**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF TENNESSEE**
**NASHVILLE DIVISION**

| | |
|---|---|
| UNITED STATES OF AMERICA,<br><br>Plaintiff-Intervenor,<br><br>v.<br><br>CIGNA CORPORATION, BRAVO HEALTH MID-ATLANTIC, INC., BRAVO HEALTH PENNSYLVANIA, INC., CIGNA HEALTH & LIFE INS. CO., CIGNA HEALTHCARE OF CALIFORNIA, INC., CIGNA HEALTHCARE OF COLORADO, INC., CIGNA HEALTHCARE OF CONNECTICUT, INC., CIGNA HEALTHCARE OF GEORGIA, INC., CIGNA HEALTHCARE OF NORTH CAROLINA, INC., CIGNA HEALTHCARE OF SOUTH CAROLINA, INC., CIGNA HEALTHCARE OF ST. LOUIS, INC., HEALTHSPRING OF FLORIDA, INC., and HEALTHSPRING LIFE & HEALTH INS. CO.,<br><br>Defendants. | **Civil Action No. 3:21-cv-00748**<br>**JUDGE RICHARDSON**<br>**MAGISTRATE JUDGE FRENSLEY**<br><br>**JURY TRIAL DEMANDED** |

# COMPLAINT IN INTERVENTION OF THE UNITED STATES OF AMERICA

## TABLE OF CONTENTS

The United States of America (the "Government"), by and through its attorneys, Damian Williams, United States Attorney for the Southern District of New York, and Mark H. Wildasin, United States Attorney for the Middle District of Tennessee, brings this Complaint-In-Intervention seeking damages and penalties against Defendants, under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and, in the alternative, under the common law, and alleges as follows:

## PRELIMINARY STATEMENT

1. From 2012 to 2019 (the "Relevant Period"), Defendants fraudulently submitted false and invalid patient diagnosis information to the Government to improperly inflate the payments they received from the Medicare Part C program, also called the Medicare Advantage Program. Specifically, for risk adjustment payment purposes, Defendants submitted to the Centers for Medicare and Medicaid Services ("CMS") false and invalid diagnoses of certain serious and chronic medical conditions that were based solely on forms completed during visits to patients' homes conducted by vendors retained and paid by Defendants. Defendants knew that: (i) the vendor healthcare providers who conducted these home visits did not perform or order the testing, imaging, or other diagnostic steps necessary to reliably diagnose these conditions; (ii) the patients did not receive any treatment for the purported medical conditions during the home visits; (iii) no other healthcare providers, such as the patients' primary care physicians, had diagnosed or treated the patients for these medical conditions during the year in which the home visits occurred; and (iv) these diagnoses did not comply with CMS's requirements for coding diagnoses. Nevertheless, Defendants submitted these diagnoses to CMS to claim increased payments, and falsely certified on an annual basis that their diagnosis data submissions were "accurate, complete, and truthful."

2. Defendant Cigna Corporation, through its subsidiaries and affiliates, owns and operates numerous Medicare Advantage Organizations ("Cigna MA Organizations") that administer Medicare Advantage healthcare plans ("Cigna MA Plans"). The Cigna MA Organizations, like other MA organizations, are responsible for covering the cost of services rendered by healthcare providers (such as hospitals and doctors) to Medicare beneficiaries enrolled in Cigna MA Plans. The Cigna MA Organizations, in turn, receive monthly capitated payments from CMS for providing such coverage. CMS adjusts these payments for demographic and health status "risk" factors that affect beneficiaries' expected healthcare expenditures. To make these adjustments, CMS relies on "risk adjustment" data, including medical diagnosis codes, submitted by MA organizations. This payment model is designed to pay MA organizations more to provide healthcare for sicker enrollees (expected to incur higher healthcare costs) and less for healthier enrollees (expected to incur lower costs). MA organizations are required under their contract with CMS and pursuant to applicable federal regulations to certify the "accuracy, completeness, and truthfulness" of the diagnosis data submitted to CMS.

3. Cigna[1] contracted with several vendors to conduct home visits of Cigna MA Plan members across the country as part of its so-called "360 comprehensive assessment" program. The home visits were typically conducted by nurse practitioners, and on occasion by other non-physician healthcare providers such as registered nurses and physician assistants (together, these individual providers are referred to as the "Vendor HCPs"). Based on each visit, the Vendor HCP completed a Cigna-created form (the "360 form") that included a check-the-box, multi-page list of a wide range of medical conditions. Cigna collected the completed 360 forms and

[1] Defendant Cigna Corporation and the Defendant Cigna MA Organization are referred to collectively as "Cigna" or "Defendants."

had its coding teams identify diagnosis codes that corresponded to the recorded medical conditions and then submitted those to CMS for risk adjustment payment purposes.

4. Cigna expressly structured the 360 home visits for the primary purpose of capturing and recording lucrative diagnosis codes that would significantly increase the monthly capitated payments made by CMS to the Cigna MA Organizations. The purpose of the visits was not to treat patients' medical conditions. Indeed, Cigna explicitly prohibited the Vendor HCPs from providing actual patient treatment or care. As Cigna explicitly acknowledged in an internal 2017 document discussing the 360 program, "[t]the primary goal of a 360 visit is administrative code capture and not chronic care or acute care management." When identifying Plan members to receive home visits, Cigna targeted beneficiaries who were likely to yield the greatest risk score increases.

5. Cigna knew that certain conditions listed on the 360 form could not be reliably diagnosed in a home setting and without extensive diagnostic testing or imaging. And Cigna also knew that the Vendor HCPs did not have the equipment necessary to conduct such testing and imaging in patients' homes, and Cigna did not permit the Vendor HCPs to order the necessary diagnostic tests or make referrals to providers who would. For example, when they went to patients' homes, the Vendor HCPs generally lacked equipment for collecting blood or urine samples and imaging technology such as an x-ray machine or echocardiographic equipment.

6. Cigna also knew that the scope of the in-home assessments was limited. The Vendor HCPs spent limited time with the patients and did not conduct a comprehensive physical examination. When completing the assessments and recording the diagnoses, the Vendor HCPs relied largely on the patients' own self-assessments and their responses to various basic screening questions. The Vendor HCPs did not have access to the patients' full medical history

and typically did not obtain or review relevant records from the patients' primary care physicians in advance of the visit.

7. Cigna submitted the diagnoses recorded via the 360 home visits to CMS. In tens of thousands of instances, Cigna submitted diagnosis codes that represent serious, complex medical conditions that (a) were based only on the home visits conducted by the Vendor HCPs; (b) required specific testing or imaging to be reliably diagnosed, which was not performed; (c) were not supported by the information documented on the 360 form completed by the Vendor HCPs; and (d) were not reported by any other healthcare provider who saw the Plan member during the year in which the home visit occurred. (These codes are referred to as "the Invalid Diagnoses.") The Invalid Diagnoses included, but are not limited to, diagnoses for chronic kidney disease, congestive heart failure, rheumatoid arthritis, and diabetes with renal complications. These kinds of conditions can be challenging to detect, frequently requiring multiple visits to specialists and extensive testing, such as blood or urine tests, imaging studies, or invasive diagnostic procedures. It is these Invalid Diagnoses—and the submission of diagnosis codes associated with these Invalid Diagnoses to CMS for risk adjustment payment purposes—that are specifically at issue in this case.

8. Cigna exercised extensive control over the 360 home visit program and dictated the manner in which the Vendor HCPs completed the visits. Cigna created and designed the 360 forms to be used by the vendors, developed the training on how to conduct the visits and record diagnoses, and provided guidance on how to report diagnoses.

9. Cigna exerted pressure on the Vendor HCPs to record high-value diagnoses that significantly increased risk adjustment payments. Cigna management identified at least twelve classes of generic chronic diagnoses that they thought were "often underdiagnosed" among

Cigna MA Plan members and, through trainings and seminars, encouraged the Vendor HCPs to make these particular diagnoses during the home visits.

10. Cigna closely tracked the volume and nature of the diagnoses generated by each vendor's home visits. Cigna also tracked how the diagnoses affected risk-adjusted payments. Cigna provided trainings to vendors to improve their "performance" when they failed to deliver the expected level of high-value diagnosis codes.

11. Indeed, Cigna tracked the return on investment ("ROI") of the 360 home visit program by comparing the costs of the in-home visits (*i.e.*, payments to vendors) against the additional Part C payments generated by increased risk scores. For example, according to an internal report, Cigna determined that, during the first nine months of 2014, one vendor's 6,658 in-home visits resulted in more than an additional $14 million in Part C payments, which dwarfed the approximately $2.13 million that Cigna paid to the vendor. According to another ROI report sent to Cigna's chief medical officer, Cigna spent about $18.8 million in total on home visits for a projected profit of approximately $61.8 million in 2014. Significantly, when calculating the costs for its ROI calculation, Cigna included only the payments to vendors for conducting the home visits–but did not count the additional costs that would be incurred for actually treating the additional medical conditions that the Vendor HCPs had supposedly diagnosed.

12. Cigna even tracked the performance of individual Vendor HCPs. Cigna reviewed the 360 forms completed by specific Vendor HCPs and compared the number of diagnoses individual providers recorded to the average number of diagnoses typically recorded. When specific Vendor HCPs were found to have captured fewer diagnoses than expected, Cigna asked the vendor to prepare a "performance improvement plan" for the HCP.

13. The Invalid Diagnoses generated by the 360 home visits did not conform with the International Classification of Diseases ("ICD") Office Guidelines for Coding and Reporting (the "ICD Guidelines"), as required by applicable federal regulations. The diagnoses did not affect patient care, treatment, or management during the home visit, as required under the ICD Guidelines, and thus were ineligible for risk adjustment. For the Invalid Diagnoses, the Plan members did not receive treatment or care for the diagnosed condition by the Vendor HCP, or for that matter by any other healthcare provider during the year in which the home visit occurred. In addition, the Invalid Diagnoses were not supported by the minimal information recorded on the 360 forms, in violation of the ICD Guidelines' medical record documentation requirement. The forms on their face did not contain sufficient information to support the Invalid Diagnoses. At best, the recorded diagnoses could be classified as uncertain, probable, or merely suspected, which rendered them invalid for diagnosis coding purposes under the ICD Guidelines and ineligible for risk adjustment.

14. Cigna knew that, pursuant to the risk adjustment system, the payment that CMS made for a Medicare Advantage patient depended directly on the diagnoses that were submitted to CMS for that patient. Cigna also knew that it had both regulatory and contractual obligations to ensure that the diagnosis data submissions were accurate and truthful, conformed with the ICD Guidelines, and were otherwise valid for risk adjustment purposes. Yet Cigna implemented the 360 home visit program knowing that certain diagnoses listed on the 360 forms could not be reliably made in the home setting given the constraints of the program and the limited information and tools available to the Vendor HCPs. In fact, this was a concern raised by Cigna's own compliance staff. Cigna also knew that the Invalid Diagnoses were not reported by other providers who had treated the Plan members during the year because these providers would have reported any such diagnoses to the Cigna MA Organization. Cigna made risk adjustment

submissions that included the Invalid Diagnoses with knowledge that the diagnoses were false and violated the ICD Guidelines, or at the very least with reckless disregard of whether the submissions were true. Cigna then falsely certified to CMS that the diagnosis data from the home visits was "accurate, complete, and truthful" based on its "best knowledge, information, and belief."

15. Through the operation of its 360 home visit program, Cigna submitted codes for tens of thousands of Invalid Diagnoses to CMS that constituted false claims for payment. Based on these unlawful false claims, Cigna improperly received tens of millions of dollars in risk adjustment payments from CMS, in violation of both the FCA and the common law. If CMS had known that Cigna had submitted false diagnosis codes based on these Invalid Diagnoses, CMS would not have made risk adjustment payments based on those specific diagnosis codes or would have taken other appropriate actions to ensure that Cigna did not retain risk adjustment payments to which it was not entitled, including by recouping payments through administrative processes, payment adjustments, or enforcement actions.

## JURISDICTION AND VENUE

16. 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.

17. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because Defendants transact business in this District and because a substantial part of the events giving rise to the claims herein occurred within this District. For example, significant decisions regarding the structure and operation of the 360 home visit program were made by Cigna's employees, including its then-chief medical officer, in Nashville, Tennessee.

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

## THE PARTIES

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

20. Relator Robert A. Cutler is an attorney who previously worked for a Cigna vendor, Texas Health Management LLC ("THM"). In 2017, Relator filed a *qui tam* complaint under the False Claims Act in the Southern District of New York. On information and belief, Mr. Cutler is a resident of Connecticut. Upon Cigna's motion, this case was transferred to this District on or about September 30, 2021.

21. Defendant Cigna Corporation is a Delaware corporation with headquarters at 900 Cottage Grove Road in Bloomfield, Connecticut. Cigna Corporation, through its subsidiaries and affiliates, owns and operates MA organizations across the United States. Cigna Corporation, through its subsidiaries and affiliates, currently operates MA plans in at least 25 states and the District of Columbia.

22. In January 2012, Cigna Corporation acquired HealthSpring, Inc. and its subsidiaries, including Bravo Health and HealthSpring of Florida. HealthSpring owned and operated MA organizations in various states. After the acquisition, Cigna Corporation owned and operated the MA organizations previously owned and operated by HealthSpring. Also, after the acquisition, Cigna often referred to itself as "Cigna-HealthSpring" or "C-HS." References to "Cigna" in this complaint include, where relevant, HealthSpring.

23. Through the Cigna MA Organizations, Cigna entered into annual contracts with CMS to offer its MA plans to Medicare beneficiaries. In addition, through the Cigna MA Organizations, the Government pays Cigna billions of dollars each year to provide healthcare services and prescription drugs for the more than 500,000 beneficiaries enrolled in Cigna MA Plans.

24. Defendant HealthSpring Life & Health Insurance Co., Inc. is a provider of insurance services and is located at 530 Great Circle Road, in Nashville, Tennessee. In 2018, HealthSpring of Alabama, Inc. and HealthSpring of Tennessee, Inc. merged with Health Spring Life & Health Insurance Co., Inc., all of which are or were MA organizations and held contracts with CMS to operate one or more MA plans during the Relevant Period.

25. Defendant Cigna Healthcare of Georgia, Inc. is a provider of insurance services and is located at Two Securities Center 3500 Piedmont Rd, Suite 2 in Atlanta, Georgia. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

26. Defendant Cigna Healthcare of Colorado, Inc. is a provider of insurance services and is located at 3900 East Mexico Avenue, Suite 1100 in Denver, Colorado. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

27. Defendant Bravo Health Mid-Atlantic, Inc. is a provider of insurance services and is located at 3601 O'Donnell Street in Baltimore, Maryland. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

28. Defendant Cigna Healthcare of Connecticut, Inc. is a provider of insurance services and is located at 901 Cottage Grove Road in Bloomfield, Connecticut. This defendant is

an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

29. Defendant Bravo Health Pennsylvania, Inc. is a provider of insurance services and is located at 1500 Spring Garden Street, Suite 800 in Philadelphia, Pennsylvania. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

30. Defendant Cigna Healthcare of South Carolina, Inc. is a provider of insurance services and is located at 4000 Faber Place Dr., Suite 220 in Charleston, South Carolina. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

31. Cigna Health & Life Ins. Co. is a provider of insurance services and is located at 900 Cottage Grove Road in Bloomfield, Connecticut. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

32. Defendant Cigna Healthcare of St. Louis, Inc. is a provider of insurance services and is located at 530 Great Circle Road in Nashville, Tennessee. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

33. Defendant Cigna Healthcare of California, Inc. is a provider of insurance services and is located at 400 North Brand Blvd in Glendale, California. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

34. Defendant Cigna Healthcare of North Carolina, Inc. is a provider of insurance services and is located at 701 Corporate Center Dr. in Raleigh, North Carolina. This defendant is

an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

35. Defendant HealthSpring of Florida, Inc. is a provider of insurance services and is located at 8600 NW 41st Street, Suite 201 in Doral, Florida. This defendant is an MA organization and has held contracts with CMS to operate one or more MA plans during the Relevant Period.

36. As discussed more fully below, Cigna employees in Nashville, Tennessee designed, implemented, and oversaw the operation of the 360 Program. In addition, Cigna operated the 360 Program—including, as relevant here, the 360 home visits—similarly throughout the country. Each of the Defendant Cigna MA Organizations submitted home visit-generated diagnoses to CMS for risk adjustment payment purposes and each followed the same guidelines and criteria when doing so. The same vendor was frequently retained to conduct home visits for members of multiple Cigna MA Plans and conducted the visits the same way regardless of which Defendant Cigna MA Organization operated the plan.

## THE FALSE CLAIMS ACT

37. 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.

38. 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[;]" or

ii. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]"

31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B).

39. "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*.

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

41. Finally, in addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim. *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 MA Organizations

42. 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*.

43. 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 services that they have rendered. CMS, in turn, pays the providers directly for each service based on payment rates established by it.

44. Under Medicare Part C, which is at issue in this case, Medicare beneficiaries can elect to receive Part A and Part B benefits through a Medicare Advantage plan such as those offered by the Cigna MA Organizations ("MA plan" or "Part C plan"). *See* 42 U.S.C.

§§ 1395w-21 to 1395w-28. The MA plans are operated and managed by MA organizations that contract with CMS; the MA organizations are in turn owned by private insurers such as Cigna. *See* 42 C.F.R. §§ 422.2, 422.503(b)(2).

45. Under Medicare Part C, beneficiaries receive healthcare services from providers, such as hospitals and doctors, who contract with and are paid by the MA organizations. 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 MA organization that operates the MA plan to receive payment from the MA organization. This data includes, but is not limited to, the date of the encounter, the services rendered, and the diagnosis codes depicting the medical conditions that were assessed, managed or treated during the encounter.

46. 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 MA organizations' obligations and responsibilities. *See generally* 42 C.F.R. Part 422. As discussed more fully below, *see infra* ¶¶ 87-90, CMS's Part C regulations require MA organizations to implement compliance procedures and programs and to submit annual attestations concerning the accuracy and truthfulness of the diagnosis data they submit to CMS to receive payments.

47. In addition to issuing regulations, CMS also has defined the MA organizations' obligations contractually. For example, to participate in Medicare Part C, MA organizations must execute a written agreement, or a renewal of the written agreement, with CMS on an annual basis for each of the MA plans they operate. The Defendant Cigna MA Organizations executed such agreements or renewals annually for all of the MA plans they operated during the Relevant Period. The relevant terms and conditions in the Part C annual agreements and renewals remained largely the same during the Relevant Period.

48. By executing these contracts, the Defendant Cigna MA Organizations agreed to comply with CMS's requirements relating to the submission of diagnosis data. Specifically, the contracts require the MA organizations to operate MA plans "in compliance with the requirements of [] applicable Federal statutes, regulations, and policies," including the "Medicare Managed Care Manual," and would "implement a compliance plan in accordance with [42 C.F.R.] § 422.503(b)(4)(vi)." As discussed further below, federal regulations and policies include requirements relating to the submission of diagnosis data.

### 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

49. Under the Medicare Advantage Program, CMS makes monthly capitated payments to MA organizations for each beneficiary enrolled in each of the MA organizations' MA plans. These per-member per-month capitated payments are pre-determined and fixed before the beginning of each payment year as part of a bidding and contract negotiation process specified by statute. These payments do not depend on the amount or types of services actually provided to the beneficiary during the payment year. Hereinafter, this Complaint refers to these payments as "PMPM payments."

50. Under the Medicare Advantage Program, CMS adjusts these PMPM payments for each beneficiary. These adjustments reflect the predicted cost of insuring each beneficiary, which is referred to as the predicted risk. The predicted risk reflects the beneficiary's age, sex, and other demographic factors and his or her health status. 42 U.S.C. § 1395w-23(a)(1)(C). CMS uses its risk adjustment payment system to adjust the capitated amounts based on the expected risk of insuring each beneficiary.

51. More specifically, for each beneficiary enrolled in a Part C plan, CMS calculates a risk score—also known as the risk adjustment factor or "RAF"—which acts as a multiplier for

purposes of determining the PMPM payment for that beneficiary. *See* 42 C.F.R. § 422.308(e).[2] Beneficiaries who have severe and chronic medical conditions have higher risk scores. Thus, CMS pays MA organizations more for beneficiaries with such medical conditions and less for beneficiaries without those conditions.

52. Since 2004, CMS has employed a Hierarchical Condition Category ("HCC") model to calculate the risk score for Medicare beneficiaries enrolled in MA plans. The HCC model takes into account both the demographic factors and health status of Medicare beneficiaries. *See* 42 C.F.R. § 422.2.

53. HCCs refer to disease groupings that include diagnosis codes that predict average healthcare spending. *See id*. Between 2004 and 2013, there were 70 HCCs in CMS's Part C risk adjustment model. Starting in 2014, when CMS revised its model, the number of HCCs increased to 79.

54. Each HCC correlates with the marginal predicted cost of medical care for a set of medical conditions included in a category. Some examples of HCC codes are HIV/AIDS (HCC 1), metastatic cancer and leukemia (HCC 8), rheumatoid arthritis (HCC 38), congestive heart failure (HCC 80), and ischemic stroke (HCC 100).[3] 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.

---

[2] 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 MA organization, 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.

[3] 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.

55. A particular Medicare beneficiary may have conditions that are included in none of the HCCs or may have conditions that are included in multiple HCCs. This will affect the PMPM payment calculated by CMS for that beneficiary.

56. 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 the MA organization $20,700 more in risk adjustment payments for that beneficiary in 2014.

57. To determine which HCCs, if any, apply to a particular Medicare beneficiary, the HCC model relies on the diagnoses—more specifically the diagnosis codes—assigned to the beneficiaries. The MA organizations submit these diagnosis codes to CMS. They obtain the codes from various sources, including, but not limited to, the claims and encounter data submitted to them by healthcare providers that treat plan members. Whatever the source of the diagnosis codes, the MA organizations are responsible for their accuracy and truthfulness. *See* 42 C.F.R. § 422.504(i)(1) ("Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.").

58. ICD diagnosis codes are alphanumeric codes used by healthcare providers, insurance companies, and public health agencies to represent medical conditions; every disease, injury, infection, and symptom has its own code. The applicable ICD diagnosis codes are set forth in the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9") through October 1, 2015, and thereafter in the International Classification of Diseases,

Tenth Revision, Clinical Modification ("ICD-10") ("ICD Guidelines"). *See* 45 C.F.R. § 162.1002 (listing dates for use of medical data code sets). The particular ICD Guidelines provisions relevant to the allegations in this Complaint have remained the same during the Relevant Period. HHS regulations require that MA organizations submit data that conforms to the ICD, including the ICD Guidelines. *See* 42 C.F.R. § 422.310(d)(1) (requiring MA organizations to submit data that conforms to relevant national standards); 45 C.F.R. § 162.1002(a)(1) (determining that the ICD is a national standard).

59. 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 Part C beneficiary 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 56 above, the higher a Part C beneficiary's risk score, the higher the PMPM payments made by CMS to the MA organization.

### C. The Risk Adjustment Payment Process and Diagnosis Data Reporting Systems

60. 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.

- First, based on a face-to-face encounter between a healthcare provider and a Part C beneficiary, the provider documents the encounter in the beneficiary's medical record, including the beneficiary's illnesses or medical conditions.
- Second, the provider—or, most often, a coder working for the provider—assigns the diagnosis codes reflecting the beneficiary's medical conditions documented by the provider in the beneficiary's medical record for that encounter.

- Third, MA organizations like the Defendant Cigna MA Organizations receive claims data from the provider, which includes the diagnosis codes assigned by the provider or coder. Healthcare providers can transmit diagnosis codes to an MA Organization when they submit claims for payment for treating the beneficiary, in encounter records reporting the services rendered, or by alternative means.
- Fourth, the MA organizations submit the diagnosis codes to CMS using CMS' risk adjustment data submission systems.
- Finally, CMS relies on the submitted codes to map the beneficiary's diagnosis codes to HCCs and to determine each beneficiary's risk score or RAF, and the use that score to calculate the risk-adjusted PMPM payment for that beneficiary.

61. The CMS-HCC model relies upon MA organizations and their contracted providers, including hospitals and physicians, to correctly document and submit ICD diagnosis codes for their patients pursuant to the ICD Guidelines. When a Medicare Advantage insurer reports to CMS a relevant diagnosis for a covered patient, that reported diagnosis can directly increase the amount that CMS pays the insurer for providing coverage. A higher risk score translates into higher payments by CMS to the MA organization. Thus, the risk adjustment diagnosis codes that correspond to HCCs directly impact how much money CMS pays an MA organization. The CMS-HCC model does not predict any costs associated with a patient simply having a condition or having been diagnosed with a condition in the past. Rather, as explained above, the CMS-HCC model predicts expected costs based upon particular ICD diagnoses coded in conformance with the ICD Guidelines during the service year directly preceding the payment year.

62. CMS, through its regulations and guidance, has made clear to MA organizations like the Defendant Cigna MA Organizations that it relies on the risk-adjusting diagnosis codes to

determine and make accurate payments for each patient enrolled in a MA plan. "Accurate risk-adjusted payments rely on the diagnosis coding derived from a member's medical record." CMS, *2013 National Technical Assistance Risk Adjustment 101 Participant Guide* 13 (2013); *see also* 42 C.F.R. § 422.504(*l*).

63. During the Relevant Period, 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 calculated risk adjustment payments using a combination of RAPS and EDPS-submitted diagnosis data.

64. The data that MA organizations 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 MA organization. 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."[4] Each diagnostic cluster includes a distinct diagnosis that can increase a beneficiary's risk score.[5]

65. Each diagnosis cluster submitted by an MA organization is a claim for payment for purposes of the FCA because the reported diagnosis code in the cluster factors directly into

[4] This indicator allows MA organizations to correct or withdraw a false cluster by advising CMS to delete the inaccurate diagnosis code in that cluster.

[5] In the EDPS system, MA organizations similarly submit data with a number of components, known as "loops." ICD diagnosis codes are among the data that MA organizations are required to submit to CMS using EDPS.

CMS's risk adjustment calculations and impacts the resulting payments made by CMS to the MA organization for each beneficiary enrolled in the MA plan.

66. During the Relevant Period, CMS determined the PMPM payments made to MA organizations in three phases. First, CMS made an initial calculation based on the diagnosis data reported by the MA organization 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 MA organizations to submit such diagnosis data by September of the year preceding the payment year). This initial calculation determined the interim monthly payments that CMS made to the MA organization in the first six months of the payment year. Second, CMS recalculated the risk scores for beneficiaries enrolled in the MA organization's plans based on diagnosis data for medical encounters during the year immediately preceding the payment year (*e.g.*, diagnosis data from January through December 2012 for payment 2013). Based on that recalculation, CMS would make retroactive adjustments to payments made during the first half of the payment year and also update the interim PMPM payments for the second half of the payment year. Third, after the payment year ended but before MA organizations are required to submit their Risk Adjustment Attestations, CMS provided a further opportunity for the MA organizations to submit additional diagnosis data or correct the diagnosis data already submitted by deleting diagnoses (also referred to as making deletions or retractions). Based on the additional submissions or corrections, CMS recalculated the risk scores again "to determine if adjustments to payments [were] necessary." 42 C.F.R. § 422.310(g)(2). CMS would then make any necessary adjustments as part of the annul reconciliation process to ensure that the final payments to the MA organization were accurate.

67. In addition, since at least 2003, MA organizations and entities that submit risk adjustment data on their behalf have been required to execute Electronic Data Interchange

("EDI") agreements prior to submitting risk adjustment data. These EDI agreements are contracts pursuant to which the MA organizations attest to the accuracy of the data submitted. Even if another entity submits the data, the MA organizations are still responsible for the content of the submissions. *See, e.g.*, 2003 Regional Risk Adjustment Training for Medicare+Choice Organizations Participant Guide, § 6.1; 2004 Regional Risk Adjustment Training for Medicare+Choice Organizations Participant Guide, § 4.1; 2005 Risk Adjustment Data Basic Training for Medicare Advantage Organizations Participant Guide § 4.1; 2006 Risk Adjustment Data Basic Training for Medicare Advantage Organizations Participant Guide § 4.1; 2007 Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide § 4.1; 2008 Risk Adjustment Technical Assistance for Medicare Advantage Organizations Participant Guide § 4.1; Risk Adjustment 101 Participant Guide § 2.1 (2013). *See* also Medicare Managed Care Manual, Chapter 7, § 111.6.1 (Rev. 57, 08-13-04); *id*. § 120.2.1 (Rev. 114, 06-07-13). By executing these EDI agreements, the MA organizations promise that (i) they will be responsible for all risk adjustment data submitted to CMS by themselves, their employees, and their agents; (ii) they will submit risk adjustment data that is accurate, complete, and truthful based on best knowledge, information, and belief; (iii) they will research and correct risk adjustment data discrepancies; and (iv) CMS has the right to audit and confirm the risk adjustment data, including diagnoses, submitted by the MA organization, and the right of access to the beneficiaries' medical records to conduct such audits. During the Relevant Period, Cigna executed numerous EDI agreements.

**D. MA Organizations' Attestation Obligations**

68. Given the material impact of diagnoses in calculating payments, CMS requires MA organizations to ensure—and attest—that the diagnosis codes submitted for risk adjustment payments are accurate, complete, and truthful.

69. Medicare Advantage regulations require MA organizations, including the Cigna MA Organizations, to submit annual attestations to CMS about the validity of the diagnosis data they submit for the relevant payment year. *See* 42 C.F.R. § 422.504(l). The regulations further specify that the MA organizations' submission of their annual attestations is a condition of payment. *Id*.

70. In addition, the MA organizations' obligation to submit these annual attestations is included in their contracts with CMS. A copy of the attestation is attached to each contract. The contracts specify that "[a]s a condition of receiving a monthly payment under" the contract, the MA organization must "request payment … on the forms attached" to the contract. The attached forms include "Attachment B," which requires the MA organization to certify the "accuracy, completeness, and truthfulness" of the diagnosis data submitted to CMS. As previously alleged, the Defendant Cigna MA Organizations entered into such contracts (or renewals of such contracts) each year during the Relevant Period.

71. Accordingly, each time a Defendant Cigna MA Organization executed a contract with CMS, it affirmatively accepted the obligation to ensure that the risk adjustment data it submitted to CMS was "accurate, complete, and truthful." Relatedly, and in accordance with CMS regulations, *see* 42 C.F.R. § 422.510, the contracts also specified that CMS could terminate the Cigna MA Organization's participation in the Medicare Advantage Program if CMS determined that the Cigna MA Organization had submitted false data or "fail[ed] to provide CMS with valid risk adjustment data."

72. Since 2000, CMS has put MA organizations on notice that the purpose of the annual attestation requirement is to place the responsibility on them to make "good faith efforts to certify the accuracy" of the diagnosis data they submit. *See* 65 Fed. Reg. 40,170, 50,268 (June 29, 2000); *see also* MMC Manual Chap. 7, § 111.7 (2004) ("CMS expects [MA Organizations]

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.").

73. During the Relevant Period, senior Cigna executives signed and submitted the annual attestations to CMS. Cigna submitted those annual attestations after the final submission deadline for reporting the diagnosis data for each payment year.

74. High-level Cigna executives signed the attestations. For example, for payment year 2016 (for dates of service in 2015), the chief financial officer and vice president for Cigna's government business unit (the "CFO") signed the attestations submitted to CMS. In each attestation, he certified that each Cigna MA Organization understood that the diagnosis data that it submitted "directly affect[ed] the calculation of CMS payments" it received, and that "misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution." Having "acknowledge[d]" that understanding, the CFO further certified that "all information submitted to CMS" by the Cigna MA Organization for risk adjustment payments was "accurate, complete, and truthful" according to its "best knowledge, information, and belief." *Id*. The following is an example of an attestation submitted for payment year 2016:

# Review and Certify Risk Adjustment Data Confirmation - Payment Year 2016 (Dates of Service 2015)

**Confirmation #:** 614

**ATTACHMENT B**

**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION, MEDICARE MEDICAID PLAN OR PACE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and BRAVO HEALTH PENNSYLVANIA, INC. (H3949), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 009, 013, 016, 024, 026, 027, 028, 029, 804, 806, 807, 808, 809, 810, the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2015, to December 31, 2015, all risk adjustment data (*inpatient hospital, outpatient hospital, and physician*) available to the MA Organization, Medicare Medicaid Plan or PACE Organization as of the applicable deadline(s), with respect to the above-stated MA, MMP, and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

RYAN MCGROARTY on behalf of

BRAVO HEALTH PENNSYLVANIA, INC. (H3949)

10/15/2018

75. When executing and submitting the attestations, the senior Cigna executives relied on sub-attestations provided to them by other Cigna senior managers responsible for the accuracy and truthfulness of the diagnosis data submitted to CMS for payment, including the accuracy and truthfulness of diagnoses from the 360 home visits. These sub-attestations were provided by various senior managers responsible for the design, implementation and management of the 360 Program, including, but not limited to, the vice president of Cigna's Medicare Data Quality Operations.

### E. Standards and Requirements Governing Diagnosis Reporting and Risk Adjustment Payments

76. In addition to the attestations described in the previous section, CMS imposes, and MA organizations like the Defendant Cigna MA Organizations contractually agreed to, numerous obligations with respect to the diagnosis codes submitted to obtain risk adjustment payments.

77. Diagnosis codes submitted for risk adjustment payments must be in conformance with the ICD, including the ICD Guidelines. *See, e.g.*, 42 C.F.R. § 422.310(d)(1) ("MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards."); 45 C.F.R. § 162.1002(a)(1)(i), (b)(1), (c)(2)(i) (establishing the ICD, including the ICD Guidelines, as the national standard for diagnosis coding); 42 C.F.R. § 422.504(h)(2) (requiring MA organizations to comply with HIPAA simplification rules at 45 C.F.R. part 162, which includes the adoption of the ICD and ICD Guidelines as the national standard); *see also* CMS, *Medicare Managed Care Manual*, Chapter 7 § 40 (Rev. 118, Sept. 19, 2014)[6] ("The diagnosis must be coded according to *International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting*."); CMS, *Medicare Managed Care Manual*, Chapter 7 § 40 (Rev. 114, June 7, 2013); CMS, *Medicare Managed Manual*, Chapter 7, (Rev. 57, Aug. 13, 2004); ICD Guidelines, Preamble ("These guidelines are a set of rules that have been developed to accompany and complement the official conventions and instructions provided within the ICD-10-CM itself. . . . Adherence to these guidelines when assigning ICD-10-CM diagnosis codes is required under [HIPAA].").

78. The ICD Guidelines impose numerous requirements and limitations on what diagnoses may be coded for a particular medical encounter. The Guidelines provide different standards for permissible coding of diagnoses depending on whether an encounter is an outpatient visit or a non-outpatient visit (*i.e.*, hospitalization). *Compare* ICD Guidelines §§ II, III (non-outpatient guidelines), *with* § IV (outpatient guidelines). This Complaint concerns outpatient visits, which are covered by Section IV of the ICD Guidelines.

[6] As alleged above, the Defendant Cigna MA Organizations' annual Medicare Advantage contracts with CMS expressly required them to comply with this Manual.

79. To begin, the ICD Guidelines provide that if a patient does not have a medical condition at the time of an encounter, it may not be coded. Moreover, the guidelines provide that uncertain conditions—those characterized as probable, suspected, questionable, working diagnoses, or the like—may not be coded. *See* ICD-10 Guidelines § IV.H; ICD-9 Guidelines § IV.I. In addition, prior conditions (those that no longer exist) may be coded only with special ICD "history codes" if the prior condition has an impact on current care or influences treatment. *See* ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K.

80. Significantly, for an outpatient medical encounter, the ICD Guidelines only permit the coding of documented conditions that both exist at the time of the encounter *and* that "require or affect patient care treatment or management." ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K. In other words, it is not enough that a condition merely exists; the condition must have specifically mattered to patient care treatment or management during the encounter with the patient. Furthermore, the ICD Guidelines state that "[c]hronic diseases treated on an ongoing basis may be coded and reported as many times as the patient *received treatment and care* for the condition(s)." ICD-10 Guidelines § IV.I (emphasis added); ICD-9 Guidelines § IV.J.

81. Even if an MA organization knows that a patient was previously diagnosed with a chronic condition, the MA organization may not submit the diagnosis for payment for the current payment year unless the patient had an encounter with a healthcare provider during the preceding date of service year and the chronic condition required or affected patient care, treatment, or management during that encounter.

82. In addition, diagnosis codes submitted for risk adjustment payments are valid only if they are documented in the medical record as a result of a face-to-face encounter between the patient and a healthcare provider. *See, e.g.*, CMS, *Medicare Managed Care Manual*, Chapter 7 § 40 (Rev. 118, Sept. 19, 2014) ("All diagnosis codes submitted must be documented in the

medical record and must be documented as a result of a face-to-face visit."); CMS, *Medicare Managed Manual*, Chapter 7 § 111.3 (Rev. 57, Aug. 13, 2004) ("Physician risk adjustment data is defined as diagnoses that are noted as a result of a face-to-face visit by a patient to a physician (as defined above) for medical services.").

83. As relevant here, the ICD Guidelines consistently provided that "accurate coding cannot be achieved" in the absence of "complete documentation in the medical record." *See*, *e.g.*, ICD-10 Guidelines at 1. The requirement that all reported diagnosis codes assigned to patients be supported by information set forth in their medical records is well-established and widely understood by MA organizations, including Cigna and the Cigna MA Organizations, and is commonly referred to as the "medical record documentation" requirement. Pursuant to this requirement, a diagnosis code is accurate and valid for risk adjustment payment purposes only if it is documented in and supported by the medical record for a particular face-to-face encounter between a patient and a healthcare provider. *See* ICD-10 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").

84. CMS has repeatedly provided training and instructions to MA organizations on how to implement the medical record documentation requirement. For example, CMS emphasized to MA organizations 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 that they must ensure that "[a]ll diagnosis codes submitted [are] documented in the medical record," *see* MMC Manual Chap. 7, § 40 (June 2013).

85. CMS offered trainings to MA organizations on how to implement this regulatory requirement starting as early as 2003. *See* 2003 Regional Risk Adjustment Training for MA

Organizations Participant Guide § 4.1 (MA organizations "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 MA organizations understood it, CMS continued to provide training on this regulatory requirement in from 2004 until at least 2014. *See* 2004 Regional Risk Adjustment Training for MA Organizations 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 MA Organizations Participant Guide §§ 5.1, 5.4, 5.5, 7.7.3, 8.1, 8.2; 2007 Risk Adjustment Data Training for MA Organizations 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).[7]

86. Further, as MA organizations frequently do not directly provide medical care to Part C beneficiaries, 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 MA organizations § 8.7.3. More specifically, CMS explained that MA organizations "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*.

### F. MA Organizations' Obligation to Implement an Effective Compliance Program

87. CMS requires MA organizations to implement effective compliance programs. This requirement is a prerequisite to obtaining and a condition of retaining payments under the Medicare Advantage Program. *See* 42 U.S.C. § 422.503(a). As CMS explained as early as June

[7] These trainings are available at https://www.hhs.gov/guidance/ and https://www.csscoperations.com/ .

2000, one purpose of requiring MA organizations 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).

88. CMS' regulations require MA organizations—including the Defendant Cigna MA Organizations—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).

89. CMS' regulations specify that the MA organizations' compliance programs "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 MA organization'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).

90. In the event that an MA organization uncovers "evidence of misconduct related to payment," the regulations require the MA organization 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). The regulations also require MA

organizations to "have procedures to voluntarily self-report potential fraud or misconduct related to [the Part C] program to CMS or its designee." *Id*.

### G. The "Materiality" of Accurate and Truthful Diagnosis Data

91. The accuracy and validity of the diagnosis data reported by MA organizations has always been "material" to CMS' payments because the data directly impacts the amounts paid to the MA plan for each beneficiary. Indeed, since the early 2000s, CMS has conducted audits of diagnosis codes submitted by MA organizations, known as Risk Adjustment Data Validation ("RADV") audits. The HHS Office of the Inspector General conducts similar audits of the validity of the diagnosis data submitted by MA organizations for payments.

92. In 2001, CMS alerted MA Organizations 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 MA organizations 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 MA organizations 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). For each audit, CMS selects a sample of enrollees in an MA organization's MA plans and reviews the medical records for

those enrollees to determine if the diagnosis codes submitted by the MA organizations are supported by those records.

94. CMS regulations and contracts with MA organizations also make clear that the requirement that risk adjustment data be accurate and valid is a condition of payment. *See* 42 C.F.R. § 422.504(*l*).

95. In addition to the materiality of the diagnosis codes to payment, the annual Risk Adjustment Attestations are also material to payment. As previously alleged, their submission to CMS is a condition of payment.

96. Furthermore, because the accuracy and validity of 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 MA organizations that have knowingly submitted inaccurate and untruthful diagnosis data to CMS as well as healthcare providers that knowingly caused MA organizations to submit inaccurate and untruthful diagnosis data to CMS.

97. In August 2012, for example, the Government reached a $3.82 million settlement with 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 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.

98. Further, in May 2017, the Government obtained a $32.5 million settlement from Freedom Health, Inc., a Tampa-based MA organization, to resolve allegations brought in a *qui tam* action that Freedom Health had submitted unsupported diagnosis codes to CMS on behalf of

two MA 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).

99. 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 report inaccurate diagnosis codes to MA organizations to boost the payments received by DaVita from these MA organizations. The settlement also addressed claims that DaVita had hired coding companies to perform retrospective chart reviews to identify new diagnosis codes to report to MA organizations for submission to CMS, but that DaVita did not take corrective action with respect to previously-submitted codes that were not be substantiated by these chart reviews.

100. Likewise, in August 2019, the Government entered into a settlement with Beaver Medical Group, L.P., a California-based physician group, to resolve allegations that, to increase its payments from MA organizations 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.

101. And in August 2021, the Government entered into a $90 million settlement with Sutter Health, a California-based health care services provider, and certain affiliates, based on allegations that Sutter Health had knowingly submitted unsupported diagnosis codes for certain

patient encounters for beneficiaries under its care, which caused inflated payments to be made to certain MA organizations as well as to Sutter Health.

## CIGNA KNOWINGLY SUBMITTED OR CAUSED TO BE SUBMITTED FALSE AND INVALID DIAGNOSIS CODES FOR SERIOUS, COMPLEX MEDICAL CONDITIONS THAT WERE BASED ONLY ON HOME VISITS CONDUCTED THROUGH THE 360 HOME VISIT PROGRAM

102. Cigna's 360 home visit program regularly generated false diagnosis codes—the Invalid Diagnoses—for certain serious, complex conditions that cannot be readily or reliably diagnosed in a home setting without conducting extensive testing, imaging, or other diagnostic steps. These Invalid Diagnoses included, but were not limited to, rheumatoid arthritis, congestive heart failure, chronic kidney disease, and diabetes with renal complications. Cigna knew that its 360 home visit program generated these false diagnoses, but it continued to submit them because doing so was profitable and boosted its Medicare Part C payments.

### A. The 360 Home Visit Program.

103. Through what it called its "360 comprehensive assessment" program, Cigna sought to have its MA plan members assessed once a year by a healthcare provider. There were two different types of assessments: in-office 360 assessments performed by the patient's primary care provider ("PCP"), and in-home assessments performed by healthcare providers employed by vendors that separately contracted with Cigna. This complaint concerns only the latter category: in-home 360 assessments and the Invalid Diagnoses generated as a result.

104. The 360 program was designed and operated by a Cigna business unit named Medicare Data Quality Operations, or "MDQO," based in Nashville, Tennessee. MDQO was responsible for submitting Part C risk adjustment data on behalf of the Cigna MA Organizations using CMS's RAPS and EDPS systems. Senior employees within MDQO were also responsible for providing sub-attestations to the Cigna executives who signed the annual attestations provided to CMS.

105. The 360 in-home visits were designed to generate risk adjustment diagnosis codes that had not been submitted to CMS for a given service year from another source, such as a visit to a doctor's office or hospital. Submitting these home visit diagnosis codes increased Cigna MA Plan members' risk adjustment scores, and, thus, CMS's Part C payments to Cigna MA Organizations. During a 2013 meeting discussing issues and potential changes to the 360 program, Cigna's chief medical officer openly acknowledged that the 360 program was "created originally" to achieve "revenue generation" as one of its goals.

106. Cigna was aware that patients needed to have "face-to-face encounters" with a healthcare provider before a diagnosis code could be reported for risk adjustment purposes. The 360 in-home visits frequently served as a manufactured "face-to-face" encounter to justify reporting diagnosis codes that had not been previously submitted by a patient's primary care physician or another doctor.

107. The Vendor HCPs who conducted the home visits were typically nurse practitioners, although in some instances vendors used other non-physician healthcare providers such as registered nurses or physician assistants. At any given time, Cigna contracted with approximately five to ten different vendors to conduct 360 home visits in different parts of the country. The vendors were paid a fixed amount for each home visit conducted.

108. Cigna identified which MA Plan members would receive home visits. Cigna prioritized "high-value" and "critical-value" members, using data analyses to identify members it believed were more likely to have conditions that had not been reported by other healthcare providers so that the visits would result in a significant boost in PMPM payments. According to a 2015 Cigna presentation, the data analyses included models designed to predict the likelihood that a given patient had a condition mapping to an HCC, the likelihood that the condition/HCC would not be captured through other claims data, and the likelihood that a patient would be

receptive to a home visit. The output of this assessment included a "prioritized target file," so that members could be prioritized based on, among other things, the "predicted incremental RAF score for each member"—that is, the specific predicted increase in a patient's risk score, which (as Cigna knew) was tied directly to how much money Cigna would be paid by CMS.

109. The home visits were in essence brief patient screenings that did not involve the provision of any actual medical treatment or care to the Plan members. The Vendor HCPs often spent no more than approximately 30 minutes with a Plan member.

110. When completing the 360 forms, the Vendor HCPs relied largely on the patient's own self-assessment and their responses to various basic screening questions. The Vendor HCPs did not have access to the patient's full medical history, and the Vendor HCPs typically did not obtain and review the medical records maintained by the patient's PCP in advance of the visit. Instead, Cigna provided the Vendor HCPs with limited information regarding the Plan member's medication and diagnosis history, which was based on encounter data submitted by other healthcare providers who had seen the Plan member during prior years.

111. The Vendor HCPs were not permitted to provide medical care or treatment during the home visit. Indeed, Cigna's contracts with its vendors explicitly stated that the contracted Vendor HCPs could not furnish medical treatment. By prohibiting medical care, Cigna sought to avoid the prospect of medical malpractice liability, which would have significantly increased the costs of the visits for Cigna. Vendor HCPs were generally not permitted to write prescriptions, perform or order diagnostic tests (such as blood tests, laboratory work, or imaging), or refer members for medical care. For example, Cigna's contract with one vendor, Examination Management Services, Inc. ("EMSI"), provided that the 360 assessment "excludes treatment." An agreement with another vendor, Alegis Care Services ("Alegis"), provided that "[n]either Company nor an Authorized Medical Professional shall provide any prescriptions or

recommendations for medical care to Members in connection with the 360 Comprehensive Assessments unless approved by Cigna-HealthSpring." And an agreement with another vendor, THM, is similar: "Neither Vendor nor its Assessing Providers shall provide any prescriptions or recommendations for medical care to Members…."

112. Cigna recognized that the 360 home visits were not an appropriate substitute for actual visits to a doctor's office. For example, a 2016 template for a letter from Cigna's chief medical officer to physicians states that the 360 home visit program was "in no way meant to replace the care you provide through your regular visits with the patient," since the "visiting professional . . . does not have access to the member's complete medical history," and would "not be able to perform certain tasks such as write prescriptions or make referrals."

113. Instead of providing actual treatment or care, the Vendor HCP's main task during the home visit was to complete the 360 form, which included long checklists of potential diagnoses. The Vendor HCPs would typically go through the form and check boxes for the purportedly applicable diagnoses and conditions.

114. As Cigna knew, although Vendor HCPs carried certain basic diagnostic equipment, such as a stethoscope and blood pressure cuff, they generally lacked the equipment necessary to diagnose serious, complex conditions in the home setting. For example, Cigna's agreement with EMSI provided a specific list of equipment that the Vendor HCPs must have for home visits. The twelve-item list includes a photo ID, white lab jacket, stethoscope, ophthalmoscope, monofilament, tongue blade, urine dipstick for protein and glucose testing, tuning fork for vibratory sense testing, blood pressure cuff, bone density machine (Dexa scan), and spirometer. The list does not include equipment for taking blood draws, for collecting urine samples for analysis, for conducting imaging, or for performing other tests necessary to diagnose

certain serious and chronic conditions. And the Vendor HCPs did not order these diagnostic tests or make referrals for such testing before making diagnoses.

115. Cigna created the 360 form and distributed it to its vendors. In some cases, Cigna also approved substantively equivalent forms that vendors created and that met Cigna's specifications—for example, a vendor might create a version of the 360 form to be used electronically with the vendor's systems. The Vendor HCPs completed similar forms in a similar manner for members of the various Cigna MA Plans administered by the Defendant Cigna MA Organizations.

116. The 360 form contained set fields for the Vendor HCP to complete. While the form changed somewhat over time, it was similar in most respects throughout the Relevant Period. After preliminary fields to record the patient's medical history, the limited physical exam findings, and the patient's vital signs, the majority of the several-page form consisted of checklists of conditions grouped by type—for example, cardiovascular; nutritional/metabolic/endocrine; diabetes; respiratory; musculoskeletal; skin/subcutaneous; renal/urinary; gastrointestinal; eye; active neoplasms/blood disorders and current treatment; neurological; and psychiatric. Most groups contained at least a dozen medical conditions, each with its own checkbox.

117. The 360 form listed numerous serious, complex conditions, including congestive heart failure; metabolic diseases, including hyper- and hypo-thyroidism; diabetes, with various types of complications; sarcoidosis; autoimmune diseases, including rheumatoid arthritis and lupus; chronic kidney disease; and neurological disorders such as myasthenia gravis and ALS.

118. Cigna determined all aspects of the 360 form's content and structure, down to seemingly minor details. For example, minutes of an October 2012 meeting on "360 Form Discussion and Finalization for 2013," attended by Cigna's chief medical officer, include a

review of each page of the 360 form with discussion of potential changes to numerous fields. For example, the group discussed how to structure the chronic kidney disease part of the form and concluded that the "unspecified" checkbox should be placed last, "to discourage providers from selecting it" instead of a specific stage of chronic kidney disease. More advanced stages of chronic kidney disease map to more serious HCCs and greater risk adjustment scores.

119. Once a visit was complete, Cigna collected the completed 360 forms from the vendors and had its own coding teams assign the diagnosis codes that corresponded with the medical conditions recorded on the forms. Cigna ultimately included these home-visit generated diagnoses codes in its risk adjustment submissions to CMS.

120. Cigna provided the completed 360 home visit forms to the patient's PCP. But for most of the Relevant Period, Cigna made little or no effort to follow up with the patient or the patient's PCP to ensure that the patient actually sought and received treatment for the conditions recorded on the 360 form. Nor did Cigna limit its risk adjustment submissions from the 360 visits to conditions that were later diagnosed and treated by a PCP or other provider during the same service year.

121. Although Cigna employed contractors to conduct the 360 in-home visits, the contractors were far from independent. Cigna exercised careful control over how the visits were conducted and the Vendor HCPs who conducted them. Unlike a patient's PCP, the patient could not choose which Vendor HCPs visited them; instead, Cigna assigned patients to 360 vendors. The Vendor HCPs were not allowed to exercise independent medical judgment about a patient's care; they could not provide treatment or make referrals. And Cigna evaluated the vendors' performance based on their diagnosis rate and worked on improving their rates when considered insufficient, as discussed in Section C, below.

122. Cigna also developed the training that the Vendor HCPs received, to ensure that the providers would focus on diagnosing the conditions that Cigna prioritized and would using Cigna's clinical criteria. The Cigna-vendor contracts required vendors to use the Cigna prepared training materials.

123. Cigna created a team within MDQO—the so-called Chronic Care Quality Initiative ("CCQI")—to provide training and education to PCPs and Vendor HCPs performing 360 home visits. The CCQI team provided guidance on how to diagnose specific conditions, including the complex conditions at issue in this complaint. Cigna expected its vendors to use these and other Cigna-provided materials to train the Vendor HCPs using Cigna's standards.

### B. The Home Visits Were Designed to Generate Revenue for Cigna, Not to Provide Medical Care or Treatment.

124. The 360 home visit program was created to generate revenue for Cigna by capturing additional diagnosis codes that could be reported to CMS to increase risk scores—and therefore the capitated payments that Cigna received for each Plan member.

125. The 360 home visit program was significant in size. From 2013 through 2018, Cigna conducted over the 297,000 individual home visits through its vendors. In addition, for the period 2015 to 2018 alone, Cigna generated more than 266,000 HCCs from the home visit program.

126. From its inception, Cigna viewed the 360 program as a vehicle to obtain additional Part C payments by capturing high-value diagnosis codes that were not reported through a Plan member's medical visits during the service year. Indeed, an internal HealthSpring document titled "360 Program Description" created in 2009 identifies "diagnostic coding opportunities" as one of the program's purposes. And the 360 program remained a central component of Cigna's strategy to maximize the number of HCCs it submitted to CMS each year. As noted in an internal 2017 company document discussing the program, "[t]he primary goal of a

360 visit is administrative code capture and not chronic care or acute care management." Of course, this was not disclosed to Cigna's Plan members when the home visit was scheduled or during the actual visit.

127. Cigna knew that the more its 360 home visit program could generate risk adjustment submissions, the more lucrative it would be. In a September 2015 email, a Cigna senior medical director for CCQI noted that "vendor performed exams" would lead to a "revenue bump" because, on average, the vendors' exams had increased the risk scores of beneficiaries who had been visited by .188. Cigna also believed some diagnoses were especially valuable and likely to be turned up by 360 home visits. According to a senior Cigna employee in a 2015 email, the value of 360 visits was finding "the golden nuggets we are looking for." According to the employee, the "golden nuggets" that needed to be captured included conditions such as diabetes with complications, major depression, and vascular disease.

128. Cigna carefully tracked the return on investment ("ROI") from the 360 home visits by comparing the total amounts paid to vendors to perform the in-home visits to the additional PMPM payments generated by the resulting increased risk scores for Plan members.

129. For example, according to an internal report, Cigna determined that, during the first nine months of 2014, one vendor's 6,658 in-home visits resulted in more than an additional $14 million in Part C payments, which far dwarfed the approximately $2.13 million that Cigna paid to the vendor.

130. In addition, according to an analysis prepared by a Cigna senior medical director and sent to its chief medical officer, Cigna spent about $18.8 million on home visits for a projected profit of about $61.8 million for 2014. The same analysis showed that in the first eight months of 2015, Cigna spent about $8.7 million for a projected profit of about $38.8 million.

131. Tellingly, the ROI calculations included as a cost only the payments to vendors for conducting home visits—but did not incorporate any additional costs for actually treating the additional medical conditions that the Vendor HCPs had purportedly diagnosed.

### C. Cigna Pressured Vendors to Report as Many High-Value Diagnosis Codes as Possible.

132. Cigna exerted pressure on its vendors to maximize the number of high-value diagnoses reported—including diagnoses of medical conditions that Cigna knew could not be reliably diagnosed in its 360 home visit program, given its limits—by meticulously tracking and managing the overall performance of each of its vendors as well as the performance of individual Vendor HCPs.

133. Cigna identified twelve HCCs corresponding to chronic conditions that it believed were "often under diagnosed." Cigna encouraged its vendors to prioritize diagnosing these conditions. Cigna sent regular monthly reports to its vendors summarizing their performance with respect to recording diagnoses that mapped to the specific priority HCCs.

134. In these monthly reports, Cigna assessed vendors performance primarily based on two factors: (1) how often the vendor was able to diagnose patients with certain chronic conditions that had been submitted in the patient's claim data in a prior year (what it termed the "chronic condition retention rate"); and (2) the number of diagnoses the vendor generated. The monthly reports allowed vendors to understand whether they were meeting Cigna's expectations.

135. When a vendor performed poorly compared to other vendors, Cigna provided detailed suggestions and worked closely with the underperforming vendor to improve its performance. For example, in 2017, when one vendor—Alegis—had below-average performance on certain HCCs in some markets, Alegis drafted a "quality improvement plan" that was extensively reviewed and approved by Cigna. The plan required Alegis to identify "markets that have the greatest opportunity for improvement impact" and "[d]isease specific themes." After

identifying these target markets and diseases, the plan called for Alegis to offer "[s]pecific education . . . in the form of personal coaching, self-directed [l]earning, or group facilitation" to its Vendor HCPs to realize gains in Cigna's metrics.

136. Likewise, in a September 2016 email, a Cigna manager provided detailed feedback to another vendor, THM, that identified specific conditions (including diabetes with chronic complications and congestive heart failure) as "strengths," and other conditions (including COPD and diabetes without complications) as "[a]reas to improve." Cigna recommended that THM conduct trainings on those conditions with its staff to increase diagnosis rates.

137. Cigna tracked performance not only at the vendor level, but even at the level of individual Vendor HCPs to see whether they were meeting Cigna's expectations on specific HCCs. For example, a report prepared for Cigna's chief medical officer shows that in 2014, Cigna oversaw implementation of performance improvement plans for employees of four different vendors. Three of these plans targeted specific providers who had "lower than expected disease prevalence" for valuable conditions—congestive heart failure and chronic obstructive pulmonary disease. Cigna required similar performance improvement plans again in 2015.

138. The goal of performance improvement plans was not just to improve performance, but to eliminate Vendor HCPs who could not meet Cigna's expectations: According to a September 2015 email from Cigna's senior medical director for CCQI, Vendor HCPs who performed poorly should be "weed[ed] out" using what he termed an "internal quality program."

139. Cigna also tracked the financial performance of vendors against each other and made business decisions based on the ability of vendors to increase patient risk scores at the lowest cost. For example, in an August 2014 email, a Cigna senior medical director circulated

year-to-date data tracking the average "RIA," or risk score impact, of different vendors. In response, another Cigna employee emailed back seeking advice about which of two vendors to use in a particular market. The senior medical director recommended the vendor that would be cheaper to use. But because the vendor's performance in terms of increasing patient risk scores was mediocre, the senior medical director said he would like to find better options than either of the available vendors.

**D. Many Home Visits Resulted in Invalid Diagnoses.**

140. Cigna's 360 home visit program produced "diagnoses"—the Invalid Diagnoses—that could not be reliably made in a home setting and were not supported by clinical findings or information documented by the Vendor HCP in the 360 form or in any other medical record. In many cases, based on the information available to Cigna and the content of the 360 forms, there was no sound basis to conclude that the Plan member had the medical conditions recorded during the visit. Yet, Cigna included the Invalid Diagnoses in the risk adjustment data submitted to CMS and falsely certified that the data was accurate and truthful. At the very least, Cigna showed reckless disregard for the truth and accuracy of the submissions.

141. Cigna asked the Vendor HCPs performing in-home visits to make the same set of diagnoses that PCPs or other physicians would make when they examined patients in a doctor's office, clinic, or hospital. Cigna used the same standard 360 forms with the same lists of diagnoses for in-office and in-home 360 visits. Yet, as Cigna knew, the Vendor HCPs conducting home visits could not and did not perform tests, imaging, or other steps necessary to make the many of the diagnoses listed on the 360 form—because they lacked the equipment to do so in the home, and could not and did not order tests or make referrals to confirm potential diagnoses. And even though senior Cigna staff were aware of the problems of using the same form for both in-office and in-home visits, they decided not to change the form. For example,

when finalizing the 360 form for 2013—a process that involved Cigna's chief medical officer—Cigna considered, and rejected, creating and using a different version of the form for in-home-assessments.

142. According to Cigna's own clinical guidelines, accurately diagnosing serious and chronic conditions such as chronic kidney disease, rheumatoid arthritis, congestive heart failure, and diabetes with renal complications requires specialized testing.

143. For example, a document created by Cigna's CCQI team designed to help support clinicians—including those conducting 360 assessments—stated that for early-stage chronic kidney disease, "clinical assessment relies heavily on laboratory evaluation and diagnostic imaging." The same document specifically states that patients at risk for chronic kidney disease may be evaluated by a combination of measurements: measuring creatinine level in the blood to estimate kidney function (known as "eGFR"), and urine testing—either the albumin-to-creatinine ratio, or presence of albumin. These requirements for laboratory testing are consistent with guidelines promulgated by governmental and professional groups. For example, the National Institute of Diabetes and Digestive and Kidney Diseases, part of the National Institutes of Health, states that to diagnose chronic kidney disease, providers should conduct a blood test to measure GFR and test the urine for albumin. *See* https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd/tests-diagnosis. But as Cigna knew, the Vendor HCPs did not take these blood and urine measurements or order that these tests be performed by another provider. Nonetheless, Cigna included hundreds of chronic kidney disease diagnoses based on home visits in its risk adjustment submissions to CMS each year.

144. The 360 form also included the diagnosis of diabetes with renal complications. Diagnosing this condition requires, in addition to a diagnosis of diabetes, meeting the criteria for chronic kidney disease discussed in the previous paragraph, which requires urine testing and

blood testing to measure GFR. *See, e.g.*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6336222/. Nonetheless, Cigna frequently submitted diagnoses for diabetes with renal complications based on home visits in its risk adjustment submissions to CMS each year, even though they knew that the Vendor HCPs had not taken the necessary blood and urine measurement to make this diagnosis.

145. The 360 form also included the diagnosis of rheumatoid arthritis, an autoimmune disease. According to Cigna's CCQI guidelines for diagnosing rheumatoid arthritis, the second step—after a history and physical—is blood testing to detect antibodies, and the third step is blood testing to detect acute phase reactants. According to widely accepted guidelines established by the American College of Rheumatology—on which the CCQI guidelines are based—diagnosing rheumatoid arthritis generally requires multiple types of blood testing, x-ray imaging, or both. *See* American College of Rheumatology, 2010 Rheumatoid Arthritis Classification, available at https://www.rheumatology.org/Portals/0/Files/2010%20Rheumatoid%20Arthritis%20Classification_EXCERPT%202010.pdf. Again, as Cigna knew, the Vendor HCPs did not administer or order these blood tests or x-rays during home visits. Nonetheless, Cigna submitted thousands of rheumatoid arthritis diagnoses based on home visits in its risk adjustment submissions to CMS each year.

146. The 360 form also included the diagnosis of congestive heart failure ("CHF"). Cigna's CCQI guidelines state for evaluating CHF "[g]enerally…includes," in addition to a history or physical exam, "[o]bjective data such as: chest film, echocardiogram, cardiac MRI, and lab work—namely, a Brain Natriuretic Peptide (BNP)." Likewise, according to the American College of Cardiologists ("ACC"), the criteria for a diagnosis of heart failure with either reduced ejection fraction (also called systolic heart failure) or preserved ejection fraction

(also called diastolic heart failure) include "evidence of increased [left ventricle] filling pressures at rest, exercise, or other provocations," which can be fulfilled with three types of findings: "findings of elevated levels of natriuretic peptides," which requires a blood test; "echocardiographic diastolic parameters . . . or other evidence of elevated filling pressures," which requires an echocardiogram; "or invasive hemodynamic measurement at rest or exercise," which generally requires performing a heart catheterization procedure. *See* Paul A. Heidenreich et al., 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure, JACC VOL. 79, NO. 17, 2022, May 3, 2022:e263 – e421, *available at* https://www.jacc.org/doi/pdf/10.1016/j.jacc.2021.12.012?_ga=2.28435068.17658883.1663959878-1483381516.1663959878&_gl=1*1661lo0*_ga*MTQ4MzM4MTUxNi4xNjYzOTU5ODc4*_ga_2V8VW4Y237*MTY2Mzk1OTg3OC4xLjAuMTY2Mzk1OTg3OS41OS4wLjA at e277. The same ACC guidelines also cite favorably a European diagnostic algorithm that includes electrocardiography, blood tests, and echocardiography—among other steps—to confirm a suspected diagnosis and classify it properly. *Id*. at e278. Once again, as Cigna knew, the Vendor HCPs did not perform these diagnostic tests and procedures, or have access to the results from them, before diagnosing patients with CHF. Nonetheless, Cigna submitted thousands of congestive heart failure diagnoses based on home visits in its risk adjustment submissions to CMS each year.

147. With respect to the Invalid Diagnoses, the 360 forms themselves also lack findings or information supporting the purportedly diagnosed conditions. Often, the only "support" in the 360 form for the diagnosis is the checkbox recording the condition. Cigna's coders acted with reckless disregard for the truth or falsity of these diagnoses when assigning ICD codes to them despite the lack of supporting clinical information on the forms.

148. In many cases, even a cursory review of the forms would have made clear that that was no sound clinical basis for recording the Invalid Diagnosis. In fact, in some cases, the 360 forms show clinical exam findings that contradict the supposed diagnosis. For example, one patient received a CHF diagnosis from a 2016 home visit even though the 360 form explicitly noted that physical exam results found her heart to be "regular" and "normal," and stated "cardiac reviewed and unremarkable."

149. Furthermore, the fact that no other healthcare provider who treated or cared for the Plan member during the year of the home visit reported that the Plan member suffered from the Invalid Diagnosis casts further doubt on the truth, reliability and accuracy of these diagnoses.

150. Cigna possessed diagnosis and encounter data for all members of its MA Plans, so it knew when it submitted the Invalid Diagnoses to CMS that: (i) the diagnoses were solely based on the 360 home-visit forms completed for Plan members; and (ii) no other healthcare provider had reported that the Plan member suffered from the condition during the date of service year, and, for some of the Plan members, this was the first time the condition was reflected in any diagnosis data. Indeed, in many instances, according to Cigna's own data, the Plan members did not receive treatment for the Invalid Diagnoses during a period of years prior to and including the year of the home visit. In many of those instances, the diagnosis ultimately did not appear in risk adjustment data for the year or two years following the visit, either. Cigna, however, recklessly disregarded this information when it submitted the Invalid Diagnoses to CMS for payment and when it made its annual risk adjustment attestations.

151. Cigna repeatedly falsely certified to CMS in its attestations that their risk adjustment submissions were accurate, complete, and truthful according to their best knowledge, information and belief. *See supra* ¶¶ 68-73; 42 C.F.R. § 422.504(*l*). In addition, Cigna acted with reckless disregard about the truth of their risk adjustment submissions. Cigna knew that it was

regularly submitting Invalid Diagnoses, that the Vendor HCPs had not performed or ordered testing and other diagnostic steps necessary to reliably make such diagnoses, and that the 360 forms on their face did not support the Invalid Diagnoses. And they knew that these same diagnoses had not been reported by any other healthcare provider during the service year (and in many cases during the years before the service year).

152. By submitting diagnosis data that it knew was not complete, accurate, and truthful, Cigna also violated CMS regulations and policies applicable to the submission of risk adjustment data provided at 42 C.F.R. § 422.310. Compliance with applicable CMS regulations was also incorporated into the Cigna MA Organizations' contracts with CMS. *See* 42 C.F.R. § 422.504(a)(8).

### E. The Invalid Diagnoses Did Not Conform with the ICD Guidelines and thus Were Improperly Submitted for Risk Adjustment Purposes.

153. The Invalid Diagnoses also did not conform with the ICD Guidelines as required under applicable CMS regulations and Cigna MA Organizations' Part C contracts. Cigna submitted or caused to be submitted false claims for payment by knowingly submitting diagnosis codes for Plan members that were inconsistent with the ICD Guidelines and thus ineligible for risk adjustment.

154. *First,* the ICD Guidelines permit coding for conditions diagnosed during outpatient visits only when the condition exists at the visit *and* it "require[s] or affect[s] patient care treatment or management." ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K. For chronic diseases specifically, the ICD Guidelines state that "[c]hronic diseases treated on an ongoing basis may be coded and reported as many times as the patient received treatment and care for the condition(s)." ICD-10 Guidelines § IV.I; ICD-9 Guidelines § IV.J. The ICD Guidelines do not permit reporting a code to "confirm" a previously made diagnosis for a

chronic condition if the diagnosis does not affect patient care, treatment, and management during the visit.

155. Cigna regularly submitted codes for diagnoses generated from its 360 home visit program that did not meet these requirements. Specifically, as discussed above, Cigna explicitly instructed its contractors that the Vendor HCPs who performed 360 home visits were *not* to provide medical care or treatment during the home visit. They could not prescribe medication for the condition or even refer the patient to a specialist. And for the Invalid Diagnoses, the Plan member received no care or treatment for the condition at any time during the entire service year. Although the results of the 360 home visits may have been forwarded to the Plan member's PCP, neither the PCP nor any other physician actually provided care or treatment to the member for the purported medical condition during the service year for the Invalid Diagnoses. Thus, as Cigna knew, the Invalid Diagnoses did not, contrary to the ICD Guidelines, "require or affect patient care treatment or management" during any medical encounter during the relevant date of service year. ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K.

156. *Second*, the ICD Guidelines also prohibit coding questionable diagnoses (for example, those that are merely suspected or probable) during outpatient visits. *See* ICD-10 Guidelines § IV.H; ICD-9 Guidelines § IV.I. Nonetheless, as discussed above, Cigna's contractors regularly recorded Invalid Diagnoses during 360 home visits for complex conditions without performing the testing, imaging, or other diagnostic clinical steps necessary to establish those diagnoses. Submitting codes for diagnoses that were merely suspected, or which appeared previously in a patient's history but were not properly diagnosed at the time of the 360 home visit, violated the ICD Guidelines.

157. *Third*, the ICD Guidelines require that all diagnosis codes assigned to patients be supported by the information set forth in their medical records. The Guidelines specify that

"accurate coding cannot be achieved" in the absence of "complete documentation in the medical record." *See supra* ¶¶ 77-83.

158. However, as discussed above, the Invalid Diagnoses do not satisfy this medical record documentation requirement. The information on the 360 form itself—often little more than a checked box to indicate a condition was purportedly assessed—did not support assigning a diagnosis code and submitting it to CMS for payment. For the Invalid Diagnoses, the 360 forms do not substantiate that the patient actually had the condition and that condition affected patient care, treatment, and management during the home visit.

### F. Cigna Submitted False Risk Adjustment Data that It Knew Included Invalid Diagnoses that Did Not Comply with Applicable Regulatory Requirements.

159. Cigna's failure to comply with its contractual and regulatory obligations was not due to ignorance or mistake. Cigna—which operates a sophisticated Part C business that receives billions of dollars from CMS each year—was aware of CMS program requirements for MA organizations. Defendants understood the structure of the risk adjustment payment system and their responsibilities as MA organizations, including the direct impact that diagnosis data has on CMS' risk adjustment payment calculations, their obligation to ensure that the risk adjustment data was accurate and truthful, and their obligation to submit diagnosis codes that complied with ICD Guidelines. Indeed, senior Cigna executives certified each year to CMS that the risk adjustment data was accurate, complete, and truthful.

160. Yet Cigna submitted diagnosis codes to CMS that were based solely on the 360 home visits and which Cigna knew were likely false and invalid for risk adjustment purposes. Cigna management knowingly structured the 360 home visit program in a manner that created a significant risk of generating Invalid Diagnoses by asking Vendor HCPs to record serious, complex medical conditions on the 360 form that ordinarily cannot be diagnosed in a home setting without performing necessary testing, imaging, or other diagnostic steps. As discussed in

Section D, above, the clinical guidance Cigna itself wrote and gave to providers recognized this. And, as discussed above in Section A, Cigna knew the limitation of the in-home visits, including that the Vendor HCPs lacked the tools or equipment to conduct this type of diagnostic testing, that the visits were typically relatively brief encounters during which the Vender HCPs relied largely on the patient's responses to basic screening questions, and that the Vendor HCPs only had access to limited information related to the Plan member's medical history.

161. Cigna nonetheless submitted the risk adjustment diagnosis codes for the Invalid Diagnoses while also knowing—based on the claims and encounter data which it possessed—that no other provider had submitted the diagnosis for the service year. Further, Cigna had access to the 360 forms completed by the Vendor HCPs, which on their face often did not include any findings or clinical basis to justify the Invalid Diagnoses.

162. Dating back to the early stages of the 360 program, Cigna compliance staff expressed concerns about the reliability and accuracy of risk adjustment submissions from home 360 visits. For example, at a November 2011 meeting attended by senior Cigna staff, including Cigna's chief medical officer and a manager in charge of medical data quality, a compliance manager pointed out problems with Cigna's one-size-fits-all approach to in-home and office 360 visits. The compliance manager specifically noted that in contrast to PCPs performing exams in their offices, the Vendor HCPs performing home 360 visits often lacked access to lab testing. The compliance manager went on to suggest that Cigna should "filter [] out on the back end" the conditions that "should never be diagnosed in the home." Yet Cigna continued to require providers to complete the same checklist of conditions on the 360 form regardless of whether the assessment occurred in a physician's office or at a Plan member's home.

163. Similarly, according to minutes of a "360 summit" meeting that likely occurred in late 2011 or 2012, Cigna's compliance staff raised additional concerns about the "quality of new

diagnoses" from 360 home visits, including the risk of reporting "diagnoses that cannot be diagnosed in a home visit" and diagnoses reported solely from a 360 visit. Cigna did not take the necessary steps to address these concerns, and it continued to report diagnoses generated solely from 360 visits to CMS.

164. Senior Cigna executives also knew that asking the Vendor HCPs to diagnose the same types of serious medical conditions during home visits as PCPs were asked to make during office visits was inappropriate. As early as November of 2011, Cigna's vice president of MDQO noted that he had "discussed" with Cigna's chief medical officer "developing a separate 360 exam form for use in a home setting," but that the company had not begun that process. He asked whether a "360 light" form for home visits could be created. In response, a director in MDQO wrote that she "personally would strongly advocate a separate form be used," because that "would reduce risk" from an "evaluation" and "coding standpoint." She also said it could be done quickly. But Cigna never created such a separate 360 form for home visit.

165. Other Cigna employees also expressed concerns about complex diagnoses being made for the first time in the home setting. For instance, in October 2013, a Cigna coding and performance manager raised concerns with a vendor about a specific instance in which a nurse practitioner had purportedly diagnosed a specific stage of chronic kidney disease during a home visit. The Cigna manager wrote that "we also need to make sure the [nurse practitioners] are not diagnosing [chronic kidney disease] for the first time in the home setting," since this would require "two 'abnormal' eGFR [estimated glomerular filtration rate] values separated by 3 months." The Cigna manager further noted that coding a specific stage of chronic kidney disease during a home visit was also improper, since that required "access to previous eGFR values," which were not available to the vendor HCPs. Nonetheless, Cigna continued to allow Vendor

HCPs to record chronic kidney disease diagnoses on 360 forms based on home visits and continued to report these diagnoses to CMS to inflate risk adjustment payments.

166. Furthermore, during the Relevant Period, Cigna was well aware that CMS had repeatedly expressed concerns about MA organizations' use of home visits as a source of risk adjustment diagnosis submissions to increase payments without providing medical care. For example, in February 2013, CMS expressed concern that home assessments like those made via the 360 home visit program could be "used as a vehicle for collecting risk adjustment diagnoses without follow-up care or treatment being provided to the beneficiary by the plan." *See Advance Notice of Methodological Changes for Calendar Year 2014* at 22 (https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/advance2014.pdf). In early 2014, moreover, CMS proposed "to exclude for payment purposes diagnoses identified during a home visit that are not confirmed by a subsequent clinical encounter." *See Advance Notice of Methodological Changes for Calendar Year 2015* at 21 (https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/advance2015.pdf). Ultimately, CMS declined to categorically exclude such diagnoses for risk adjustment payment purposes, opting instead to require MA organizations to "flag" such diagnoses with coding identifiers and to encourage MA organizations to follow certain "best practices." *See*, *e.g.*, 2015 Final Call Letter at 28 (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2015.pdf). In doing so, CMS reiterated its continuing concern that "many home visits are being used primarily for the gathering of diagnoses for payment rather than to provide treatment and/or follow-up care to beneficiaries." *Id*.

167. Senior Cigna executives were aware of and discussed CMS's concerns about home visit programs. A July 2014 internal Cigna email written by a Cigna senior vice president summarizes a meeting that AHIP (America's Health Insurance Plans, a trade association) convened with CMS leadership that month. The email discusses CMS's concerns that in-home assessments were being used as a device for generating revenue without providing medical care or treatment:

> CMS said they are concerned about that part of the industry (some outside vendors) they feel are just doing in-home assessments to gather codes, maximize reimbursement and still provide no real linkage of the data gathered back to the members' medical record for subsequent treatment (where necessary). They are still unclear as to "how in home assessments contribute to the overall improvement in the health status of the members."

168. During the previous summer, hoping to head off or assuage CMS's concerns, Cigna had provided CMS with a description of its 360 home visit program that omitted important details. In a June 24, 2013 email to CMS, a Cigna senior vice president described the 360 exams as "intensive physical examinations that are provided to our members, which are performed to identify any healthcare needs that the member may have, so that we may treat those needs through a care management program," and claimed that "while we do identify codes through this process also, the primary purpose is to get to know our members, from a clinical perspective." Then, in a follow-up presentation to CMS two months later, Cigna stated that the purpose of the 360 exams was, among other things, to "identify medical care intervention opportunities for our members" and to engage preventive health care metrics for members. In neither the email nor the presentation did Cigna mention revenue generation—even though Cigna employees had acknowledged that was a key goal of the program from the outset. Nor did the email or slide presentation mention that Cigna's Vendor HCPs did not provide medical care during the visits,

did not perform the tests or imaging needed to accurately diagnose certain conditions, and did not have the ability to refer patients for such testing or imaging before reporting a diagnosis.

## CIGNA'S KNOWING DECISION TO DISREGARD ITS REGULATORY AND CONTRACTUAL OBLIGATIONS RESULTED IN THE SUBMISSIONS OF FALSE CLAIMS

169. As set forth above, Cigna understood its obligation to submit valid, truthful and accurate diagnosis data to CMS. Cigna, however, chose to prioritize profitability over compliance. As result of that choice, Cigna knowingly caused CMS to calculate the risk adjustment payments it made to the Defendant Cigna MA Organizations on the basis of tens of thousands of false and invalid diagnosis codes. Examples of those instances include:

a. Patient A[8]: Bravo Health Pennsylvania, Inc. submitted a false claim and received money from CMS based on a diagnosis made during a 360 home visit of Patient A that was false and invalid and did not conform with the ICD Guidelines. Based solely on a home 360 visit conducted by a Cigna vendor on August 31, 2016, Bravo Health Pennsylvania, Inc. submitted an ICD diagnosis code for diabetes with hyperglycemia (which mapped to HCC 18) for Patient A and received an additional risk adjustment payment of $1775 for payment year 2017 based on that submission. Cigna Corporation and Bravo Health Pennsylvania, Inc. knew that the Vendor HCP who recorded this diagnosis did not conduct the testing, imaging, or other clinical steps necessary to reliably make this diagnosis. The information recorded in the 360 form for this visit does not support or substantiate this diagnosis. Further, no other provider reported this diagnosis (or any other diagnosis that mapped to HCC 18) for Patient A during 2016.

b. Patient B: Bravo Health Pennsylvania, Inc. submitted a false claim and received money from CMS based on a diagnosis made during a 360 home visit of Patient B that was false and invalid and did not conform with the ICD

[8] In order to protect the confidentiality of patients' personal health information, this complaint does include the names of specific patients. The Government will disclose the names of these patients to Defendants upon request.

Guidelines. Based solely on a home 360 visit conducted by a Cigna vendor on March 20, 2014, Bravo Health Pennsylvania, Inc. submitted an ICD diagnosis code for rheumatoid arthritis (which mapped to HCC 40) for Patient B and received an additional risk adjustment payment of $3,366 for payment year 2015 based on that submission. Cigna Corporation and Bravo Health Pennsylvania, Inc. knew that the Vendor HCP who recorded this diagnosis did not conduct the testing, imaging, or other clinical steps necessary to reliably make this diagnosis. The information recorded in the 360 form for this visit does not support or substantiate this diagnosis. Further, no other provider reported this diagnosis (or any other diagnosis that mapped to HCC 40) for Patient B during 2014.

c. Patient C: Bravo Health Pennsylvania, Inc. submitted a false claim and received money from CMS based on a diagnosis made during a 360 home visit of Patient C that was false and invalid and did not conform with the ICD Guidelines. Based solely on a home 360 visit conducted by a Cigna vendor on February 14, 2014, Bravo Health Pennsylvania, Inc. submitted an ICD diagnosis code for diabetes with neurological manifestations (which mapped to HCC 18) for Patient C and received an additional risk adjustment payment of $1,463 for payment year 2015 based on that submission. Cigna Corporation and Bravo Health Pennsylvania, Inc. knew that the Vendor HCP who recorded this diagnosis did not conduct the testing, imaging, or other clinical steps necessary to reliably make this diagnosis. The information recorded in the 360 form for this visit does not support or substantiate this diagnosis. Further, no other provider reported this diagnosis (or any other diagnosis that mapped to HCC 18) for Patient C during 2014.

d. Patient D: Bravo Health Mid-Atlantic, Inc., submitted a false claim and received money from CMS based on a diagnosis made during a 360 home visit of Patient D that was false and invalid and did not conform with the ICD Guidelines. Based solely on a home 360 visit conducted by a Cigna vendor on January 20, 2014, Bravo Health Mid-Atlantic, Inc. submitted an ICD diagnosis code for rheumatoid arthritis (which mapped to HCC 40) for Patient

D and received an additional risk adjustment payment of $3,756 for payment year 2015 based on that submission. Cigna Corporation and Bravo Health Mid-Atlantic, Inc. knew that the Vendor HCP who recorded this diagnosis did not conduct the testing, imaging, or other clinical steps necessary to reliably make this diagnosis. The information recorded in the 360 form for this visit does not support or substantiate this diagnosis. Further, no other provider reported this diagnosis (or any other diagnosis that mapped to HCC 40) for Patient D during 2014.

e. Patient E: HealthSpring of Florida, Inc. submitted a false claim and received money from CMS based on a diagnosis made during a 360 home visit of Patient E that was false and invalid and did not conform with the ICD Guidelines. Based solely on a home 360 visit conducted by a Cigna vendor on July 7, 2016, HealthSpring of Florida, Inc. submitted an ICD diagnosis code for cardiomyopathy, unspecified (which mapped to HCC 85) for Patient E and received an additional risk adjustment payment of $3,283 for payment year 2017 based on that submission. Cigna Corporation and HealthSpring of Florida, Inc. knew that the Vendor HCP who recorded this diagnosis did not conduct the testing, imaging, or other clinical steps necessary to reliably make this diagnosis. The information recorded in the 360 form for this visit does not support or substantiate this diagnosis. Further, no other provider reported this diagnosis (or any other diagnosis that mapped to HCC 85) for Patient E during 2016.

f. Patient F: Bravo Health Mid-Atlantic, Inc., submitted a false claim and received money from CMS based on a diagnosis made during a 360 home visit of Patient F that was false and invalid and did not conform with the ICD Guidelines. Based solely on a home 360 visit conducted by a Cigna vendor on June 29, 2015, Bravo Health Mid-Atlantic, Inc. submitted an ICD diagnosis code for congestive heart failure (which mapped to HCC 85) for Patient F and received an additional risk adjustment payment of $8,167 for payment year 2016 based on that submission. Cigna Corporation and Bravo Health Mid-Atlantic, Inc. knew that the Vendor HCP who recorded this diagnosis did not

conduct the testing, imaging, or other clinical steps necessary to reliably make this diagnosis. The information recorded in the 360 form for this visit does not support or substantiate this diagnosis. Further, no other provider reported this diagnosis (or any other diagnosis that mapped to HCC 85) for Patient F during 2015.

g. Patient G: Bravo Health Pennsylvania, Inc. submitted a false claim and received money from CMS based on a diagnosis made during a 360 home visit of Patient G that was false and invalid and did not conform with the ICD Guidelines. Based solely on a home 360 visit conducted by a Cigna vendor on December 18, 2015, Bravo Health Pennsylvania, Inc. submitted an ICD diagnosis code for hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease (which mapped to HCC 136) for Patient G and received an additional risk adjustment payment of $2,493 for payment year 2016 based on that submission. Cigna Corporation and Bravo Health Pennsylvania, Inc. knew that the Vendor HCP who recorded this diagnosis did not conduct the testing, imaging, or other clinical steps necessary to reliably make this diagnosis. The information recorded in the 360 form for this visit does not support or substantiate this diagnosis. Further, no other provider reported this diagnosis (or any other diagnosis that mapped to HCC 136) for Patient G during 2015.

170. In these and tens of thousands of other instances, Cigna's misconduct had a direct and foreseeable impact on CMS. Specifically, Cigna's misconduct not only enabled Cigna to obtain and retain artificially inflated risk adjustment payments from CMS, it also adversely affected the integrity and accuracy of CMS's risk adjustment payment system.

171. Further, for each payment year in the Relevant Period, Cigna submitted Part C annual attestations for its MA plans, which certified to CMS that the risk adjustment diagnosis data Cigna had submitted for those MA plans was "accurate, complete, and truthful" based on Cigna's "best knowledge, information, and belief."

172. As Cigna knew, each of those Part C attestations was false. Specifically, Cigna knew that invalid diagnoses like the examples enumerated in paragraph 169 above were present in its risk adjustment data submissions.

173. Cigna also knew that its ongoing submission of the false annual attestations to CMS had a direct and foreseeable impact on CMS. Specifically, as Cigna knew, CMS's procedures require MA organizations to submit Part C annual attestations before CMS will proceed with the final reconciliation phase of the risk adjustment payment process. Thus, the false attestations submitted by Cigna caused CMS to move forward with final reconciliation for the Cigna MA Plans and disburse inflated final reconciliation payments to Cigna during the Relevant Period.

**FIRST CLAIM**
**Violation of the FCA: Presentation of False or Fraudulent Claims for Payment**
**31 U.S.C. § 3729(a)(1)(A)**

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

175. Cigna violated 31 U.S.C. § 3729(a)(1)(A) by knowingly (with actual knowledge or deliberate ignorance or reckless disregard of the truth) presenting, or causing to be presented, false or fraudulent claims for payment or approval to CMS resulting in Cigna's receiving Medicare payments from CMS to which it was not entitled.

176. Specifically, Cigna knowingly (with actual knowledge or deliberate ignorance or reckless disregard of the truth) presented or caused to be presented false claims for risk adjustment payments by submitting false, inaccurate, improper, and invalid diagnosis codes for Medicare Part C patients enrolled in Cigna MA Plans, in violation of CMS regulations and policies and other requirements, which Cigna agreed to and was obligated to comply with.

177. If CMS had known that Cigna had presented or caused to be presented false claims based on these false, inaccurate, improper, and invalid diagnosis codes, CMS would have refused to make risk adjustment payments based on the false, inaccurate, improper, and invalid coding and/or taken other appropriate actions to ensure that Cigna did not receive or retain risk adjustment payments to which it was not entitled, including by recouping payments through administrative processes, payment adjustments, or obtaining repayments in enforcement actions.

178. By reason of the false claims that Cigna knowingly presented or caused to be presented, the United States 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.

**SECOND CLAIM**
**Violation of the FCA: Making and Using False Records or Statements**
**31 U.S.C. § 3729(a)(1)(B)**

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

180. Defendants violated 31 U.S.C. § 3729(a)(1)(b) by knowingly (with actual knowledge or deliberate ignorance or reckless disregard of the truth) making, using, or causing to be made or used false records and statements material to false or fraudulent claims, resulting in Cigna's receiving Medicare payments from CMS to which it was not entitled.

181. Specifically, Cigna knowingly (with actual knowledge or deliberate ignorance or reckless disregard of the truth) made, used, or caused to be made or used false records and statements—in the form of, for example, false risk adjustment submissions and false annual Part C attestations—that were material to the payment of false claims for risk adjustment payments for Medicare Part C patients.

182. If CMS had known that Cigna had made, used, or caused to be made or used false records or statements material to these false claims, CMS would have refused to make risk

adjustment payments based on the inaccurate, improper, and invalid coding and/or taken other appropriate actions to ensure that Cigna did not receive or retain risk adjustment payments to which it was not entitled, including by recouping payments through administrative processes, payment adjustments, or obtaining repayments in enforcement actions.

183. 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.

**THIRD CLAIM**
**Unjust Enrichment**

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

185. Through the acts set forth above, Cigna has received payments from the Government to which it was not entitled, which unjustly enriched Cigna, and for which it must make restitution. Cigna received such payments based on the submission of false, inaccurate, improper, and invalid diagnosis codes included in their risk adjustment data submissions to CMS. In equity and good conscience, such money belongs to the Government and to the Medicare Program and should not be retained by Cigna.

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

**FOURTH CLAIM**
**Payment By Mistake**

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

188. The Government paid money to Cigna as a result of a mistaken understanding. Specifically, the Government paid Cigna's claims for risk adjustment payments under the

mistaken and erroneous belief that such claims were based on the submission of true, accurate, proper, and valid diagnosis codes included in their risk adjustment data submissions to CMS. Had the Government known the truth, it would not have paid such claims. Those payments were therefore by mistake.

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

**PRAYER FOR RELIEF**

WHEREFORE, the United States respectfully requests that judgment be entered in its favor against Defendants as follows:

(a) On the First and Second Claims for relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B)), a judgment against Defendants 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 Defendants.

(b) On the Third Claim and Fourth Claims for relief (Unjust Enrichment and Payment by Mistake), a judgment against Defendants for damages to the extent allowed by law.

(c) Costs and such further relief as the Court may deem appropriate.

Dated: New York, New York
October 14, 2022

Respectfully submitted,

DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York

By: */s/ Peter Aronoff*
PETER ARONOFF
*Admitted pro hac vice*
Assistant United States Attorney
United States Attorney's Office, Civil Division
86 Chambers Street, 3rd Floor

New York, NY 10007
Tel: (212) 637-2697
Email: peter.aronoff@usdoj.gov

MARK H. WILDASIN
United States Attorney for the
Middle District of Tennessee
By: */s/ Kara F. Sweet*
KARA F. SWEET
Assistant United States Attorney
719 Church Street, Suite 3300
Nashville, Tennessee 37203
Tel.: (615) 736-5151
Email: kara.sweet@usdoj.gov

*Attorneys for the United States*