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

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

