in diabetes, for diabetes with neuropathy. Words such as "with," "with mention of," "associated with," and "in" indicate that both elements in the title must be present in the diagnostic statement or procedural statement. Although they do not necessarily indicate a cause-effect relationship, they occur together much of the time and the classification system indicates this relationship. (AHA Coding Clinic, 2008, Q3)

In ICD-9-CM's Alphabetic Index, the subentry term "with" means associated with or due to. For example, if the provider documents "diabetes with neuropathy," assign codes 250.6X (diabetes with neurological manifestations) and 357.2 (polyneuropathy in diabetes). (AHA Coding Clinic, 2009, Q2)

Coders need to be cautious with vague terms such as "with" ensuring that the medical record supports a diabetic manifestation. The Coding Clinic question pertains to the diagnostic statement of diabetes with neuropathy.

- If HPI states, "diabetes with CKD, CAD, and hypertension" this would not be considered linked as it is not the diagnostic statement. Additionally, it is unclear as to whether CKD is a manifestation of diabetes since there are multiple conditions included in the sentence.
- If Assessment states, "diabetes with CKD- follow with nephrologist." This would be considered linked since it is the diagnostic statement and there is supportive documentation for the diabetic manifestation.

The Coding Clinic examples of "with" is between diabetes and a specific condition, neuropathy. Diabetes with neurological, ophthalmic, renal, or peripheral circulatory manifestation/complications must include the specific condition that falls under that category in order to additionally code the manifestation.

For instance, the diagnostic statement reads, "diabetes with renal manifestations." What renal manifestation?

- Chronic Kidney Disease
- Diabetic Nephropathy
- Diabetic Nephrosis
- Intercapillary Glomerulosclerosis
- Kimmelstiel-Wilson Syndrome

If it is unclear as to what the specific diabetic manifestation is, default to diabetes without complication code 250.0x (HCC 19).

7.3.3 Diabetic Examinations

If the patient is being seen for a *diabetic* eye or foot exam, it would be appropriate to code the confirmed diabetic manifestation.

- During the diabetic eye exam, the patient is diagnosed with PDR (proliferative diabetic retinopathy). It would be appropriate to code 250.50 and 362.02 for this encounter as instructed by ICD-9 guidelines (code first diabetes).

Medicare Advantage Risk Adjustment Programs

- During the diabetic foot exam, the patient is diagnosed with Diabetic Peripheral Neuropathy. It would be appropriate to code 250.60 and 357.2 for this encounter as instructed by ICD-9 guidelines (code first underlying disease).

Common forms of TAMPER for diabetes include, but are not limited to:

- A1C – blood test checks how well your diabetes has been recently controlled
- Oral Glucose Tolerance Test or Plasma Glucose Test – a blood test given after more than 8 hours of fasting followed by a dose of glucose, additional testing is then performed to determine the level of glucose that remains in the blood.
- Documenting the review of home blood sugars
- Insulin – currently used or prescribed (code V58.67 in addition to diabetes type II)

7.4 Peripheral Neuropathy

Peripheral neuropathy, code 356.9 (HCC 71/no HCC) is a result of nerve damage, often causing numbness and tingling in the hands and feet. One of the most common causes of peripheral neuropathy is diabetes.

Assign code 356.9, Polyneuropathy unspecified, for peripheral neuropathy of both extremities. Because the disease is affecting multiple nerves, this would be classified as a polyneuropathy. (AHA Coding Clinic, 2013, Q1)

7.5 Morbid Obesity/Body Mass Index (BMI)

Morbid obesity, code 278.01 (no HCC/22), is defined in ICD-9-CM as a BMI of 40 or greater (based on WHO criteria). BMI codes V85.4x (no HCC/22) should only be assigned as a secondary diagnosis when a clinical condition has been stated by the provider. According to the ICD-9-CM codebook, when coding for overweight and obesity an additional code should be used to identify the BMI, if known. Ensure that the BMI supports the corresponding diagnosis of morbid obesity.

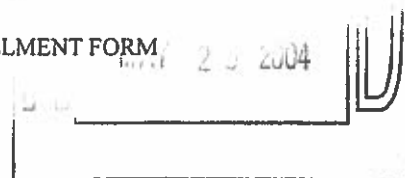
Individuals who are overweight, obese, or morbidly obese are at an increased risk for certain medical conditions when compared to persons of normal weight. Therefore, these conditions are always clinically significant and reportable when documented by the provider. (AHA Coding Clinic, 2004, Q3)

If the BMI has clinical significance for the patient encounter, the specific BMI value may be picked up from the dietitian's documentation. The provider must provide documentation of a clinical condition, such as obesity, to justify reporting a code for the body mass index. To meet the criteria for a reportable secondary diagnosis, the BMI would need to have some bearing or relevance in terms of patient care. For reporting purpose, the definition for "other diagnoses" is interpreted as additional conditions that affect patient care in terms of requiring: Clinical evaluation; or Therapeutic treatment; or Diagnostic procedures; or Extended length of hospital stay; or Increased nursing care and/or monitoring. Once the provider has provided documentation of the clinical condition, such as obesity, the coder can use the dietitian's note to assign the appropriate BMI codes from category V85 (AHA Coding Clinic, 2008, Q4)

Medicare+Choice Organization**Electronic Data Interchange Enrollment Form****MANAGED CARE ELECTRONIC DATA INTERCHANGE (EDI) ENROLLMENT FORM**

ONLY for the Collection of Risk Adjustment Data and/or

With Medicare+Choice Eligible Organizations



The eligible organization agrees to the following provisions for submitting Medicare risk adjustment data electronically to the Centers for Medicare & Medicaid Services (CMS) or to CMS' contractors.

A. The Eligible Organization Agrees:

1. That it will be responsible for all Medicare risk adjustment data submitted to CMS by itself, its employees, or its agents.
2. That it will not disclose any information concerning a Medicare beneficiary to any other person or organization, except CMS and/or its contractors, without the express written permission of the Medicare beneficiary or his/her parent or legal guardian, or where required for the care and treatment of a beneficiary who is unable to provide written consent, or to bill insurance primary or supplementary to Medicare, or as required by State or Federal law.
3. That it will ensure that every electronic entry can be readily associated and identified with an original source document. Each source document must reflect the following information:
 - Beneficiary's name,
 - Beneficiary's health insurance claim number,
 - Date(s) of service,
 - Diagnosis/nature of illness
4. That the Secretary of Health and Human Services or his/her designee and/or the contractor has the right to audit and confirm information submitted by the eligible organization and shall have access to all original source documents and medical records related to the eligible organization's submissions, including the beneficiary's authorization and signature.
5. Based on best knowledge, information, and belief, that it will submit risk adjustment data that are accurate, complete, and truthful.
6. That it will retain all original source documentation and medical records pertaining to any such particular Medicare risk adjustment data for a period of at least 6 years, 3 months after the risk adjustment data is received and processed.
7. That it will affix the CMS-assigned unique identifier number of the eligible organization on each risk adjustment data electronically transmitted to the contractor.
8. That the CMS-assigned unique identifier number constitutes the eligible organization's legal electronic signature.
9. That it will use sufficient security procedures to ensure that all transmissions of documents are authorized and protect all beneficiary-specific data from improper access.
10. That it will establish and maintain procedures and controls so that information concerning Medicare beneficiaries, or any information obtained from CMS or its contractor, shall not be used by agents, officers, or employees of the billing service except as provided by the contractor (in accordance with §1106(a) of the Act).
11. That it will research and correct risk adjustment data discrepancies.
12. That it will notify the contractor or CMS within 2 business days if any transmitted data are received in an unintelligible or garbled form.

B. The Centers for Medicare & Medicaid Services Agrees To:

1. Transmit to the eligible organization an acknowledgment of risk adjustment data receipt.
2. Affix the intermediary/carrier number, as its electronic signature, on each response/report sent to the eligible organization.
3. Ensure that no contractor may require the eligible organization to purchase any or all electronic services from the contractor or from any subsidiary of the contractor or from any company for which the contractor has an interest.

4. The contractor will make alternative means available to any electronic biller to obtain such services.
5. Ensure that all Medicare electronic transmitters have equal access to any services that CMS requires Medicare contractors to make available to eligible organizations or their billing services, regardless of the electronic billing technique or service they choose. Equal access will be granted to any services the contractor sells directly, indirectly, or by arrangement.
6. Notify the provider within 2 business days if any transmitted data are received in an unintelligible or garbled form.

NOTICE:

Federal law shall govern both the interpretation of this document and the appropriate jurisdiction and venue for appealing any final decision made by CMS under this document.

This document shall become effective when signed by the eligible organization. The responsibilities and obligations contained in this document will remain in effect as long as Medicare risk adjustment data are submitted to CMS or the contractor. Either party may terminate this arrangement by giving the other party (30) days written notice of its intent to terminate. In the event that the notice is mailed, the written notice of termination shall be deemed to have been given upon the date of mailing, as established by the postmark or other appropriate evidence of transmittal.

C. Signature:

I am authorized to sign this document on behalf of the indicated party and I have read and agree to the foregoing provisions and acknowledge same by signing below.

Eligible Organization's

Name: ANTHEM BLUE CROSS BLUE SHIELD

Title: ANTHEM SENIOR ADVANTAGE

Address: 1351 WILLIAM HOWARD TAFT

City/State/ZIP: CINTI, OHIO 45206

By: [Signature]

Title: Manager, Reconciliation Date: 5-19-04

cc: Regional Offices

Please retain a copy of all forms submitted for your records.

Complete and mail this form with original signature to:

M+CO EDI Enrollment

P.O. Box 100275, AG-570

Columbia, SC 29202-3275



Medicare Advantage Organization

Electronic Data Interchange Enrollment Form

MANAGED CARE ELECTRONIC DATA INTERCHANGE (EDI) ENROLLMENT FORM

ONLY for the Collection of Risk Adjustment Data and/or

With Medicare Advantage Eligible Organizations

H9886

The eligible organization agrees to the following provisions for submitting Medicare risk adjustment data electronically to The Centers for Medicare & Medicaid Services (CMS) or to CMS's contractors.

A. The Eligible Organization Agrees:

1. That it will be responsible for all Medicare risk adjustment data submitted to CMS by itself, its employees, or its agents.
2. That it will not disclose any information concerning a Medicare beneficiary to any other person or organization, except CMS and/or its contractors, without the express written permission of the Medicare beneficiary or his/her parent or legal guardian, or where required for the care and treatment of a beneficiary who is unable to provide written consent, or to bill insurance primary or supplementary to Medicare, or as required by State or Federal law.
3. That it will ensure that every electronic entry can be readily associated and identified with an original source document. Each source document must reflect the following information:
 - Beneficiary's name,
 - Beneficiary's health insurance claim number,
 - Date(s) of service,
 - Diagnosis/nature of illness
4. That the Secretary of Health and Human Services or his/her designee and/or the contractor has the right to audit and confirm information submitted by the eligible organization and shall have access to all original source documents and medical records related to the eligible organization's submissions, including the beneficiary's authorization and signature.
5. Based on best knowledge, information, and belief, that it will submit risk adjustment data that are accurate, complete, and truthful.
6. That it will retain all original source documentation and medical records pertaining to any such particular Medicare risk adjustment data for a period of at least 6 years, 3 months after the risk adjustment data is received and processed.
7. That it will affix the CMS-assigned unique identifier number of the eligible organization on each risk adjustment data electronically transmitted to the contractor.
8. That the CMS-assigned unique identifier number constitutes the eligible organization's legal electronic signature.
9. That it will use sufficient security procedures to ensure that all transmissions of documents are authorized and protect all beneficiary-specific data from improper access.
10. That it will establish and maintain procedures and controls so that information concerning Medicare beneficiaries, or any information obtained from CMS or its contractor, shall not be used by agents, officers, or employees of the billing service except as provided by the contractor (in accordance with § 1106(a) of the Act).
11. That it will research and correct risk adjustment data discrepancies.



H99 9886

12. That it will notify the contractor or CMS within 2 business days if any transmitted data are received in an unintelligible or garbled form.

B. The Centers for Medicare & Medicaid Services Agrees To:

1. Transmit to the eligible organization an acknowledgment of risk adjustment data receipt.
2. Affix the intermediary/carrier number, as its electronic signature, on each response/report sent to the eligible organization.
3. Ensure that no contractor may require the eligible organization to purchase any or all electronic services from the contractor or from any subsidiary of the contractor or from any company for which the contractor has an interest.
4. The contractor will make alternative means available to any electronic biller to obtain such services.
5. Ensure that all Medicare electronic transmitters have equal access to any services that CMS requires Medicare contractors to make available to eligible organizations or their billing services, regardless of the electronic billing technique or service they choose. Equal access will be granted to any services the contractor sells directly, indirectly, or by arrangement.
6. Notify the provider within 2 business days if any transmitted data are received in an unintelligible or garbled form.

NOTICE:

Federal law shall govern both the interpretation of this document and the appropriate jurisdiction and venue for appealing any final decision made by CMS under this document.

This document shall become effective when signed by the eligible organization. The responsibilities and obligations contained in this document will remain in effect as long as Medicare risk adjustment data are submitted to CMS or the contractor. Either party may terminate this arrangement by giving the other party (30) days written notice of its intent to terminate. In the event that the notice is mailed, the written notice of termination shall be deemed to have been given upon the date of mailing, as established by the postmark or other appropriate evidence of transmittal.

C. Signature:

I am authorized to sign this document on behalf of the indicated party and I have read and agree to the foregoing provisions and acknowledge same by signing below.

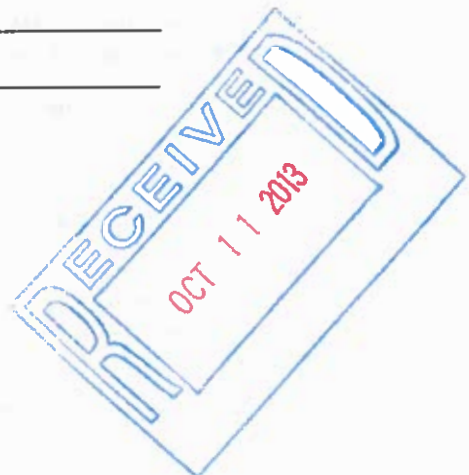
Eligible Organization's Name: The WellPoint Companies, Inc.

Contract Number: H9886

Signature: Jamille Welch

Name: J. Camille Welch

Title: Director, Medicare Risk & Recovery





**MEDICARE
CSSC OPERATIONS**

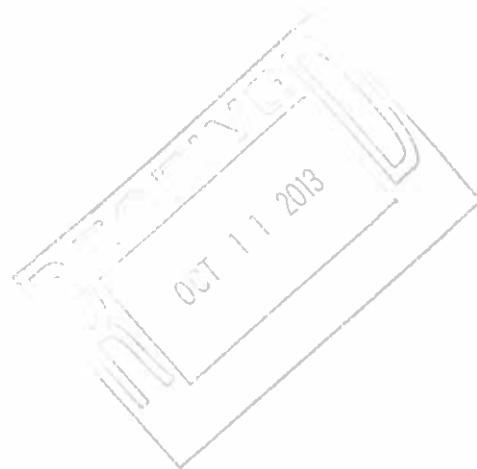
Dial up / Modem _____

GENTRAN _____

Please return the completed submitter application, EDI Agreement and CONNECT:DIRECT dataset specifications, if applicable, to CSSC Operations at the address below.

Palmetto GBA
CSSC Operations, AG-570
2300 Springdale Drive, Bldg. One ■ Camden, South Carolina ■ 29020
www.csscoperations.com
A CMS Contracted Intermediary and Carrier

2



CP D 15343023100003 15343 05005



Medicare Advantage Organization

Electronic Data Interchange Enrollment Form

MANAGED CARE ELECTRONIC DATA INTERCHANGE (EDI) ENROLLMENT FORM

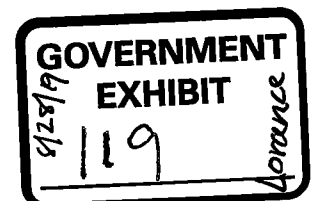
ONLY for the Collection of Risk Adjustment Data and/or

With Medicare Advantage Eligible Organizations

The eligible organization agrees to the following provisions for submitting Medicare risk adjustment data electronically to The Centers for Medicare & Medicaid Services (CMS) or to CMS's contractors.

A. The Eligible Organization Agrees:

1. That it will be responsible for all Medicare risk adjustment data submitted to CMS by itself, its employees, or its agents.
2. That it will not disclose any information concerning a Medicare beneficiary to any other person or organization, except CMS and/or its contractors, without the express written permission of the Medicare beneficiary or his/her parent or legal guardian, or where required for the care and treatment of a beneficiary who is unable to provide written consent, or to bill insurance primary or supplementary to Medicare, or as required by State or Federal law.
3. That it will ensure that every electronic entry can be readily associated and identified with an original source document. Each source document must reflect the following information:
 - Beneficiary's name,
 - Beneficiary's health insurance claim number,
 - Date(s) of service,
 - Diagnosis/nature of illness
4. That the Secretary of Health and Human Services or his/her designee and/or the contractor has the right to audit and confirm information submitted by the eligible organization and shall have access to all original source documents and medical records related to the eligible organization's submissions, including the beneficiary's authorization and signature.
5. Based on best knowledge, information, and belief, that it will submit risk adjustment data that are accurate, complete, and truthful.
6. That it will retain all original source documentation and medical records pertaining to any such particular Medicare risk adjustment data for a period of at least 6 years, 3 months after the risk adjustment data is received and processed.
7. That it will affix the CMS-assigned unique identifier number of the eligible organization on each risk adjustment data electronically transmitted to the contractor.
8. That the CMS-assigned unique identifier number constitutes the eligible organization's legal electronic signature.
9. That it will use sufficient security procedures to ensure that all transmissions of documents are authorized and protect all beneficiary-specific data from improper access.
10. That it will establish and maintain procedures and controls so that information concerning Medicare beneficiaries, or any information obtained from CMS or its contractor, shall not be used by agents, officers, or employees of the billing service except as provided by the contractor (in accordance with §1106(a) of the Act).
11. That it will research and correct risk adjustment data discrepancies.



R D 15343C23100003 1534300006

H1394



- 12. That it will notify the contractor or CMS within 2 business days if any transmitted data are received in an unintelligible or garbled form.

B. The Centers for Medicare & Medicaid Services Agrees To:

- 1. Transmit to the eligible organization an acknowledgment of risk adjustment data receipt.
- 2. Affix the intermediary/carrier number, as its electronic signature, on each response/report sent to the eligible organization.
- 3. Ensure that no contractor may require the eligible organization to purchase any or all electronic services from the contractor or from any subsidiary of the contractor or from any company for which the contractor has an interest.
- 4. The contractor will make alternative means available to any electronic biller to obtain such services.
- 5. Ensure that all Medicare electronic transmitters have equal access to any services that CMS requires Medicare contractors to make available to eligible organizations or their billing services, regardless of the electronic billing technique or service they choose. Equal access will be granted to any services the contractor sells directly, indirectly, or by arrangement.
- 6. Notify the provider within 2 business days if any transmitted data are received in an unintelligible or garbled form.

NOTICE:

Federal law shall govern both the interpretation of this document and the appropriate jurisdiction and venue for appealing any final decision made by CMS under this document.

This document shall become effective when signed by the eligible organization. The responsibilities and obligations contained in this document will remain in effect as long as Medicare risk adjustment data are submitted to CMS or the contractor. Either party may terminate this arrangement by giving the other party (30) days written notice of its intent to terminate. In the event that the notice is mailed, the written notice of termination shall be deemed to have been given upon the date of mailing, as established by the postmark or other appropriate evidence of transmittal.

C. Signature:

I am authorized to sign this document on behalf of the indicated party and I have read and agree to the foregoing provisions and acknowledge same by signing below.

Eligible Organization's Name: HMO COLORADO, INC.

Contract Number: H1394

Signature: _____

Name: Jeff Deshay

Title: Director, Reporting & Data Analysis

RDD 15343023100003 15343 0007



Address: 700 Broadway

City/State/ZIP: Denver CO 80273

Phone: (724) 996-5258

Email: jeff.deshay@anthem.com

Date: 12/2/2015

cc: Regional Offices

Please retain a copy of all forms submitted for your records.

Complete and mail this form with original signature to:

**Medicare Advantage EDI Enrollment
CSSC Operations AG-570
2300 Springdale Drive Bldg. One
Camden, SC 29020-1728**

**Phone (877) 534-2772
www.csscoperations.com**

Review and Certify Risk Adjustment Data Confirmation - Payment Year 2014 (Dates of Service 2013)

Confirmation #: 1172

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 ANTHEM HEALTH PLANS, INC. (H5854), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 005, 801, 803, 805, 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 misrepresentation 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 for the period of January 1, 2013, to December 31, 2013, all risk adjustment data (INPATIENT HOSPITAL, OUTPATIENT HOSPITAL, AND PHYSICIAN) available to the MA Organization as of January 31, 2015, with respect to the above-stated MA and MA-PD 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.

MARC RUSSO on behalf of

ANTHEM HEALTH PLANS, INC. (H5854)

6/26/2015

Review and Certify Risk Adjustment Data Confirmation

Confirmation #: 530

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 AMERIGROUP GEORGIA MANAGED CARE COMPANY, INC. (H4211), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 001, 003, 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 misrepresentation 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 for the period of January 1, 2012, to December 31, 2012, all risk adjustment data (INPATIENT HOSPITAL, OUTPATIENT HOSPITAL, AND PHYSICIAN) available to the MA Organization as of January 31, 2014, with respect to the above-stated MA and MA-PD 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.

MARC RUSSO on behalf of

AMERIGROUP GEORGIA MANAGED CARE COMPANY, INC. (H4211)

4/30/2014





FAQ'S REGARDING RETROSPECTIVE MEDICAL RECORD REVIEW AND MEDICONNECT GLOBAL

Question: **Who is MediConnect?**

Answer: MediConnect is a leading document management company, located in South Jordan, Utah, that provides medical record retrieval services for health and life insurance companies and law firms. In addition, MediConnect provides other medical record management and coding services as part of its record retrieval services.

Question: **What services is MediConnect performing on behalf of WellPoint?**

Answer: MediConnect is assisting WellPoint in retrieving Medicare Advantage member medical records from physicians throughout the WellPoint regions and from a select number of hospitals. Like last year, CV Infosys, another WellPoint vendor, will be retrieving record summaries from all other hospitals.

Once the records are retrieved from the provider, MediConnect will perform a record review to capture diagnosis data from the record for submission to CMS as part of WellPoint's risk adjustment data submissions.

This review is referred to as the retrospective medical record review.

Question: **Why is MediConnect assisting in performing the retrospective medical record review?**

Answer: CMS *requires* Medicare Advantage health plans to submit all ICD9 codes for all Medicare Advantage members in order to ensure adequate and accurate risk adjusted payment to the Medicare Advantage health plan. While WellPoint collects all submittable ICD 9 codes from available encounter data (e.g. claim files and encounter files), WellPoint also collects ICD9 codes from medical record documentation in order to ensure that it is meeting its CMS obligations concerning the submission of *all* member diagnosis data.

In addition, CMS requires that medical record documentation support the ICD9 code selected and substantiate that proper coding guidelines were followed. Therefore, the retrospective medical record review will ensure that ICD9 codes have been reported by the provider correctly.

Question: **Is the retrospective medical record review an audit?**

Answer: No, this is not an audit. This is an oversight activity related to the collection and reporting of member diagnosis data which must be supported by medical record documentation as required by CMS.

Question: **Does the retrospective medical record review process apply to all medical records?**

Answer: No, under the CMS-HCC model of payment, Medicare Advantage health plans may only submit diagnosis data that is obtained from physicians and IP or OP hospital visits or encounters. This means that we will be collecting records from physicians and hospitals only.

MediConnect is assisting WellPoint in collecting medical records from **all** physicians and select hospitals. WellPoint is using another vendor, CV Infosys, to assist in collecting record summaries from all other hospitals.

Question: **Is WellPoint asking for medical records for all dates of service?**

Answer: No. We are asking that providers supply medical records having a date of service of January 1, 2010 to current date.

Question: **Are we collecting medical records for all Medicare Advantage members?**

Answer: No. WellPoint will be targeting Medicare Advantage members who are flagged using an algorithm that has been developed based on claims and pharmacy data. The flagged member names will be compiled into a chase list that will be supplied to MediConnect to initiate the retrieval process.

Question: **What is the provider notification process?**

Answer: Beginning on May 16, 2011, MediConnect will initiate the record retrieval process. The process begins with telephonic outreach to the provider which is followed by a written request. The written request addresses the role of MediConnect, the purpose of the medical record retrieval request, the action being requested (i.e. submission of the entire medical record), the name of the member and the dates of service being requested. A sample of the provider record request letter is attached at the end of this document.

Question: **When does the provider need to submit the requested medical records?**

Answer: The provider should supply the medical records within 2 weeks following receipt of the request.

Question: **What should the provider do if the information being requested does not appear in the medical record (e.g., the provider did not actually see the patient during the requested date(s) of service)?**

Answer: The provider should return the request to MediConnect with an explanation that no information relative to the request appears on the patient's medical record.

Question: **How does the provider submit a medical record? Are there different submission options?**

Answer: The medical record(s) may be returned to MediConnect using the following methods:

1. Secure Fax: 800-391-1807
2. Mail: Prepaid Postage
3. EMR Integration
 - a. Remote access to Provider's EMR system by MediConnect
 - b. Print to file and (1) electronic upload or (2) save to encrypted CD, DVD or thumb drive
 - c. Implement secure FTP with Provider
4. Secure FTP Transfer
5. Provider Portal Upload
 - a. www.submitrecords.com/
 - b. Password: secure62
 - c. Click select and select records to upload from provider's Windows Explorer.
 - d. Records (PDF or TIF) can be uploaded individually or in batch.
6. Onsite Scanning

Question: **Once the medical record is submitted to MediConnect, what happens?**

Answer: Upon receipt of the medical record, it will be imaged and uploaded into MediConnect's web-based medical record management system. A MediConnect coder will review the medical record and the medical conditions reported on the record will be assigned a diagnosis code in the web-based medical record management system. Diagnoses codes identified in the record will be extracted into a file and provided to WellPoint.

Question: **What happens with the ICD9 codes collected from the medical records?**

Answer: MediConnect will provide to WellPoint a file of all ICD9 codes extracted from the medical record. This information will then be submitted to CMS through the CMS risk adjustment data processing system. This system is designed for the submission of member diagnosis data collected from all Medicare Advantage health plans.

Question: **Is the provider required to comply with the request for medical records?**

Answer: Yes. CMS requires that the MA health plan submit to CMS **all** acceptable diagnosis codes for a Medicare Advantage member. The medical record is used for purposes of extracting ICD9 codes that were not reported on the member's claim or encounter file. In addition, CMS requires that medical record documentation support the ICD9 code selected and substantiate that proper coding guidelines were followed. Therefore, the review process will help ensure that the ICD9 codes have been reported accurately.

Also, in accordance with the language in the provider agreement/terms and conditions of payment, **all providers** are required to comply with WLP's request for medical records to facilitate WellPoint's review of risk adjustment data.

Question: **Does the provider need a HIPAA authorization or release in order to supply the medical records?**

Answer: No. The HIPAA Privacy Rule allows for the disclosure of protected health information without a HIPAA authorization form or release of information when such information is being disclosed for payment, treatment and health care operations (45 CFR 164.506). The release of medical records for purpose of the Medicare Advantage health plan extracting diagnosis data to be submitted to CMS for risk adjustment purposes is considered a health care operation activity.

Question: **Will the provider be reimbursed for supplying the medical records?**

Answer: No, the provider will not be paid for producing the record. CMS requires that MA health plans support their member diagnosis data with medical record documentation. This requirement, as well as the provider agreement/terms and conditions of payment, mandate that **all providers** comply with WellPoint's request for medical records to facilitate WellPoint's review of risk adjustment data.

Question: **Who can I contact if I have questions?**

Answer: Matt Cogdill, Manager of Retrospective Risk Adjustment Programs
(614)880-6268
brian.cogdill@wellpoint.com

Question: **What is the timeline for the medical record retrieval process?**

Answer: See below.

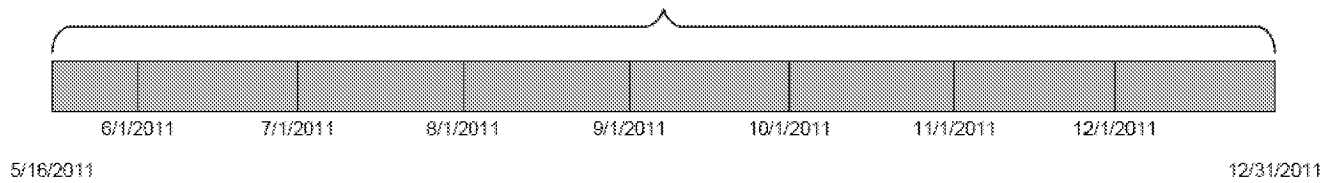
MediConnect Record Retrieval Timeline

5/16/2011 - 12/31/2011

MediConnect begins to request records starting 5/16/11 and continues requesting or pursuing records through 12/31/11. Providers mail, fax or upload records to MediConnect throughout this period.

As records are received, records are imaged and uploaded into record management system. Diagnosis codes are extracted from record and populated into data file. Produces data file 2 x month for submission to CMS.

Note: 5/16/2011 is a tentative begin date



Empire Blue Cross Blue Shield Teams With MediConnect Global, Inc.



July 1, 2010

Empire Blue Cross Blue Shield (Empire) is pleased to announce its collaboration with MediConnect Global, Inc. ("MediConnect"), a leading records retrieval and electronic document management company that specializes in medical records retrieval, digitization, coding and delivery via the internet. MediConnect's web based workflows will help reduce time and improve efficiency and costs associated with record retrieval, coding, and document management.



CMS requires that we perform oversight activities related to the collection and reporting of member diagnosis data which must be supported by medical record documentation. As such, Empire has engaged MediConnect to perform retrospective reviews of our Medicare Advantage member medical records. MediConnect's role in record retrieval, review and coding will be instrumental in helping Empire ensure risk adjustment payment integrity and accuracy.

If you have any questions regarding MediConnect Global, Inc., or this record retrieval process contact your Provider Services Representative.

Services provided by Empire HealthChoice HMO, Inc. and/or Empire HealthChoice Assurance, Inc., licensees of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield plans. The Blue Cross and Blue Shield names and symbols are registered marks of the Blue Cross and Blue Shield Association.

MediConnect Global, Inc. is an independent company providing medical record retrieval services.

Excludes Simply			
Membership			
Program			2015 Program Actual
Program Expense Aligned to Revenue Payment Year			
Program	2015 Unit Cost	2015 Volumes	2015 Actual
Housecalls			
In Office			
Retro Charts ¹	\$ 37	511,190	\$ 18,811,606
Non-HDC Total ²			\$ 66,081,057

Program Revenue Aligned to Expense Year			
Program	2015 Unit Revenue	2015 Volumes	Revenue on 2015 Actual
Housecalls			
In Office			
Retro Charts	\$ 170	\$ 511,190	\$ 112,929,769
Non-HDC Total			

Program Revenue ROI (i.e. Revenue/Expense)		Revenue on 2015 Budget
Program		
Housecalls		3.77
In Office		1.31
Retro Charts		6.00
Non-HDC Total		3.25

Notes

¹ 2015 include \$1.3M of re-code of 2014 charts; 2016 include \$2.4M of targeting improvement benefits (i.e. worth \$5/chart cost impr
 [Redacted]

⁴ Program volumes and \$ are aligned with the revenue payment year